



BỘ Y TẾ
ĐẠI HỌC Y DƯỢC THÀNH PHỐ HỒ CHÍ MINH
TRUNG TÂM KIỂM CHUẨN CHẤT LƯỢNG XÉT NGHIỆM Y HỌC - BỘ MÔN XÉT NGHIỆM



TÀI LIỆU HỘI NGHỊ QUỐC TẾ

VỀ XÉT NGHIỆM Y HỌC VÀ TỔNG KẾT QUẢN LÝ CHẤT LƯỢNG 2025: HÀNH TRÌNH **15**^{năm} PHÁT TRIỂN

*International conference on Medical Laboratory Science
and Quality Management 2025:
A 15-Year Journey of Development*



Annual Report on Laboratory Quality Management Activities – 2025

**Quality Control Center for Medical
 Laboratory of University of Medicine and
 Pharmacy at Ho Chi Minh City**

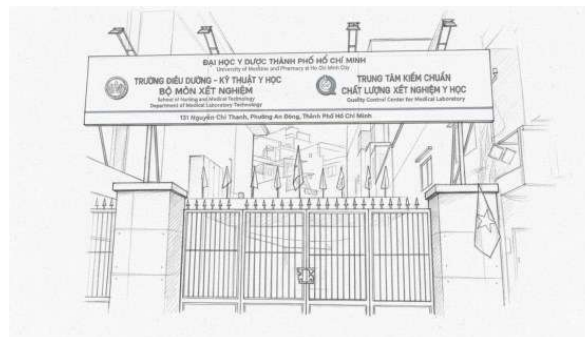


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Summary of Laboratory Quality Management Activities in 2025

Orientation for 2026

15-Year Development Journey

HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025
INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Decision No. 2718/QĐ-BYT dated July 30, 2010, on the establishment of the **Quality Control Center for Medical Laboratory of University of Medicine and Pharmacy at Ho Chi Minh City.**

BỘ Y TẾ CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc
Số: 2718/QĐ-BYT Hà Nội, ngày 30 tháng 7 năm 2010

QUYẾT ĐỊNH
Về việc thành lập Trung tâm Kiểm chuẩn chất lượng xét nghiệm y học thuộc Đại học Y Dược thành phố Hồ Chí Minh

BỘ TRƯỞNG BỘ Y TẾ
QUYẾT ĐỊNH:

Điều 1. Thành lập Trung tâm Kiểm chuẩn chất lượng xét nghiệm y học thuộc Đại học Y Dược thành phố Hồ Chí Minh.

Trung tâm Kiểm chuẩn chất lượng xét nghiệm y học là đơn vị sự nghiệp có thu, chịu sự chỉ đạo, quản lý trực tiếp của Hiệu trưởng Đại học Y Dược thành phố Hồ Chí Minh.

Trung tâm có tư cách pháp nhân, có con dấu riêng và tài khoản riêng.

Nơi nhận:
- Như Điều 5;
- Các Thứ trưởng Bộ Y tế;
- Lưu: VT, TCCB, K2ĐT.

BỘ TRƯỞNG


Nguyễn Quốc Triệu

HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025
INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

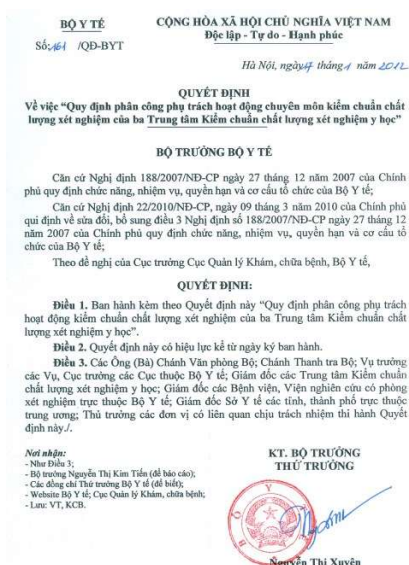
Grand Opening Ceremony on September 23, 2011



HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025

INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Functions and Responsibilities



Điều 7. Nhiệm vụ của các Trung tâm Kiểm chuẩn chất lượng xét nghiệm y học

1. Đánh giá năng lực chuyên môn, nhu cầu đào tạo về kiểm chuẩn chất lượng xét nghiệm y học của các cơ sở y tế có phòng xét nghiệm y học trên địa bàn được phân công.
2. Xây dựng kế hoạch và chương trình kiểm chuẩn chất lượng xét nghiệm y học của các cơ sở y tế trong phạm vi địa bàn được phân công.
3. Hướng dẫn và tạo điều kiện cho các cơ sở y tế nâng cao chất lượng xét nghiệm y học.
4. Thực hiện các hoạt động giám sát chương trình nội kiểm và triển khai chương trình ngoại kiểm cho các phòng xét nghiệm.
5. Theo địa bàn được phân công, Trung tâm Kiểm chuẩn có trách nhiệm tư vấn cho Bộ Y tế trong việc xem xét, công nhận và chỉ đạo các phòng xét nghiệm tham chiếu trong công tác kiểm chuẩn chất lượng xét nghiệm.
6. Cấp giấy chứng nhận tham gia chương trình ngoại kiểm và chứng nhận hợp quy cho các phòng xét nghiệm.
7. Phối hợp với các phòng xét nghiệm tham chiếu và phòng xét nghiệm của các cơ sở y tế thực hiện các biện pháp can thiệp trong công tác ngoại kiểm khi cần thiết.
8. Tổ chức thực hiện công tác đào tạo và đào tạo liên tục cho cán bộ viên chức của các cơ sở y tế có phòng xét nghiệm về kiểm chuẩn chất lượng xét nghiệm y học.
9. Phối hợp với các đơn vị trong và ngoài nước triển khai các chương trình kiểm chuẩn chất lượng xét nghiệm y học.
10. Phối hợp với Trung tâm Kiểm chuẩn chất lượng xét nghiệm y học Trường Đại học Y Hà Nội trong việc thực hiện các nội dung tại Điều 6.

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Quality Control Center Network

- Decision No. 161/QĐ-BYT dated January 17, 2012, regarding the assignment of responsibility for professional activities in medical laboratory quality control.

QCC – Hanoi Medical University

QCC – University of Medicine and Pharmacy at Ho Chi Minh City

QCC – Ho Chi Minh City Department of Health



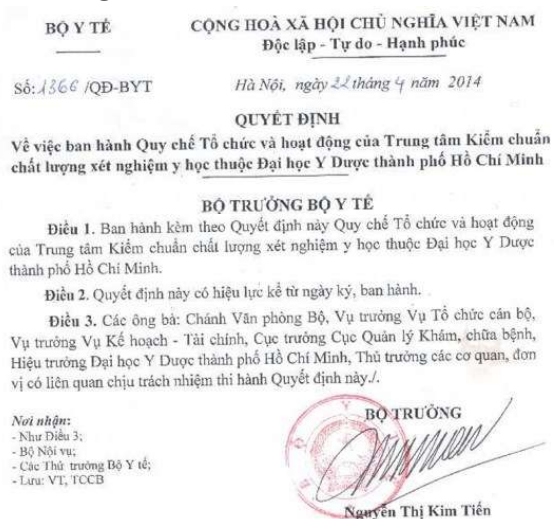
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Area of Responsibility of the Center according to Decision No. 161/QĐ-BYT dated January 17, 2012

Socio-Economic Region	Before June 12, 2025	From June 12, 2025
Southeast Region	Ho Chi Minh City (central-affiliated facilities with laboratories)	Ho Chi Minh City (central-affiliated facilities with laboratories)
South Central Coast	Da Nang, Quang Nam, Quang Ngai, Binh Dinh, Phu Yen, Khanh Hoa, Ninh Thuan, Binh Thuan	Quang Ngai (Quang Ngai + Kon Tum), Khanh Hoa (Khanh Hoa + Ninh Thuan), Da Nang City (Da Nang + Quang Nam)
Central Highlands	Gia Lai, Kon Tum, Dak Lak, Dak Nong, Lam Dong	Gia Lai (Gia Lai + Binh Dinh), Lam Dong (Lam Dong + Binh Thuan + Dak Nong), Dak Lak (Dak Lak + Phu Yen)
Southeast Region	Bà Rịa – Vũng Tàu, Binh Duong, Binh Phuoc, Dong Nai, Tay Ninh	Dong Nai (Dong Nai + Binh Phuoc), Tay Ninh (Tay Ninh + Long An)

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In 2014, the Regulation governing the organizational structure and operational activities of the Center was officially promulgated



Workshop on June 20, 2014

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Yearly Scientific Meetings and Workshops



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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Yearly Scientific Meetings and Workshops

THỦ TƯỚNG CHÍNH PHỦ CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Số: 48/CP-ĐTg
ĐẾN: ...
Ngày: ...

Hà Nội, ngày 27 tháng 06 năm 2016

QUYẾT ĐỊNH

Phê duyệt Đề án Tăng cường năng lực hệ thống quản lý chất lượng
xét nghiệm y học giai đoạn 2016 - 2025

BỘ Y TẾ

THỦ TƯỚNG CHÍNH PHỦ

Căn cứ Luật Tổ chức Chính phủ ngày 19 tháng 6 năm 2015;
Căn cứ Nghị định số 63/2012/NĐ-CP ngày 31 tháng 8 năm 2012 của Chính
phủ quy định chức năng, nhiệm vụ, quyền hạn và cơ cấu tổ chức của Bộ Y tế;
Xét đề nghị của Bộ trưởng Bộ Y tế,

TIÊU CHÍ ĐÁNH GIÁ MỨC CHẤT LƯỢNG PHÒNG XÉT NGHIỆM Y HỌC

(Ban hành kèm theo Quyết định số 2429/QĐ-BYT ngày 14 tháng 6 năm 2017
của Bộ trưởng Bộ Y tế về việc Ban hành Tiêu chí đánh giá mức chất lượng
phòng xét nghiệm y học)



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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Yearly Scientific Meetings and Workshops



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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Yearly Scientific Meetings and Workshops



HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025 INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT 2025

National Conference on the Final Review of the Project
“Enhancing the Capacity of the Medical Laboratory System
(2016–2025)” and the Implementation of Harmonization
Laboratory Test Results.



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Quality Control Center in 2025

Organizational Structure:

- 23 full-time employees
- 3 concurrently assigned staff
- 6 external associates

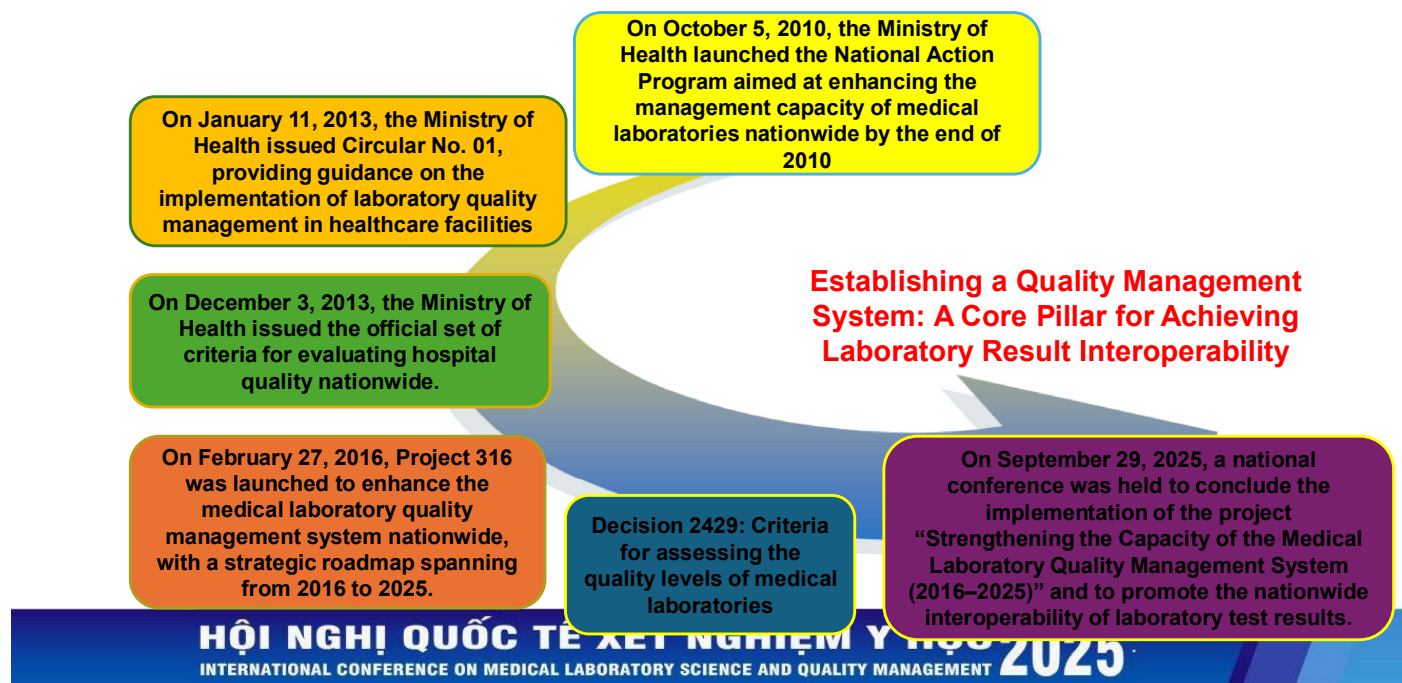


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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

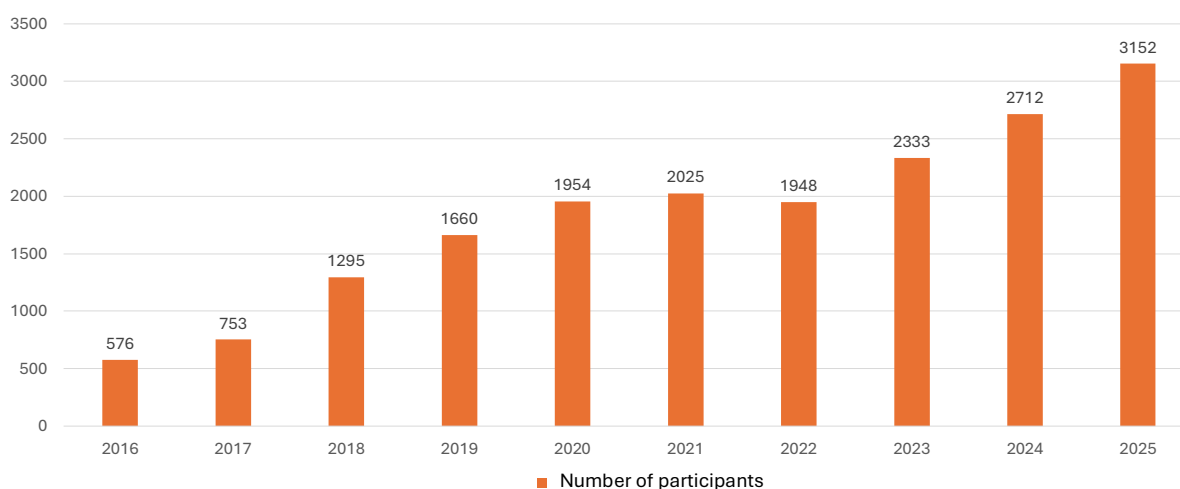
Annual Report on Laboratory Quality Management in 2025

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

The Process of Developing a Laboratory Quality Management System in the Health Sector Towards Interoperability

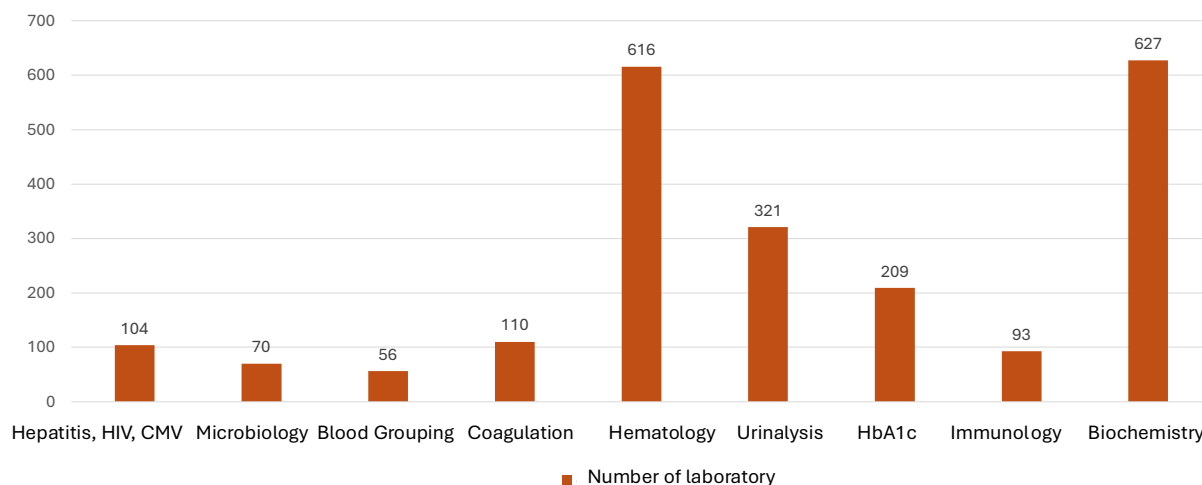


Participation Frequency in External Quality Assessment Programs at the Quality Control Center – University of Medicine and Pharmacy (QCC UMP), 2016–2025



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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

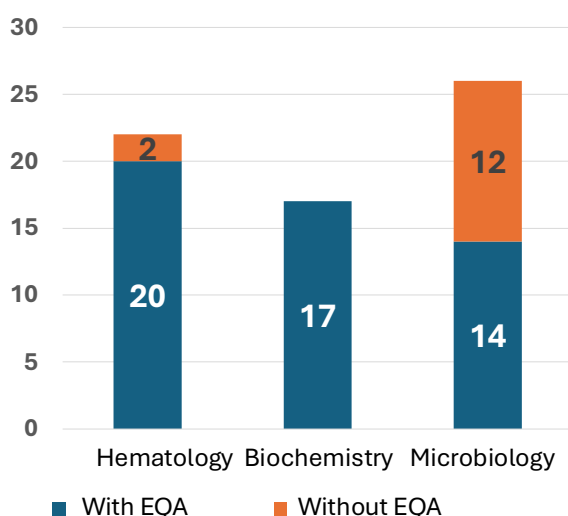
Participation of Medical Laboratories by EQA Program Group in 2025



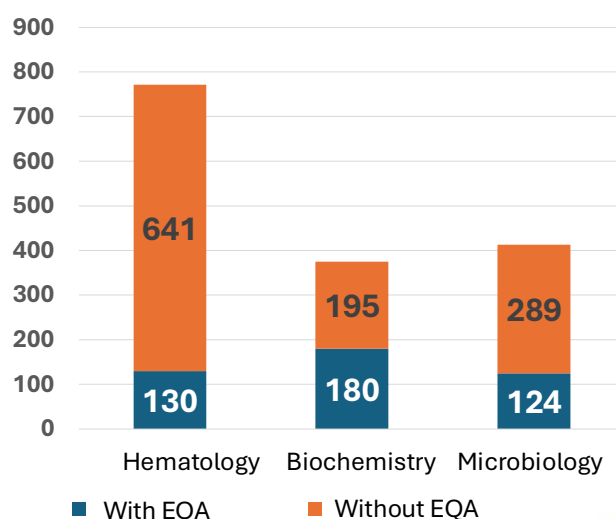
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Coverage Across Medical Laboratories

Decision 3148/QĐ-BYT



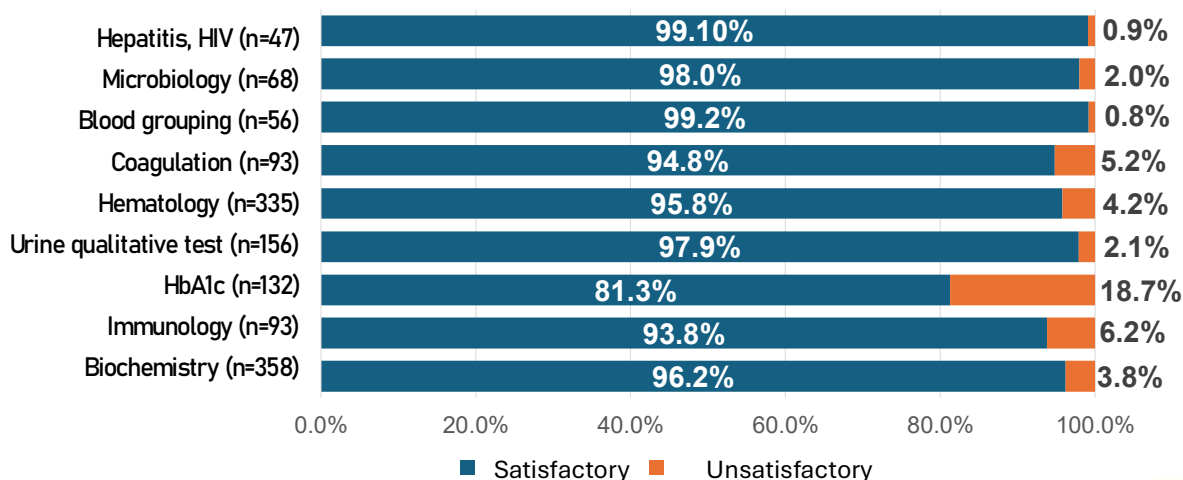
Circular No. 23/2024/TT-BYT



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External Quality Assessment (EQA) Results.

The proportion of laboratories with satisfactory External Quality Assessment (EQA) results in 2025



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External Quality Assessment Programs Implemented



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New Developments in EQA Implementation in 2026

EQA Code	Program Name	New Parameters
QE1023 (QCC UMP)	Biochemistry	eGFR
QE1018 (QCC UMP)	Urinalysis	hCG
0200 (MES)	Semen Analysis	Sperm Density
RQ9128 (Riqas)	Biochemistry	Anion Gap FIB-4 Osmolar Gap Transferin Transferin Saturation T-uptake
RQ9115 (Riqas)	Urine Biochemistry	Pro/Cre ratio
RQ9130 (Riqas)	Immunology	Estriol, total Free Androgen Index T-uptake

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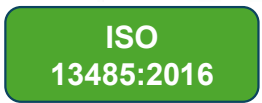
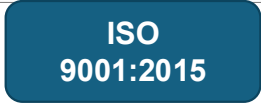
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ISO/IEC 17043 accredited PT programs



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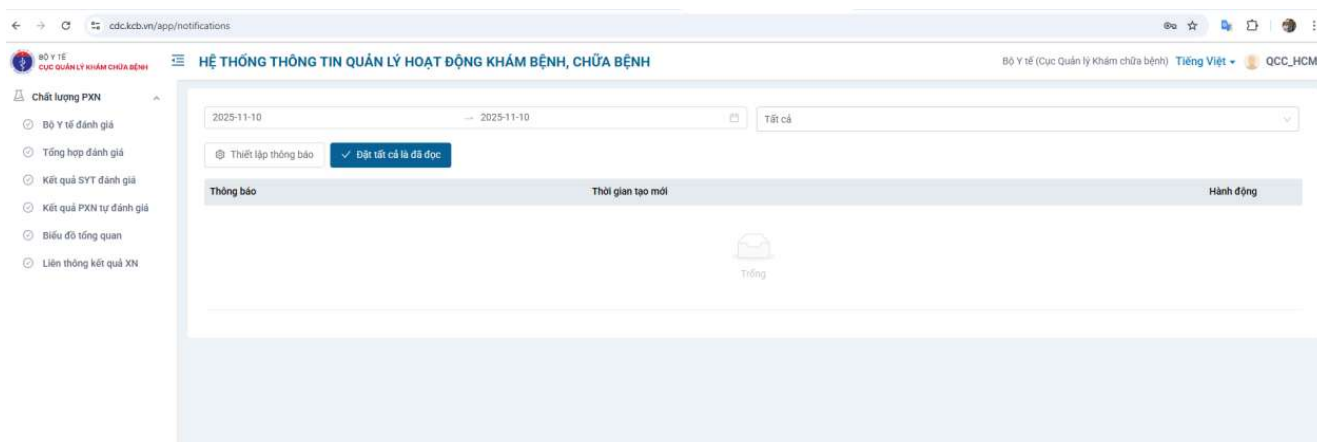


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Participation in the Ministry of Health's Laboratory Quality Assessment Team



Support for facilities in conducting 2429 assessments via the Ministry of Health's official website



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On-site technical support



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Short-term training programs

Training Courses on Medical Laboratory Techniques			
1	Quality management in medical laboratories based on the assessment criteria of Decision 2429/QĐ-BYT	10	Validation of qualitative and semi-quantitative testing methods
2	Laboratory quality management according to ISO 15189 standards	11	Procurement and management of equipment, chemicals, reagents, and consumables
3	External quality control in medical testing	12	Investigation and prevention of errors in internal and external quality control
4	Internal quality control in medical testing	13	Biosafety in medical laboratories
5	Internal quality control in microbiology and parasitology – from standards to application	14	Inter-laboratory comparison for biochemistry, microbiology, and pathology
6	Internal quality control for quantitative testing: from theory to practice	15	Application of Six Sigma in internal quality control for laboratory testing
7	Developing the Quality Manual, Customer Service Manual, and Laboratory Safety Manual	16	Training for laboratory quality management system assessors
8	Internal audit, identification of non-conformities, and continuous improvement	17	Inspection, calibration, and testing of laboratory equipment
9	Validation of quantitative testing methods	18	Good practices in storage of medicines, vaccines, and medical reagents

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Short-term training programs

Training Courses on Medical Laboratory Techniques			
19	Medical laboratory techniques – specialized training	24	5. Modern blood transfusion: challenges and emerging trends
20	1. Microbiology testing techniques	25	6. Fungal culture, antifungal susceptibility testing, and result interpretation
21	2. Rapid testing techniques applied in microbiology and parasitology	26	7. Applied molecular biology testing techniques
22	3. Identification of blood cell morphology on peripheral blood smears and bone marrow slides	27	8. Techniques and quality control for antibiotic susceptibility testing
23	4. Updates on multidrug-resistant bacteria and interpretation of antibiotic susceptibility results according to CLSI standards	28	9. Blood smear examination: a practical diagnostic approach

Total of 8,185 trainees across 163 classes

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Medical Technology Classes

From Learning to Doing



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Scientific Research Activities

- 33 research projects successfully implemented
- 6 conferences and seminars organized
- 105 scientific publications, both domestic and international.

Acta Biomed 2025, Vol. 96, N. 2: 16974
DOI: 10.23750/abm.v96i2.16974

ORIGINAL ARTICLE

Study on the stability of PT, aPTT, and fibrinogen in lyophilized plasma for external quality control

Thi Hong Nguyen^{1,2}, Thanh Tung Tran³

¹Department of Laboratory Technology, Faculty of Pharmacy, Can Tho City, Viet Nam; ²University of Viet Nam; ³Department of Hematology, Cho Ray Hospital, University of Medicine and Pharmacy, Meilatte General Hospital, Ho Chi Minh City, Viet

JMI Journal of Microbiology and Infectious

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Statistics

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Research Article



Case Report

Multidrug-resistant Edwardsiella tarda and Proteus vulgaris Wound Coinfection: a Case Report of a Fish Vendor

• Malays J Med Sci. 2025 Jun 30;32(3):144-155. doi: 10.17966/JMI.2025.30.3.66 Epub 2025 July 01.

Mental Health Burden Among Peo Vietnam: Prevalence and Novel Ri
Son Thanh Mao, Hue Van Thi Tran, Ngoc Hieu Nguyen
10.17966/JMI.2025.30.3.66 Epub 2025 July 01.

Yen Thi Hoai Phan¹, Thao Thi Ngoc Nguyen¹, Vu Hoang Anh Nguyen², Yen Thi Nguyen³, Phuong Thi Be Nguyen⁴, Thanh Nguyen Ai Tran^{4,5,6}

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PMCID: PMC12513503 PMID: 41081022

Journal of Associated Medical Sciences 2025, 58(3): 254-262

JAMS

Journal of Associated Medical Sciences

Scopus Indexed & Thai-Journal Citation Index Centre (TCI)

Journal of Associated Medical Sciences

Journal homepage: <https://www.tci-thaijo.org/index.php/bulletinJAMS/index>

Performance of line probe assay and phenotypic drug susceptibility testing in detecting drug-resistant tuberculosis

Phu Thien Truong¹, Tran Ngoc Minh Le², Van Thi Hoa Tran^{3,4}, Tung Thanh Phan⁵

¹Nephrology Department, Cho Ray Hospital, Ho Chi Minh City, Vietnam.

²Medical Laboratory Technology Department, Faculty of Nursing and Medical Technology, University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam.

³Microbiology and Parasitology Department, Faculty of Medicine, University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam.

⁴Quality Control Center for Medical Laboratory, University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam.

in freeze-dried plasma for external blood on testing programs
1 plasma liofilizado para programas de pruebas coagulacion sanguinea

01-0545-7205

5-6770-2298

14002-6173-4115

-3509-1814

¹University of Medicine and Pharmacy, Ho Chi Minh City, Vietnam.

²University of Medicine and Pharmacy, Department of Nursing and Medical Technology, Can Tho City, Vietnam.

³Cho Ray Hospital, Department of Hematology, Ho Chi Minh City, Vietnam.

⁴University of Medicine and Pharmacy, Ho Chi Minh City, Vietnam.

⁵Meilatte General Hospital, Department of Laboratory Medicine, Ho Chi Minh City, Vietnam.

*Corresponding author. Email: dr.vuongthien@gmail.com

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Organizing Conferences, Seminars, and International Collaboratio



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Participated as Chairperson and Scientific Presenter



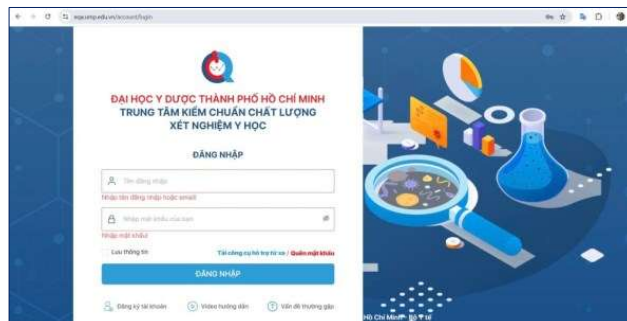
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Launching web-based software for managing external quality assurance (EQA) activities

<https://qcc.ump.edu.vn/>



<https://eqa.ump.edu.vn/account/login>



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Customer Service and Communications

- Group zalo
- Email
- Telephone
- Fanpage



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Community Services

In solidarity with Cho Ray Hospital's Blood Transfusion Center, our team joined the meaningful Humanitarian Blood Donation Day to support the community and promote the spirit of giving.

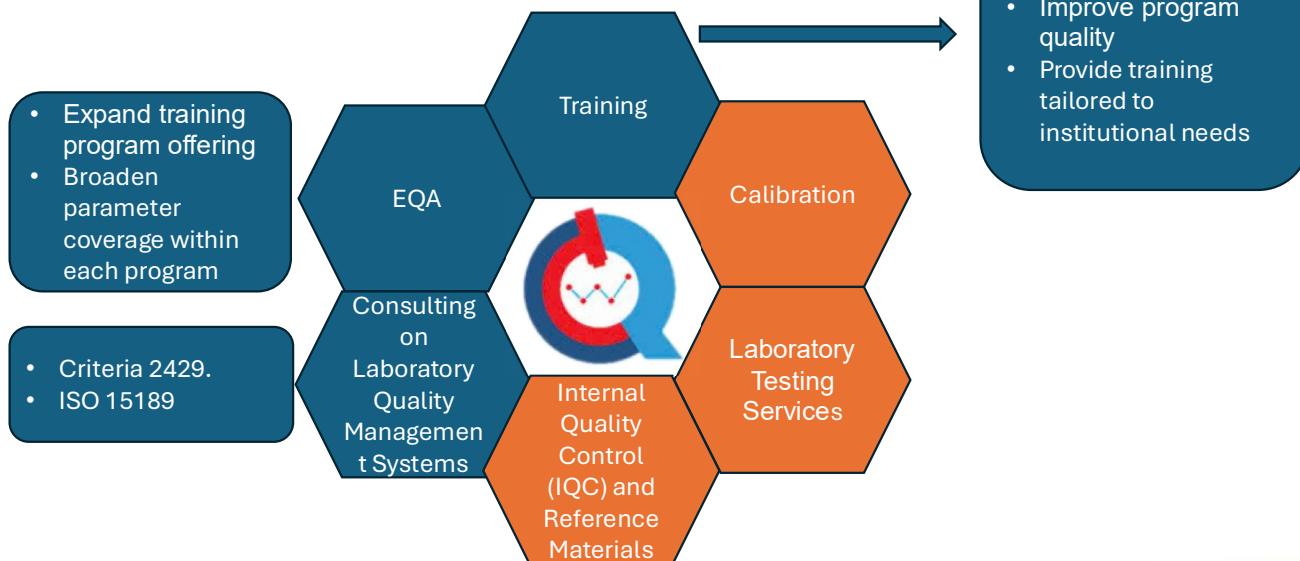


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Orientation for 2026

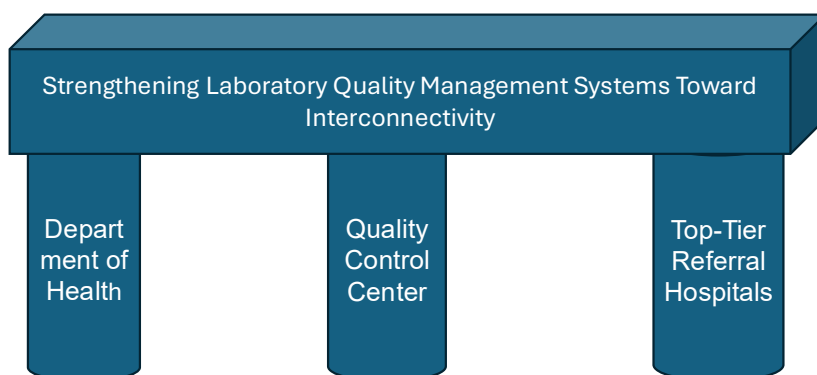
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Services to Be Delivered in 2026



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Continue Strengthening Oversight of the Laboratory Quality Management System within the Jurisdiction



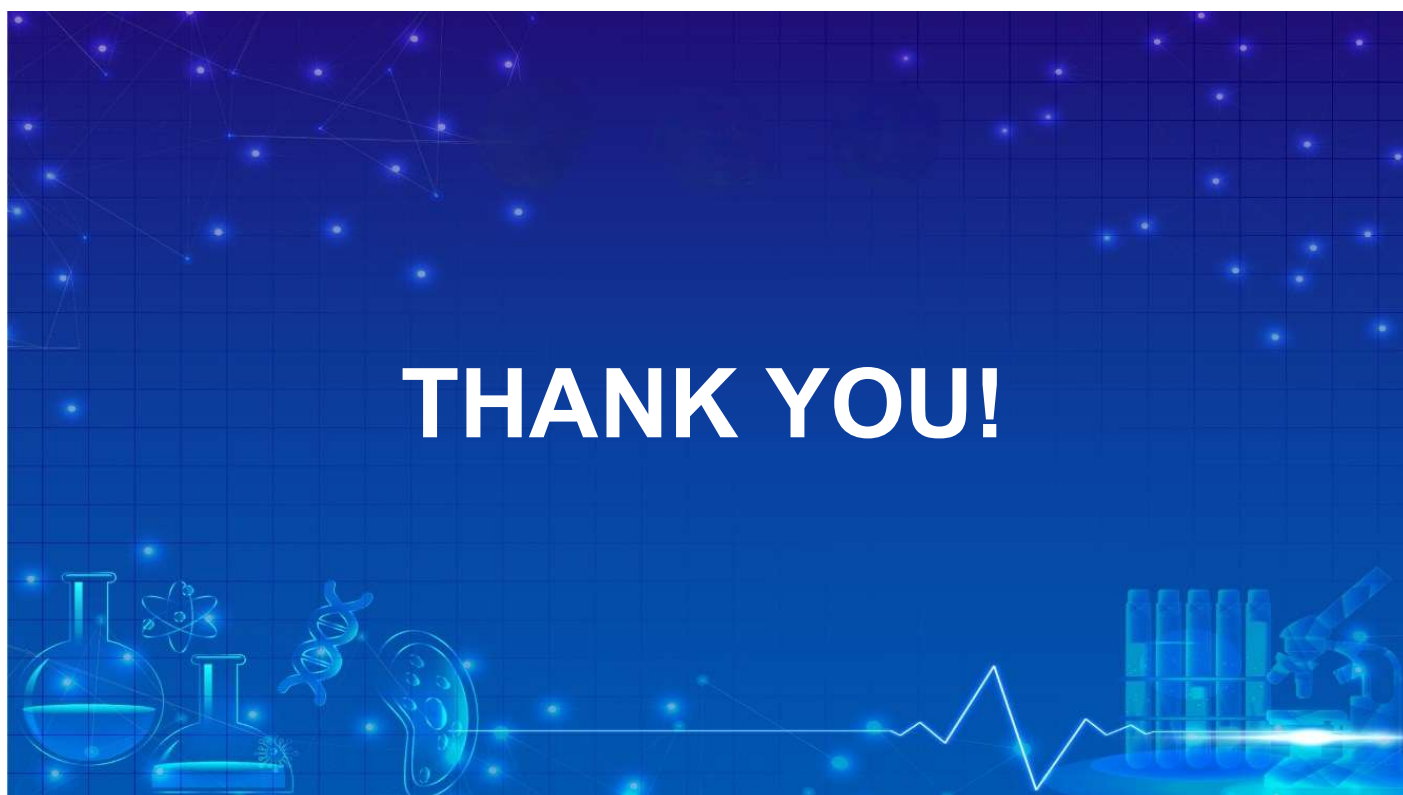
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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

THANK YOU!



EXPERIENCES WITH DEPLOYING THE EXTERNAL QUALITY ASSESSMENT (EQA) PROGRAMS IN SOUTH KOREA

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¹Department of Laboratory Medicine, National Cancer Center, Korea

²Deputy Manager of External Quality Assessment Operations, KEQAS

Contents

- Laboratory Medicine in Korea
- History of KEQAS
- EQA (PT) of KEQAS
- Process of EQA (PT)

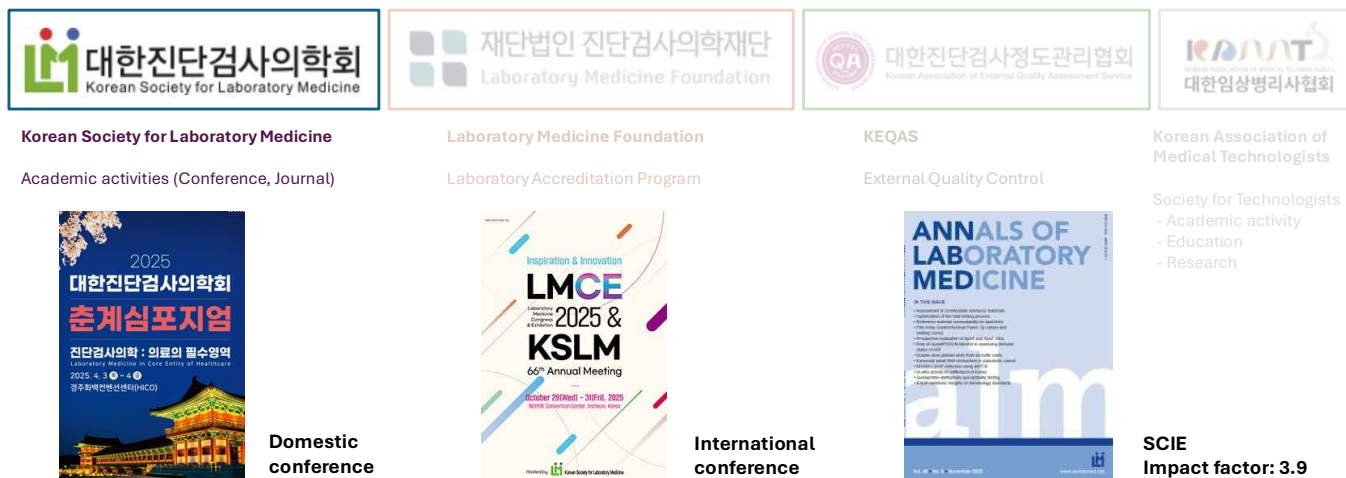
Societies for Laboratory Medicine in Korea



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Societies for Laboratory Medicine in Korea



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Societies for Laboratory Medicine in Korea



Korean Society for Laboratory Medicine

Academic activities (Conference, Journal)



Laboratory Medicine Foundation

Laboratory Accreditation Program



KEQAS

External Quality Control



Korean Association of
Medical Technologists

Society for Technologists
- Academic activity
- Education
- Research



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Societies for Laboratory Medicine in Korea



Korean Society for Laboratory Medicine

Academic activities (Conference, Journal)



Laboratory Medicine Foundation

Laboratory Accreditation Program



KEQAS

External Quality Control



Korean Association of
Medical Technologists

Society for Technologists
- Academic activity
- Education
- Research

Accreditation for

Laboratory Management	Point-of-care testing	Diagnostic Hematology	Clinical Chemistry (General, Urinalysis and Microscopy)	Clinical Microbiology	
Transfusion Medicine	Diagnostic Immunology	Flow Cytometry	Histocompatibility Testing	Cytogenetic Testing	Molecular Diagnostic Test

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Societies for Laboratory Medicine in Korea



Korean Society for Laboratory Medicine

Academic activities (Conference, Journal)

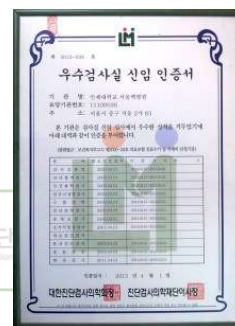


Laboratory Medicine Foundation

Laboratory Accreditation Program



KEQAS



Korean Association of Medical Technologists

Society for Technologists - Academic activity

Accreditation for

Laboratory Management	Point-of-care testing	Diagnostic Hematology	Clinical Chemist (General, Urinalysis, Microscopy)
Transfusion Medicine	Diagnostic Immunology	Flow Cytometry	Histocompatibility T



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Societies for Laboratory Medicine in Korea



Korean Society for Laboratory Medicine

Academic activities (Conference, Journal)



Laboratory Medicine Foundation

Laboratory Accreditation Program



KEQAS

External Quality Control



Korean Association of Medical Technologists

Society for Technologists - Academic activity

External Quality Control Programs (Proficiency Tests)

- Academic conferences
- Journal
- Education
- Research supporting

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Societies for Laboratory Medicine in Korea



Korean Society for Laboratory Medicine

Academic activities (Conference, Journal)



Laboratory Medicine Foundation

Laboratory Accreditation Program



KEQAS

External Quality Control



Korean Association of
Medical Technologists

Society for Technologists
- Academic activity
- Education
- Research

- Society for medical technologists

- Academic conferences

- Journal

- Education

- Research supporting

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

History of KEQAS

- 1976 Korean **Society of Quality Control** in Clinical Pathology
- 1979 **Journal** of Clinical Pathology and Quality Control
- 1990-1991 Korean **Association of Quality Assurance** for Clinical Laboratory
- 2015 **ISO 17043 Certified Proficiency Testing Organization**
- 2016 **New systems** for External Quality Control
- 2026 The 50th Anniversary International Congress of **Korean Association of External Quality Assessment Service** (KEQAS 2026)

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Proficiency tests of KEQAS

- Proficiency tests before 1991

- PT programs

- Clinical Chemistry
- Clinical Microbiology
- Diagnostic Hematology
- Immunoserology
- Urinalysis & Microscopy
- Blood Banking

사단법인 대한임상검사항도관리협회 외부정도관리사업 현황

년 도	Trial 횟 수					
	임상화학	임상미생물	진단혈액	변역혈청	임상경검	혈액은행
1977	8	2	1	-	-	-
1978	5	1	-	1	-	-
1979	7	2	2	1	-	-
1980	6	2	3	1	-	-
1981	6	2	3	1	-	-
1982	6	2	3	1	2	-
1983	6	2	3	1	2	-
1984	6	2	3	1	2	-
1985	6	2	3	1	2	-
1986	6	2	3	2	2	2
1987	6	3	3	2	2	2
1988	6	3	3	2	2	2
1989	6	3	3	2	2	2
1990	6	3	3	2	2	2
1991	6	3	2	2	2	2

HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025
INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Proficiency tests of KEQAS

- Proficiency tests between 1991~2015
- Many QC activities handled by **10 different committees** of each specialty
 - Clinical Chemistry
 - Clinical Microbiology
 - Diagnostic Hematology
 - Immunoserology
 - Urinalysis & Microscopy
 - Blood Banking
 - Therapeutic Drug Monitoring
 - Immunoassay
 - Inborn Error of Metabolism
 - Diagnostic Genetics

HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025
INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Proficiency tests of KEQAS (2025)

Discipline	Classification	Program
Transfusion Medicine	Pretransfusion Testing	Blood typing and crossmatching, general *
		Blood typing, special *
		Transfusion Ab, general *
		Transfusion Ab, special 1
		Transfusion Ab, special 2
Diagnostic Hematology	Hematology	Complete blood count (CBC)
		Erythrocyte sedimentation rate (ESR)
		Peripheral blood smear, malaria
		Peripheral blood smear
		Peripheral blood smear, special stain
		Body fluid cytology
	Coagulation	Coagulation, general 1
		Coagulation, general 2
		Coagulation, special 1
		Coagulation, special 2

HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025

INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Proficiency tests of KEQAS (2025)

Discipline		Classification	Program		
Transfusion Medicine		Pretransfusion Testing	Blood typing and crossmatching, general *		
			Blood typing, special *		
			Transfusion Ab, general *		
			Transfusion Ab, special 1		
			Transfusion Ab, special 2		
Dialysis	Program		Tests	Level	Trial
	Blood typing and crossmatching, general *		Blood crossmatching	3	2
			ABO Typing	3	2
			RhD typing	3	2
	Blood typing, special *		ABO subgroup typing	1	2
			Weak D test	1	2
			Rh CcEe antigen test	1	2
			Duffy antigen test	1	2
			Lewis antigen test	1	2
			Kidd antigen test	1	2
	Transfusion Ab, general *		Unexpected antibody (screening)	3	2
			Direct anti-human globulin test (polyspecific)	3	2
			Direct anti-human globulin test (anti-IgG monospecific)	3	2
			Direct anti-human globulin test (anti-C3d monospecific)	3	2
			Unexpected antibody (identification)	2	2
			ABO Ab titration test	1	2
			Anti-D antibody titer	3	2

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Proficiency tests of KEQAS (2025)

Discipline	Classification	Program
Clinical Chemistry	Urinalysis & Stool Occult Blood etc.	Urinalysis
		Stool occult blood
	Blood Gas Analysis	Blood gas analysis
		Blood gas analysis, POCT
	General Chemistry	Routine chemistry *
		ICG test
		Urine chemistry
		Glycated albumin
		Cystatin C
	Special proteins	Special proteins
	Carbohydrates, Lipids, Proteins & Vitamins	Glucose, POCT
		Cardiac markers
	Metabolic Diseases	Newborn screening 1
		Newborn screening 2
		Amino acid profile
		Special metabolites

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Proficiency tests of KEQAS (2025)

Discipline	Classification	Program
Clinical Chemistry	Urinalysis & Stool Occult Blood etc.	Urinalysis
		Stool occult blood
	Blood Gas Analysis	Blood gas analysis
		Blood gas analysis, POCT
	General Chemistry	Routine chemistry *
		ICG test

Program	Tests	Level	Trial
Routine chemistry *	Alanine aminotransferase	3	4
	Albumin	3	4
	Alkaline phosphatase	3	4
	Amylase	3	4
	Aspartate Aminotransferase	3	4
	Bilirubin, direct	3	4
	Bilirubin, total	3	4
	Calcium	3	4
	Chloride	3	4
	Cholesterol, total	3	4
	Creatine kinase	3	4
	Ethanol (Alcohol)	3	4
	Gamma-glutamyl transpeptidase	3	4
	High density lipoprotein cholesterol	3	4
	...	...	...

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Proficiency tests of KEQAS (2025)

Discipline	Classification	Program
Clinical Chemistry	Hormones	Hormones 1
		Hormones 2
		Hormones 3
		Hormones 4
		Hormones 5
		Hormones 6
		Hormones 7
	Tumor Markers	Tumor markers 1
		Tumor markers 2
	Therapeutic Drug Monitoring & Toxicology	Therapeutic drug monitoring, general
		Therapeutic drug monitoring, Special
		Immunosuppressants therapeutic drug monitoring
		Drug of abuse (QL)
	Accuracy-Based Chemistry	Drug anti-Epileptic drug
		Accuracy-based lipids *
		Accuracy-based Creatinine *
		Accuracy-based HbA1c *
		Accuracy-based Glucose *
		Creatinine data quality assessment

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Proficiency tests of KEQAS (2025)

Discipline	Classification	Program	Tests	Level	Trial
Clinical Chemistry	Accuracy-Based Chemistry	Accuracy-based lipids *	Total cholesterol	3	2
			High density lipoprotein cholesterol (HDL-C)	3	2
			Low density lipoprotein cholesterol (LDL-C)	3	2
			Triglyceride	3	2
			Total glyceride	3	2
			Apolipoprotein A1	3	2
			Apolipoprotein B	3	2
			Lipoprotein(a)	3	2
			Creatinine	3	2
			eGFR	3	2
	Accuracy-Based Chemistry	Accuracy-based Creatinine *	Hemoglobin A1c (NGSP)	3	2
			Glucose	3	2
			Drug anti-Epileptic drug		
			Accuracy-based lipids *		
			Accuracy-based Creatinine *		
			Accuracy-based HbA1c *		
			Accuracy-based Glucose *		
			Creatinine data quality assessment		

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Proficiency tests of KEQAS (2025)

Discipline	Classification	Program
Diagnostic Immunology	Complements & Immunoglobulins	Complements & Immunoglobulins
	Serology	Syphilis tests
		Hepatitis serology
		Hepatitis serology, quantitative
		Virus Serology 1
		Virus Serology 2
		Virus Serology 3
	Human Leukocyte Antigen	HLA typing
		HLA typing, special
		HLA crossmatching
		HLA Ab tests
	Cellular Immune Assay	Lymphocyte subset assay
		Stem/progenitor cell assay
		Hematologic malignancy immunophenotyping
	Autoimmune Diseases	Autoimmune Assay 1
		Autoimmune Assay 2
		Autoimmune Assay 3
		Autoimmune Assay 4
	Allergy	Allergy test
	Infection-Induced Immune Response	Tuberculosis Ag response
	Clinical Microbiology	Mycobacteria, general
	Clinical Microbiology	Mycobacteria, drug susceptibility
		Bacteriology
		Mycology
		Parasitology

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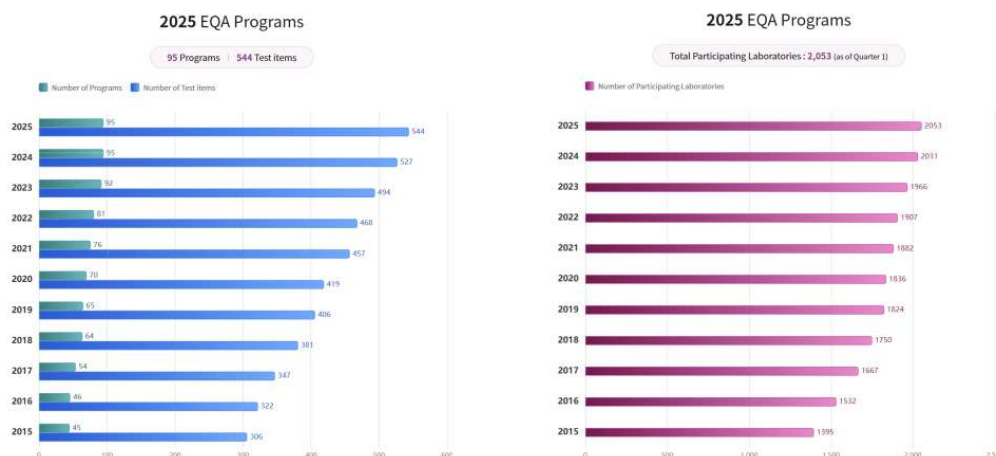
Proficiency tests of KEQAS (2025)

Discipline	Classification	Program
Molecular Diagnostics	Molecular Microbiology	Molecular microbiology, mycobacteria
		Molecular microbiology, hepatitis viruses 1
		Molecular microbiology, hepatitis viruses 2
		Molecular microbiology, viruses 1
		Molecular microbiology, viruses 2
	Human Genetics	Cytogenetics
		FISH 1
		FISH 2
		Molecular, hematologic malignancy
		Molecular, solid tumors
		Molecular, genetic disorders
		Pharmacogenetics Molecular, pharmacogenetics
		Human genetics, others Molecular, others 1
		Human genetics, others Molecular, others 2
		Liquid biopsy
		NGS, somatic
		NGS, germline
		NGS, liquid biopsy
Laboratory Management	Pre-analytical Phase	Pre-analytical quality index
		HIL index

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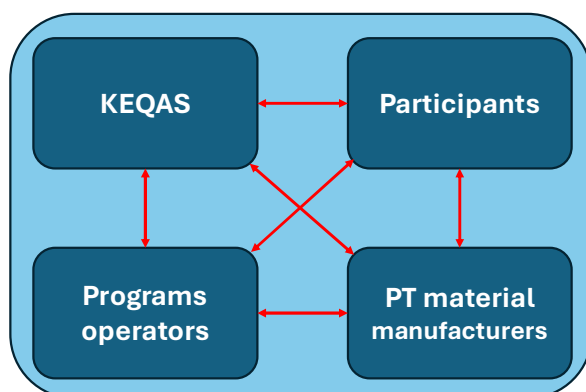
Proficiency tests of KEQAS

- Proficiency tests after 2016



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Process of KEQAS PT programs



KEQAS
= Participants
= Program operators
= PT material manufacturers

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Process of KEQAS PT programs

- Participation of laboratory
- ↓
- PT plan
- ↓
- PT materials
 - manufactured materials
 - commercialized materials
- ↓
- PT material transport, analysis, and result input
- ↓
- Data analysis and Reporting

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Process of KEQAS PT programs



KEQAS in Seoul



KEQAS office

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Process of KEQAS PT programs



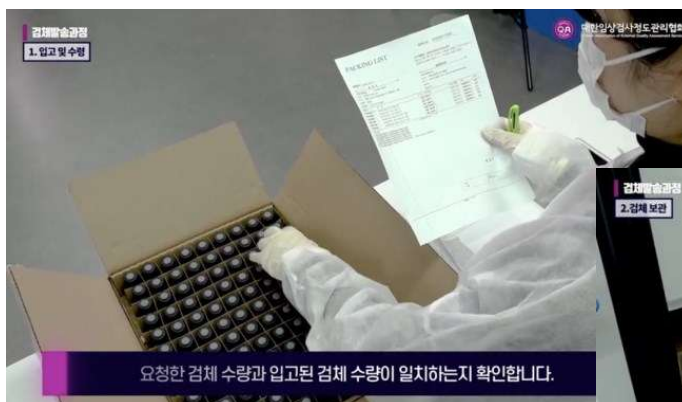
Workshop



Board meeting for PT planning

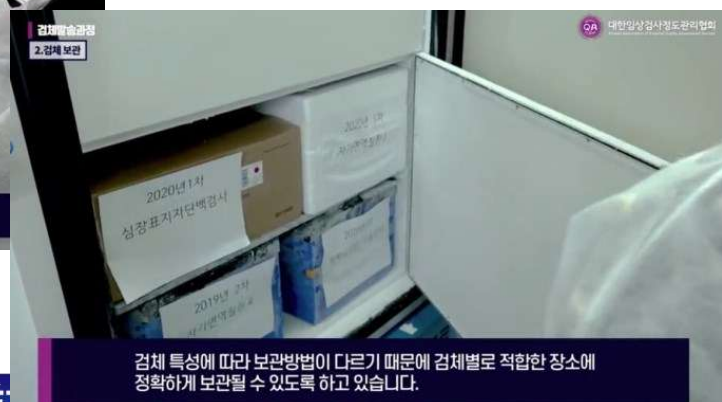
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Process of KEQAS PT programs



PT material check

PT material storage



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Process of KEQAS PT programs



Deep freezer



Cold room (refrigerator)

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Process of KEQAS PT programs



PT material packaging



PT material transportation

(over 2000 participants)

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Report of KEQAS PT programs

- Common report

2025년 01차 호르몬검사 1 공통보고서

Testosterone

CH1-25-01							
	N	Mean	SD	CV(%)	Median	Min	Max
All	130	8.5596	0.4643	5.4	8.700	0.126	12.200
Abbott	25	8.2805	0.4848	5.9	8.310	4.070	10.090
Alinity I	18	8.3663	0.4686	5.6	8.320	7.705	10.090
ARCHITECT i1000	1				8.310		
ARCHITECT i2000	6				8.000	4.070	8.460
Beckman Coulter Inc.	10	7.5436	0.2765	3.7	7.533	6.660	9.050
DXI/Access	10	7.5436	0.2765	3.7	7.533	6.660	9.050
Boditech	1				9.240		
AFLAS-10	1				9.240		
Ortho Clinical Diagnostics	2					0.126	12.200
VITROS Series	2					0.126	12.200
Roche	77	8.8092	0.1671	1.9	8.780	4.410	9.230
cobas e801	66	8.7971	0.1720	2.0	8.780	4.410	9.230
cobas pure e402	3				8.900	7.827	9.054
cobas4000 e411	2					8.820	8.910
e601/e602	6				8.845	7.920	8.970
Siemens Healthineers	15	8.0509	0.4336	5.4	8.027	7.182	8.822
ADVIA Centaur XP Series	2					7.528	7.710
Atellica IM series	13	8.1174	0.4267	5.3	8.087	7.182	8.822

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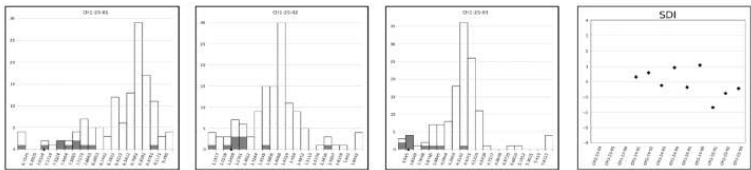
Report of KEQAS PT programs

- Individual report

Testosterone

Specimen	Your Result	Group	N	Mean	SD	CV(%)	Median	Min	Max	SDI	Remark
CH1-25-01	7.080	All	130	8.5596	0.4643	5.4	8.700	0.126	12.200		
		Beckman Coulter Inc.	10	7.5436	0.2765	3.7	7.533	6.660	9.050	-1.68	
		DXI/Access	10	7.5436	0.2765	3.7	7.533	6.660	9.050	-1.68	
CH1-25-02	1.250	All	130	1.3878	0.0693	5.0	1.405	0.018	2.610		
		Beckman Coulter Inc.	10	1.2818	0.0424	3.3	1.275	1.150	1.580	-0.75	
		DXI/Access	10	1.2818	0.0424	3.3	1.275	1.150	1.580	-0.75	
CH1-25-03	3.580	All	130	4.3330	0.1721	4.0	4.379	0.054	8.900		
		Beckman Coulter Inc.	10	3.7160	0.3079	8.3	3.570	3.350	4.370	-0.44	
		DXI/Access	10	3.7160	0.3079	8.3	3.570	3.350	4.370	-0.44	

단위: ng/mL
해당하는 분류에서 outlier를 제거 한 기판 수가 8개 미만인 경우 Mean, SD, CV(%), SDI는 제공하지 않습니다.
SDI는 기준분류 및 세분류에서만 제공됩니다. 참여기관 수 부족으로 SDI가 제시되지 않는 경우는 L-J chart에서도 나타나지 않습니다.



□ : 전체결과분포 ■ : 기준분류 분포 ▲ : 해당기관 결과

SDI : 기준 분류의 SDI

대한진단검사정보관리협회
Korea Association of External Quality Assessment Service

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Report of KEQAS PT programs

- Accuracy based PT

평가기준

Test item	Evaluation Criteria	
정확도기반 지질검사		
Cholesterol, total (mg/dL)	Accuracy-Based	≤ 9%
HDL-cholesterol (mg/dL)	Accuracy-Based	≤ 13%
LDL-cholesterol (mg/dL)	Accuracy-Based	≤ 12%
Triglyceride (glycerol blanked) (mg/dL)	Accuracy-Based	≤ 15%
Total Triglycerides (glycerol non-blanked) (mg/dL)	Accuracy-Based	≤ 15%
Apolipoprotein A1 (mg/dL)	Consensus mean (All Methods)	≤ 3 SD ¹⁾
Apolipoprotein B (mg/dL)	Consensus mean (All Methods)	≤ 3 SD ¹⁾
Lipoprotein(a) (mg/dL)	Consensus mean (All Methods)	≤ 3 SD ¹⁾
정확도기반 Creatinine검사		
Creatinine (mg/dL)	Accuracy-Based	≤ 11.4%
eGFR (mL/min/1.73 m ²)	Accuracy-Based	≤ 30%
정확도기반 HbA1c검사		
HbA1c (%)	Accuracy-Based	≤ 6.7%
정확도기반 Glucose검사		
Glucose (mg/dL)	Accuracy-Based	≤ 10%

1) Consensus mean, SD의 경우 75 percentile 값(Q3)과 25 percentile 값(Q1)의 차 (Q3 - Q1, IQR, Interquartile range)의 1.5배를 초과하여 Q1 보다 낮거나 Q3 보다 높은 결과값(< Q1 - 1.5 x IQR or > Q3 + 1.5 x IQR)을 outlier로 제거한 후 다시 분석한 값을 제시하였습니다.

HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025

INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Report of KEQAS PT programs

- Common report

2025년 01차 정확도기반 지질검사 공통보고서

Total cholesterol

CAL-25-01 Target value: 189.9 mg/dL

	N	Mean	SD	CV(%)	Median	Min	Max
All	399	188.0	2.7	1.4	188	133	206
Cholesterol esterase	399	188.0	2.7	1.4	188	133	206
신영과학	1				184		
아산제약㈜	1				185		
㈜신화메디	2					179	189
㈜지디엘코리아	2					182	193
Abbott	11	187.3	1.6	0.8	188	185	189
Beckman Coulter Inc.	60	188.6	2.2	1.2	189	152	200
Bion	2					190	194
Biosystems	7				202	191	206
JW바이오사이언스㈜(구 JW중외메디칼)	4				195	189	206
LC Diagnostics	1				190		
Minaris Medical co., Ltd	9				189	186	191
Ortho Clinical Diagnostics	1				188		
Roche	137	187.3	2.4	1.3	187	177	198
Sekisui Medical	98	188.7	2.4	1.3	189	133	195
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	3				188	179	193
Shino-Test Corporation	4				188	186	199
Siemens Healthineers	27	187.4	3.3	1.8	187	180	198
Wako	29	186.7	3.5	1.9	187	181	198

HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025

INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

Report of KEQAS PT programs

- Individual report

2025년 01차 정확도기반 지질검사 기관별 보고서

기관번호: 1000000001 기관명:

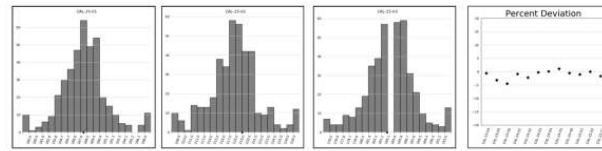
Total cholesterol

Specimen	Your result	Target value	Lower limit	Upper limit	Percent deviation (%)	Your Grade
CAL-25-01	188	189.9	172.8	207.0	-1.01	Acceptable
CAL-25-02	219	218.8	199.1	238.5	0.09	Acceptable
CAL-25-03	184	187.0	170.2	203.8	-1.60	Acceptable

단위: mg/dL, 검사방법: Cholesterol enzyme

정확도기반 검사는 Target, Lower Limit, Upper Limit 그리고 각 기관 결과의 Percent Deviation(%) 결과를 제공합니다.

정확도기반 지질 검사 프로그램 기관별 보고서의 목표 참고값은 Total cholesterol, HDL-C, LDL-C는 미국 CDC Cholesterol Reference Measurement Laboratory Network 인정 참고값이실인 캐나다의 CEQAL (<http://www.ceqal.com>)에서 CDC (Abolt-Kendall) 참고값사법으로 측정된 값으로 설정 되었습니다. Triglyceride (without glycerol blanking, R1 reagent only, Total glycerides), Triglyceride (with glycerol blanking, R1+R2 reagent, 글리세롤소거법은 모두 JCTLM 국제인증기관인 일본 RiCCS(Reference Material Institute for Clinical Chemistry Standards)에서 Isotope Dilution Mass Spectrometry 원시방법으로 측정된 값으로 설정 되었습니다. Apolipoprotein A1, Apolipoprotein B, Lipoprotein(a) 항목의 경우 all method consensus mean 을 목표 참고값으로 설정하였습니다. Percent Deviation 값은 다음의 공식 ((Your result-Target value)/Target value * 100)에 따라 산출되었습니다. 단, 각 항목별 별개의 기관별보고서의 평가기준을 참고하여 주십시오.



□ : 전체결과분포 ■ : 기준분류 분포 ▲ : 해당기관 결과

대한진단검사정보관리협회

5/11

HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025

INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT 2025

Web system of KEQAS

- Web system
 - Apply for PT
 - Select programs
 - Delivery information
 - Results input
 - Reports return



신뢰도 조사사업 공지사항 신뢰도 조사사업 등록 신청 문의처 정보게시판 사업처 정보게시판

신규 참가기관 등록 신청 질 가산율 관련 문의 기타 문의

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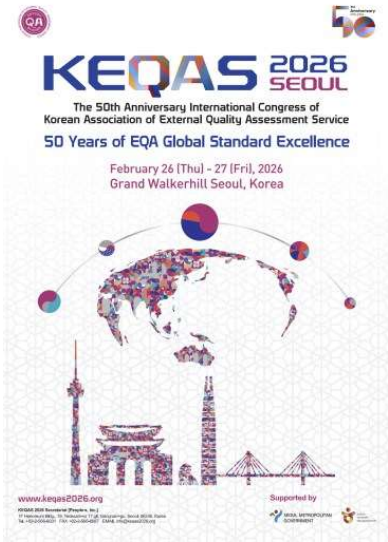
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신규 참가기관 등록 신청 질 가산율 관련 문의 기타 문의

HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025

INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT 2025

Future





The Importance of EQA Providers in Improving Clinical Laboratory Quality

Tony Badrick
The Royal College of Pathologists of Australasia, Australia

CV



Major Contributions and Current Activities of CAP in Improving Clinical Laboratory Quality

Bobbi Pritt
Mayo Clinic, USA

CV



EQA for Hematology Testing

Barbara De la salle
UK National External Quality Assessment Service, UK

CV

RCPA, Australia

NEQAS, UK

CAP, United States

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Future

Program at a Glance

FEB. 26 (Thursday)			FEB. 27 (Friday)		
Time	Room A	Room B	Time	Room A	Room B
09:30-09:50	Opening Ceremony KEQAS: A Half-Century of Excellence		09:40-09:50		Symposium 7 EQA Activities and International Cooperation to Improve Healthcare Quality in Asia
09:50-11:20	Symposium 1 Global EQA Activities for Quality Improvement of Clinical Laboratory	Symposium 2 Efforts for Quality Improvement in Transfusion Medicine	09:00-10:30	Symposium 6 Opportunities and Challenges in using Real-world Big Data for Healthcare	
11:20-12:10	Break & Visiting Booth		10:30-10:30	Break & Visiting Booth	
12:10-12:40	Plenary Lecture 1		10:50-11:30	Plenary Lecture 2	
12:40-13:40	Luncheon Symposium 1 	Luncheon Symposium 2 	11:50-12:30	Luncheon Symposium 3 	Luncheon Symposium 4 
13:40-15:10	Symposium 3 Standardization and Harmonization of Laboratory Tests and the Role of EQA	Symposium 4 Trends in Emerging Technologies	12:50-13:20	Education Workshop 5 	Education Workshop 6 
15:10-15:40	Education Workshop 1 	Education Workshop 2 	13:25-13:50	Education Workshop 7 	
15:40-16:10	Education Workshop 3 	Education Workshop 4 	13:50-14:10	Break & Visiting Booth	
16:10-16:30	Break & Visiting Booth		14:10-15:40	Symposium 8 Application of Quality Assurance Tools	Symposium 9 The Role of EQA during the Pandemic Era
16:30-18:00			15:40-17:10	Symposium 10 Ensuring Comparability of Proficiency Testing (PT) Materials in EQA	Symposium 11 The Impact of Laboratory Test Quality and EQA on Public Healthcare
18:00-19:30	Welcome Reception		17:10-17:40	Closing Ceremony	



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Harmonization Testing: Insights and Experiences from Thailand

Prasong Khaenam, Ph.D
Faculty of Medical Technology
Mahidol University
Thailand
prasong.kha@mahidol.ac.th

15th

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70th



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Quality Assurance of Clinical Laboratory

Method establishment



Manufacturer

Feasibility and Design
Development
Validation
(Doing the right test)

Package insert
(Instruction for use: IFU)



Claim

Method implementation



Clinical Laboratory

Installation and Preliminary Evaluation
Installation Qualification (IQ),
Operation Qualification (OQ),
Performance Qualification (PQ)
Verification Precision (imprecision)
Accuracy (bias)
Reportable range
Reference interval

Doing the test right

Quality assurance by IQC and EQA

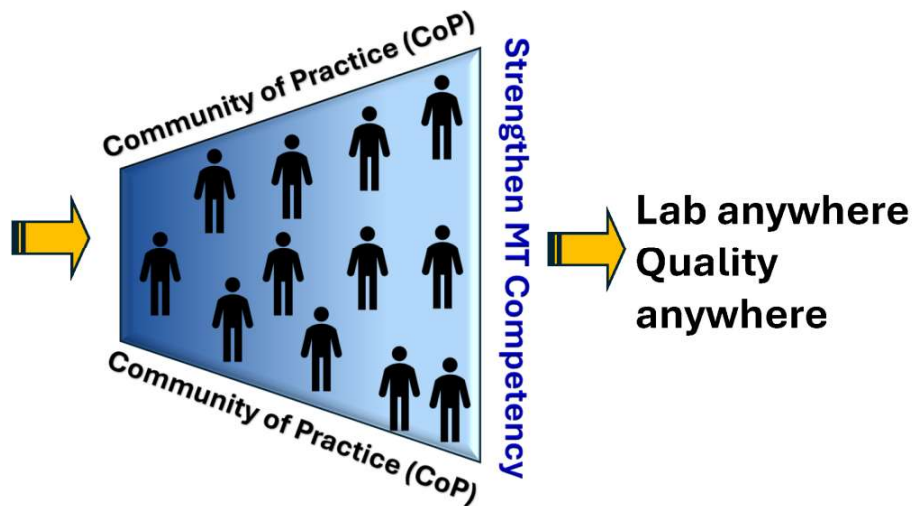
Launch
Method maintenance
Method retirement

Accreditation Body (ISO 15189, Laboratory Accreditation, MOPH, CAP)

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Ecosystem

EQA providers
Laboratories
IVD
manufacturers
Other
contributors



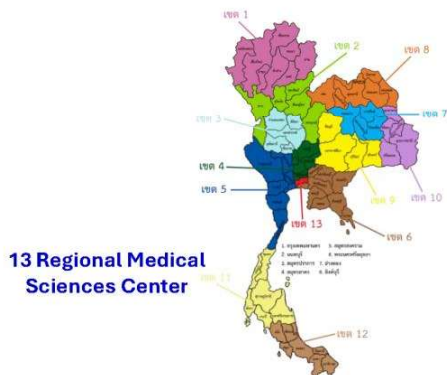
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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

EQA Providers in Thailand

Division of Proficiency Testing
Department of Medical
Sciences MOPH

**Faculty of Medical Technology,
Mahidol University (MUMT)**



5000 Participants
from approx. 1200 labs

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Mahidol University
Faculty of Medical Technology

The Establishment of EQAS-MUMT

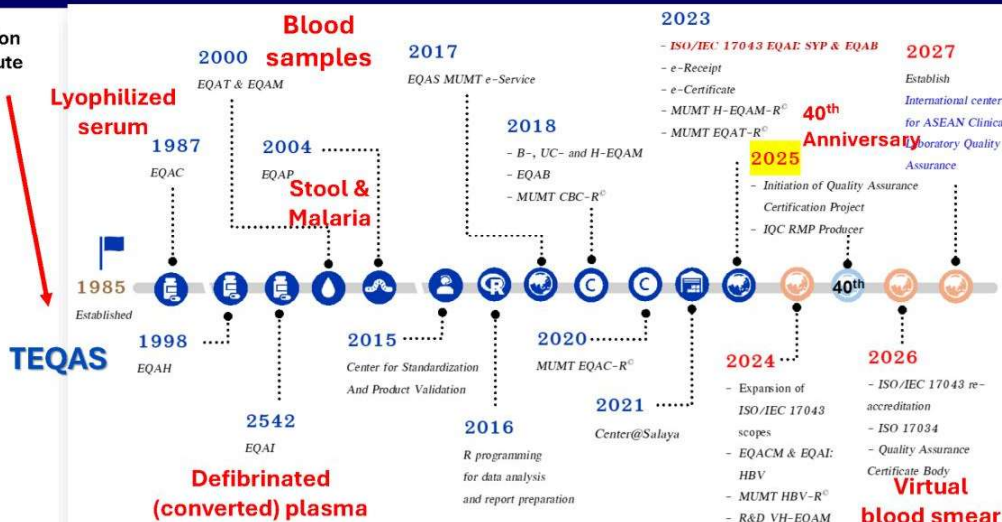
In-house QC production
by an academic institute



Assoc. Prof. Amarin
Prijavudhi



Prof. Vikul Viriyakulchai



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5



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Faculty of Medical Technology

Local providers are easier to access



<https://eqamt.mahidol.ac.th>

ศูนย์พัฒนามาตรฐานและการประเมินผลผลิตภัณฑ์
คณะเทคนิคการแพทย์ มหาวิทยาลัยมหิดล
เลขที่ 999 ถนนพุทธมณฑลสาย 4
ตำบลศาลายา อำเภอพุทธมณฑล จังหวัดนครปฐม 73170

โทรศัพท์ 0 2441 4376 ต่อ 2512
มือถือ 06 3895 1287
E mail eqamtmu@gmail.com
LINE Official @073H2fy
LINE OpenChat EQAS MUMT CONNECT



Booklet

โครงการทั้งหมด

Schemes

EQAC

EQACM

EQAH

EQAP

EQAT

EQAM

EQAI

EQAB

EQAS Status 2024

คู่มือสมัครสมาชิก

Participation Handbook

EQAS MUMT 2024 New

EQAS MUMT 2023

คู่มือสมาชิกโครงการ

Schemes Handbook

EQAC Handbook 2024

EQACM Handbook 2024

EQAH Handbook 2024

EQAP Handbook 2024

EQAT Handbook 2024

EQAM Handbook 2024

EQAI Handbook 2024

EQAB Handbook 2024

No language barrier &
Time zone – difference

Schemes	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
EQAT	19	20	21 (19)	22 (19)	23 (19)	24 (19)	25 (19)	26 (19)	27 (19)	28 (19)	29 (19)	30 (19)
EQAP	1	2	3 (2)	4 (2)	5 (2)	6 (2)	7 (2)	8 (2)	9 (2)	10 (2)	11 (2)	12 (2)
B-EQAM	1	2	3 (2)	4 (2)	5 (2)	6 (2)	7 (2)	8 (2)	9 (2)	10 (2)	11 (2)	12 (2)
H-EQAM	1	2	3 (2)	4 (2)	5 (2)	6 (2)	7 (2)	8 (2)	9 (2)	10 (2)	11 (2)	12 (2)
UC-EQAM	1	2	3 (2)	4 (2)	5 (2)	6 (2)	7 (2)	8 (2)	9 (2)	10 (2)	11 (2)	12 (2)
EQAI: BypHla	1	2	3 (2)	4 (2)	5 (2)	6 (2)	7 (2)	8 (2)	9 (2)	10 (2)	11 (2)	12 (2)
EQAI: HBV	1	2	3 (2)	4 (2)	5 (2)	6 (2)	7 (2)	8 (2)	9 (2)	10 (2)	11 (2)	12 (2)
EQAI: HCV	1	2	3 (2)	4 (2)	5 (2)	6 (2)	7 (2)	8 (2)	9 (2)	10 (2)	11 (2)	12 (2)
EQAB	1	2	3 (2)	4 (2)	5 (2)	6 (2)	7 (2)	8 (2)	9 (2)	10 (2)	11 (2)	12 (2)

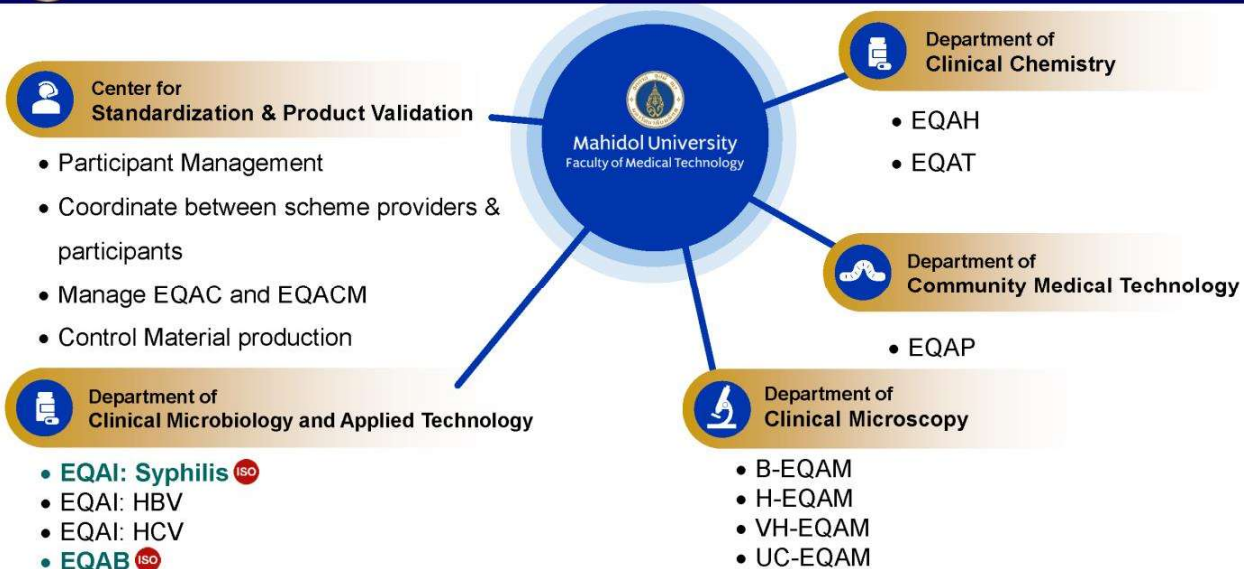
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6



13 Schemes of EQA at MUMT (compiled with ISO/IEC 17043)



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EQA Schemes at MUMT

No	Scheme	Sample	Number of Trial/Year	ISO/IEC 17043
1	Clinical Chemistry	Lyophilized serum	12	2025
2	Cardiac Markers	Lyophilized serum	6	2025
3	Tumor Markers	Lyophilized serum	6	2025
4	Hormones	Lyophilized serum	6	2025
5	Complete Blood Count	Stabilized Whole Blood	4	2025
6	Blood Smear	Blood Smear	4	2025
7	Virtual Blood Smear	Virtual Microscope	3	2025
8	Urine Sediment and Cytohematology	Photos	4	2025
9	Coagulation	Lyophilized serum	2	2025
10	Syphilis Serology	Serum	4	Since 2023
11	Hepatitis B Serology	Serum	4	2025
12	Hepatitis C Serology	Serum	4	2025
13	Bacteria (Gram/AFB/Iden/AST)	Stab/Smear	3	Since 2023
14	Parasitology	Stool sediment/Thin Film	4	2025

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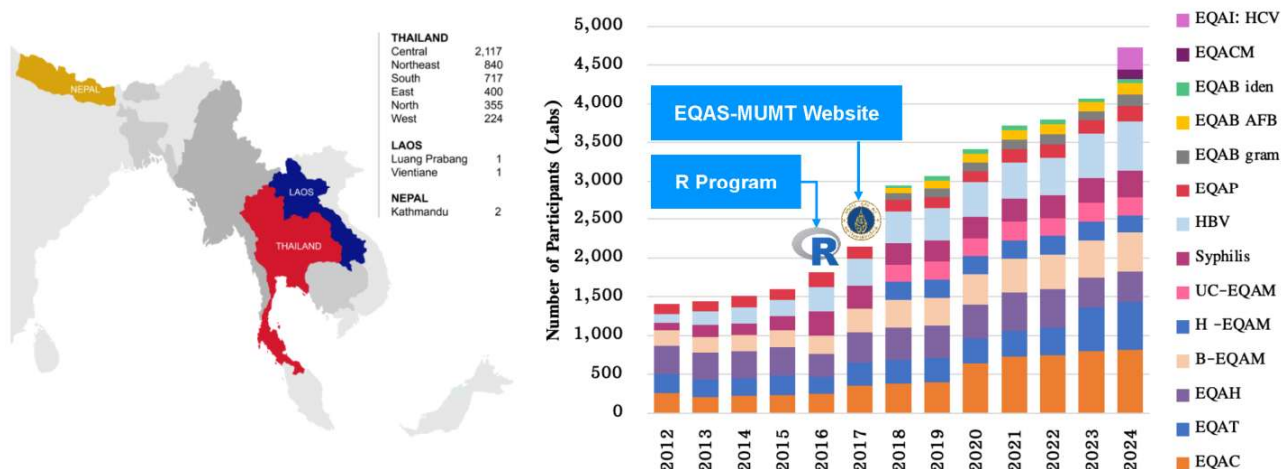
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8



Growth and Development of EQAS-MUMT

*Adopt technology to boost member capacity, efficiency,
and staff development opportunities*



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9



Mini-EQA (Interlaboratory Comparison, ILC)

Lab Anywhere:

- Private Community Lab

Partnership:

Government, Private sectors both locally and internationally

- The Association of Medical Technologist of Thailand (AMTT)
- Medical Technology Council
- IVD Companies

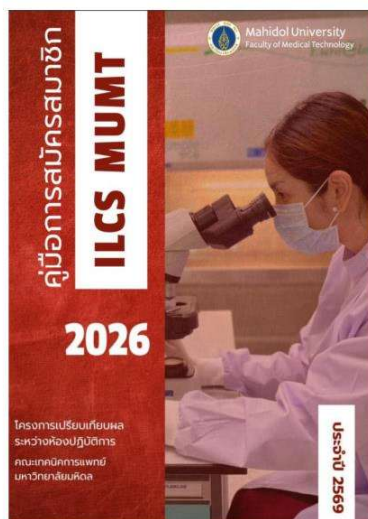


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Mini-EQA (Interlaboratory Comparison, ILC)



#	Program	Fee	Number of participants	Payment deadline
1.	ILC: Clinical Chemistry	2,000	300	October 10, 2025
2.	ILC: CBC	2,000		
3.	ILC: SYP	1,000		
4.	ILC: HBV	1,000		
5.	ILC: HCV	1,000		
6.	ILC: Thyroid	8,500	50	
7.	ILC: Inflammatory markers	7,000		
8.	ILC: Lipid profile	4,000		
9.	ILC: PIVKA-II	5,000		
10.	ILC: Bone markers	7,000		
11.	ILC: Sex Hormone	7,000		
12.	ILC: Direct Bilirubin	1,500		
13.	ILC: D-Dimer	1,500		
14.	ILC: hsCRP	1,500		

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11



Material Supply

Provided by:

Local laboratories and clinics

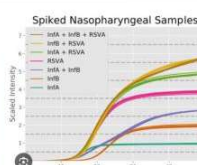
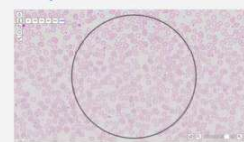
Oversea collaborators or suppliers



Blood Film Examination: H-EQAM



Virtual Blood Film Examination: VH-EQAM



PIVKA-II, PCT, D-Dimer



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EQA Providers

Clinical
Laboratories

Input

Process

Output

Design: Fit-for-purpose
Operation: Standard
(ISO /IEC17043)

Operation: Standard
- Analyze sample
- Performance review
- Corrective action

Quality
Safety
Satisfaction
Trust

Accreditation Body (ISO 15189, Laboratory Accreditation, MOPH, CAP)



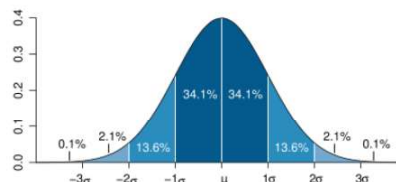
ISO 15189 Requirements

7.3.7.3 External Quality Assessment (EQA)

e) When selecting EQA programme(s), the laboratory should consider the type of target value offered.

Target values are:

- 1) Independently set by a reference method, or
- 2) Set by overall consensus data, and/or
- 3) Set by method peer group consensus data, or
- 4) Set by a panel of experts.



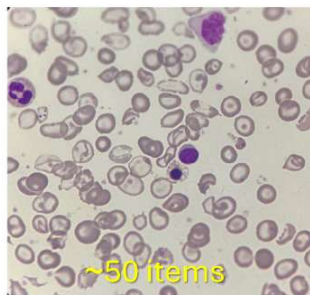
NOTE 1 When method-independent target values are not available, consensus values can be used to determine whether deviations are laboratory- or method-specific.

NOTE 2 Where lack of commutability of EQA materials can hamper comparison between some methods, it can still be useful for comparisons to be made between methods for which it is commutable, rather than relying only on within-method comparisons.



Self Evaluation and Quality Indicators

- Coverage (%) of participation
- Percentage of unacceptable performance (%) (risk & cost)
- Self evaluation & QI for each test



- WBC Differential count
- WBC morphology
- RBC distribution
- RBC morphology
- Platelet estimation
- Platelet morphology

Routine operation



% acceptable results--> Grade



Unacceptable items

Prepare a performance tracking template (in Excel or Word) to monitor performance based on quality indicators (QIs) and the defined schedule.

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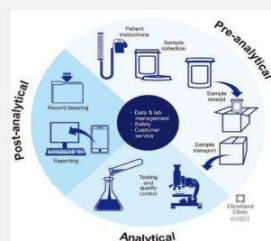


Training and Flexible Education: Reskill - Upskill

Quality Management System



Quality Assurance



IQC EQA
MV

Professional competency



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16



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Faculty of Medical Technology

Provider – Participants (P2P) Quality Meetup



พิธีเปิดงาน IQAS MPMT ครั้งที่ 1
โครงการสัมมนาเครือข่ายเพื่อพัฒนาห้องปฏิบัติการตรวจ
หาสารเสพติดในสถานพยาบาล (P2P) ครั้งที่ 2587

11.00 น.	ลงทะเบียน/รับบัตร	14.00 น.	รับประทานอาหารกลางวัน
11.30 น.	พิธีเปิดงาน	14.30 น.	การประชุมเชิงปฏิบัติการ
12.00 น.	การประชุมเชิงปฏิบัติการ	15.00 น.	การประชุมเชิงปฏิบัติการ
12.30 น.	การประชุมเชิงปฏิบัติการ	15.30 น.	การประชุมเชิงปฏิบัติการ
13.00 น.	การประชุมเชิงปฏิบัติการ	16.00 น.	การประชุมเชิงปฏิบัติการ
13.30 น.	การประชุมเชิงปฏิบัติการ	16.30 น.	การประชุมเชิงปฏิบัติการ

ติดต่อสอบถาม: 02 441 4376 หรือ 2512



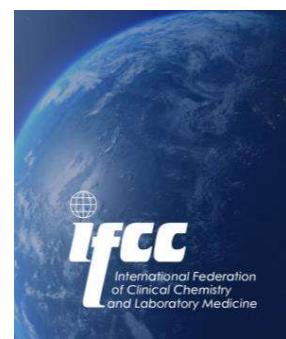
17

THANK YOU!



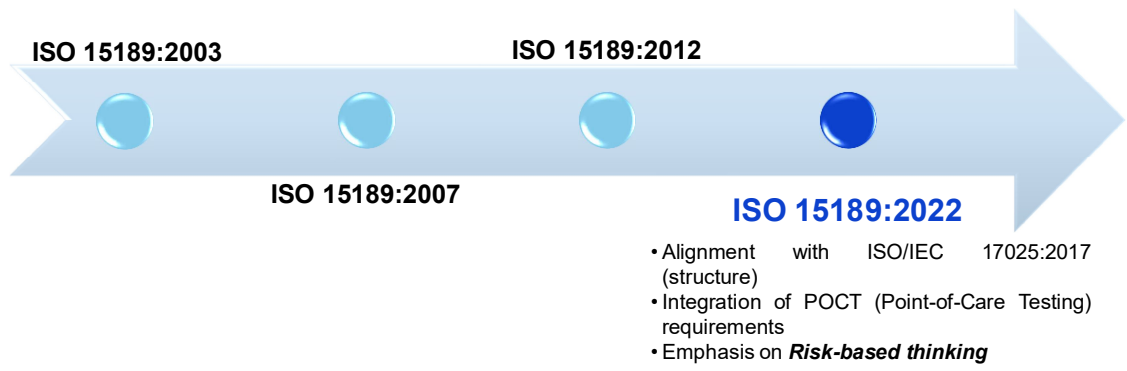
2025 IFCC Recommendations on Internal Quality Control for Medical Laboratories *In Compliance with ISO 15189:2022*

Assoc. Prof. Pham Thien Ngoc, MD. PhD



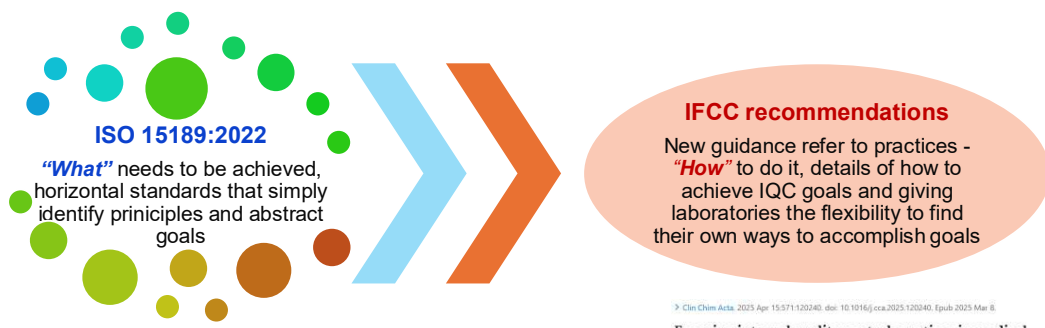
ISO 15189:2022

A comprehensive framework for quality and competence in medical laboratories



PURPOSE OF IFCC RECOMMENDATIONS

From standard to strategy



> Clin Chim Acta. 2025 Apr 15;571:120240. doi: 10.1016/j.cca.2025.120240. Epub 2025 Mar 8.

Ensuring internal quality control practices in medical Laboratories: IFCC recommendations for practical applications based on ISO 15189:2022

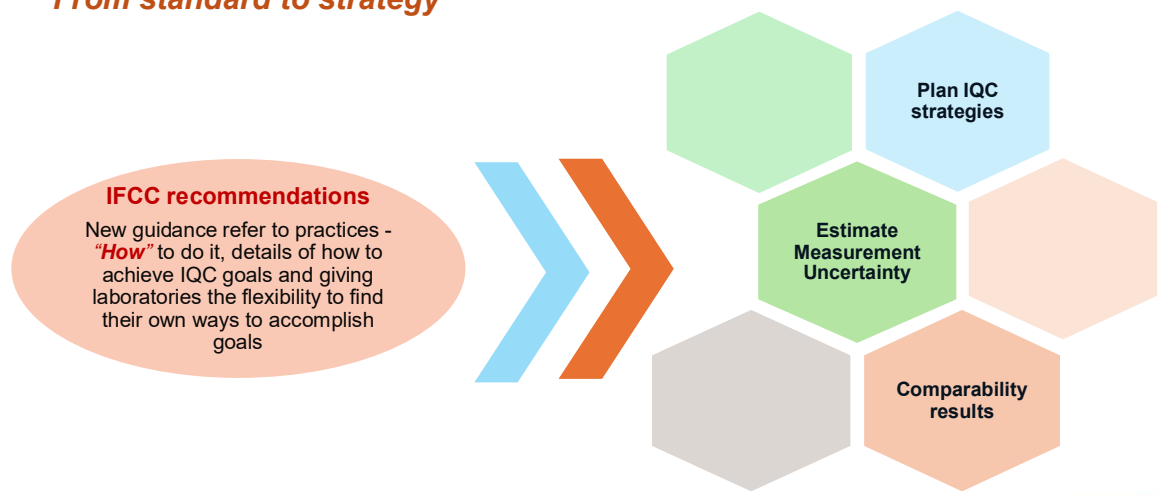
Jean-Marc Giannoli ¹, Anne Vassault ², Anna Carobene ³, Armand Perret Liaudet ⁴, Ivan M Blasutig ⁵, Pradeep Kumar Datta ⁶, Ji Lin ⁷, Annette Thomas ⁸, José Antonio Tesier Poloni ⁹, Qing-H Meng ¹⁰, Egon P Janssens ¹¹, International Federation of Clinical Chemistry, Laboratory Medicine Task Force on Global Lab Quality T1-GUQ

Affiliations + expand
 PMID: 40064457 DOI: 10.1016/j.cca.2025.120240



PURPOSE OF IFCC RECOMMENDATIONS

From standard to strategy



2025 IFCC RECOMMENDATIONS

Plan IQC strategies

ISO 15189:2012

5.6.2 The laboratory **shall design** internal quality control systems that verify the attainment of the intended quality of results. It is important that the control system provide staff members with clear and easily understood information on which to base technical and medical decisions. Special attention should be paid to the elimination of mistakes in the process of handling samples, requests, examinations, reports, etc.



ISO 15189:2022

7.3.7.2 a) The laboratory **shall have** an IQC procedure for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making.

d) IQC shall be performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result.

e) The resulting data shall be recorded in such a way that trends and shifts are detectable and, where applicable, statistical techniques shall be applied to review the results.

f) IQC data shall be reviewed with defined acceptability criteria at regular intervals, and in a timeframe that allows a meaningful indication of current performance.

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2025 IFCC RECOMMENDATIONS

Plan IQC strategies

Critical aspects of the IQC planning process are discussed:

IQC frequency

- Evaluation of method robustness (Six Sigma)
- IQC's scheduling frequency/ establishing series and critical events

Acceptability criteria

- Precision data (CVs)
- Levey-Jennings control chart
- Establishing target values
- Statistical control rules

Alternative performance monitoring methods

- Proficiency-Based Quality Reference Testing (PBQRT)
- Moving Mean or Average of Normal (AoN)
- Retesting of Patient Samples
- Pooled Patient Samples
- "Sentinel Tests"

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2025 IFCC RECOMMENDATIONS

Plan IQC strategies

IQC frequency

- Define both **frequency of IQC procedures** and **number of patient samples** analyzed for an analyte between two IQC events to ensure the stability of the analytical process with **a minimum of once per series or once per working day**
- Represents a **balance** between ensuring quality and managing risk, cost, and workload
- **Key considerations** when establishing: method robustness, test criticality, turnaround time (TAT), sample stability for re-testing...
- Using **Six Sigma Methodology** to evaluate method robustness: $\text{Sigma} = (\text{TEa} - \text{Bias})/\text{CV}$
- Positioning IQC in **critical events**: calibration, instrument maintenance or replacement of parts, adjustments, change of reagents, batches, or calibrators...
- **Perform** IQC testing both **before and after maintenance activities** to assess impact on system stability

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2025 IFCC RECOMMENDATIONS

Plan IQC strategies

Defining acceptability criteria

PRECISION DATA

- **Long-term CVs** (CVLT) account for all sources of variability calculated and used to define acceptable limits for control charts (**control limits**).
- **Sources for comparison:**
 - Primarily, CV established as standard for specific analytical system in use.
 - From BV estimated reported by EFLM.
 - Manufacturer's claim or report.
 - From peer groups of interlaboratory comparison (ILC) or external comparison of IQCs.
 - Recommendations from international or national organizations.
 - From the EQAS providers

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2025 IFCC RECOMMENDATIONS

Plan IQC strategies

Defining acceptability criteria

TARGET VALUE (TV)

- Determines the target value by calculating the **average of measurements** obtained from **sufficiently large dataset** collected over **adequate timeframe** and used as **baseline** of the control chart (**control limits**).
- Re-targeting (adjustment of TV) process includes:
 - In-depth investigation into potential sources of variation, such as personnel change, QC material stability, calibration issue, reagent batch changes, or maintenance activities → If shift exceeding 1SD, retarget mean to reduce risk of false rejection and false acceptances.
 - Evaluations with peer groups or EQAs to ensure no trueness error or inaccuracy.

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2025 IFCC RECOMMENDATIONS

Plan IQC strategies

Defining acceptability criteria

STATISTICAL CONTROL RULES

- Statistical goals for implementing Westgard rules: high probability of error detection ($P_{ED} \geq 90\%$) and low probability of false rejection ($P_{FR} \leq 5\%$)
- Using the **Sigma** level for rules selection
- Assess non-conformity based on **two levels of criteria**: **Analytical Acceptable Limits** (based on statistical performance/Sigma) and **Clinical Acceptable Limits** (determined by potential medical impact of deviation on patient care).

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2025 IFCC RECOMMENDATIONS

Plan IQC strategies

Alternative performance monitoring methods

- **Proficiency-Based Quality Reference Testing (PBQRT):** use advanced statistical techniques (EWMA based) on IQC database for drift (deviations over time) analysis → earlier detection of small deviations and systematic errors.
- **Moving mean or average of normal (AoN) of patient results:** detect drift/shift and evaluating potential bias against human sample matrix
- **Retesting of patient samples:** repeating patient samples as "patient reference sample" or "patient QC" with acceptance criterion of 2.8SD → compensating for the non-commutability of certain IQC materials, evaluating performance across different sample types.
- **Pooled patient samples:** alternative or supplementary control when standard materials are unavailable, checking analytical data at a defined critical level, validating new reagents batch/lot, assessing commutability.
- **Sentinel tests:** scheduling IQCs runs or patient sample controls for these high-sensitivity tests to monitor overall performance of analyser, evaluating the impact of maintenance activities.

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

2025 IFCC RECOMMENDATIONS

Estimate Measurement Uncertainty (MU)

ISO 15189:2012

5.6.2 The laboratory **shall determine** the uncertainty of results, **where relevant and possible**. Uncertainty components which are of importance shall be taken into account. Sources that contribute to uncertainty may include sampling, sample preparation, sample portion selection, calibrators, reference materials, input quantities, equipment used, environmental conditions, condition of the sample and changes of operators.



ISO 15189:2022

7.3.4 Evaluation of measurement uncertainty (MU)

- The MU of measured quantity values **shall be evaluated and maintained** for its intended use, **where relevant**.
- The MU shall be **compared** against performance specifications and documented.
- MU evaluations shall be regularly **reviewed**.
- MU information shall be **made available** to laboratory users on request.
- MU should be taken into consideration when performing **verification or validation** of a method, when relevant.

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2025 IFCC RECOMMENDATIONS

Estimate Measurement Uncertainty (MU)

Guide **calculation and interpretation of MU**, including identification of contributing factors such as imprecision and bias → enhance transparency of **reported results**, and support clinicians in **making informed decisions** for improved patient care.

MU calculation

"top-down" calculation of MU (95% estimate of expanded uncertainty) using data from IQC and EQA

- Bias is small and not clinically significant: $MU = 2 \cdot CV$ (long-term CV)
- Bias is significant but corrected: $MU = 2 \cdot \sqrt{CV^2 + u_{Bias}^2}$
 u_{Bias} - uncertainty related to Bias estimate (from an EQA survey)
- Lack of uncertainty of reference and calibration

MU importance and Interpretation

- **Clinical Interpretation:** evaluate MU based on clinicians' interpretation needs and specific clinical requirements.
- **Decision Thresholds:** MU is critical when results are near clinical decision thresholds that impact patient care (e.g., hemoglobin & transfusion decisions, drug dosage adjustments, treatment monitoring).

→ lack of consensus about how to estimate and apply MU

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2025 IFCC RECOMMENDATIONS

Comparability of between-analyzer results

ISO 15189:2012

5.6.4 Comparability of examination results

There shall be a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these.

The laboratory shall document, record and, as appropriate, expeditiously act upon results from the comparisons performed. Problems or deficiencies identified shall be acted upon and records of actions retained.



ISO 15189:2022

7.3.7.4 Comparability of examination results

a) When either different methods or equipment, or both, are used for an examination, and/or the examination is performed at different sites, a procedure for establishing the comparability of results for patient samples throughout the clinically significant intervals shall be specified.

c) The laboratory shall **periodically review** the comparability of results.

d) Where differences are identified, the impact of those differences on **biological reference intervals and clinical decision limits** shall be evaluated and acted upon.

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2025 IFCC RECOMMENDATIONS

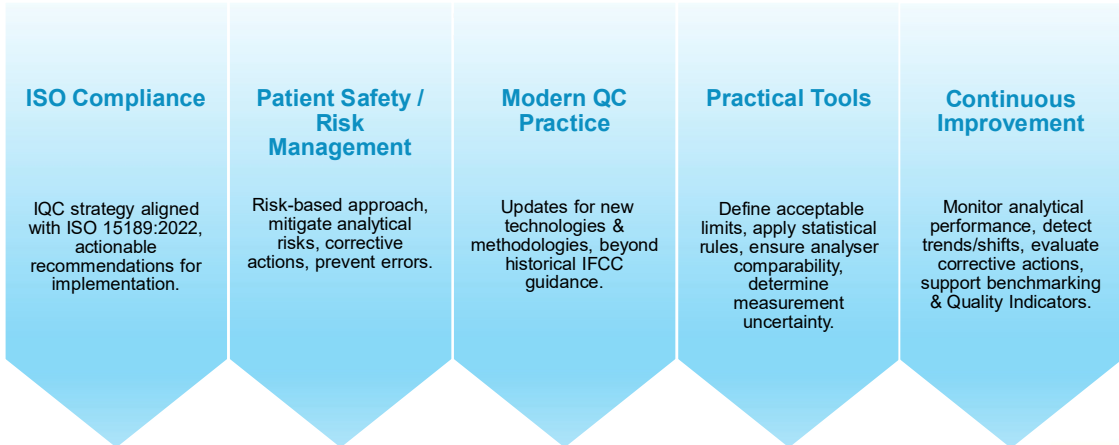
Comparability of between-analyzer results

Essential for ensuring result uniformity across multiple instruments, including POCT devices.

Frequency of Monitoring	Materials & Methods for Comparability	Indicators of System Drift	Clinical Impact Assessment	External IQC Comparison
- Not universally mandated → set via risk-based approach, justified by lab. Consider: test volume, method robustness, analytical drift impact, existing QC measures...	IQC materials → monitor assay performance. Fresh patient samples → real-time checks. Pooled samples → assess long-term consistency. EQA samples → inter-lab comparison. Patient statistics (e.g., averages, MA) → detect trends & bias.	CV trends per analyser. CV ratios between instruments. % Rejected IQCs. % Rejected patient results. EQA failures.	Set critical difference limits → evaluate impact on clinical interpretation & patient management.	Benchmark against peers. Assess trueness & support retargeting.



A comprehensive and user-friendly resource for IQC implementation in laboratory

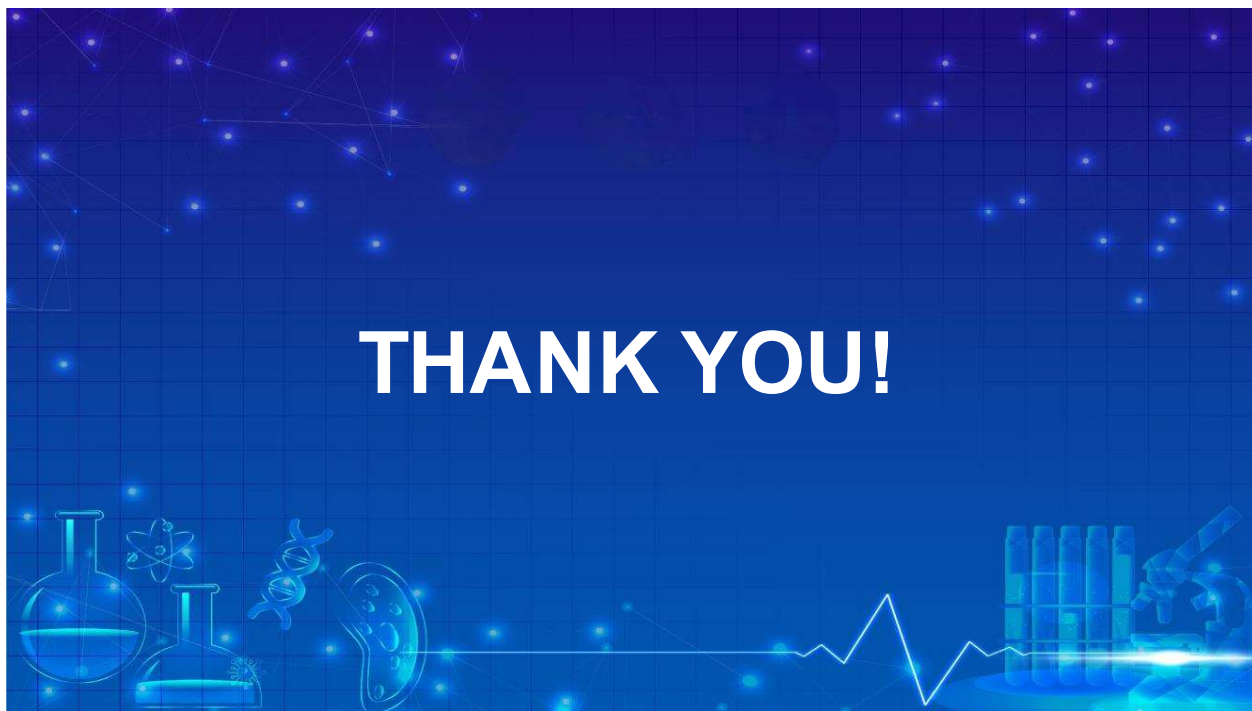


REFERENCES

- Giannoli, J.-M., Vassault, A., Carobene, A., Perret Liaudet, A., Blasutig, I. M., Dabla, P. K., Lin, J., Thomas, A., Tesser Poloni, J. A., Meng, Q. H., & Amann, E. P. (2025). *Ensuring internal quality control practices in medical Laboratories: IFCC recommendations for practical applications based on ISO 15189:2022*. *Clinica Chimica Acta*, 571, 120240. <https://doi.org/10.1016/j.cca.2025.120240>
- Westgard, J. O. (2025, March). *2025 IFCC recommendations for IQC*. Westgard QC. <https://westgard.com/essays/quality-requirements-and-standards/ifcc-iqc-2025.html>

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THANK YOU!





UNIVERSITY OF MEDICINE AND PHARMACY AT HO CHI MINH CITY
QUALITY CONTROL CENTER FOR MEDICAL LABORATORY – DEPARTMENT OF MEDICAL LABORATORY



STRATEGY FOR THE SAFE RECRUITMENT OF BLOOD DONORS REGARDING **HIV, HBV, AND HCV** AT CHO RAY BLOOD TRANSFUSION CENTER – CHO RAY HOSPITAL



Pham Le Nhat Minh, PhD

Deputy director of Cho Ray Blood Transfusion Center

15 năm

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70 năm

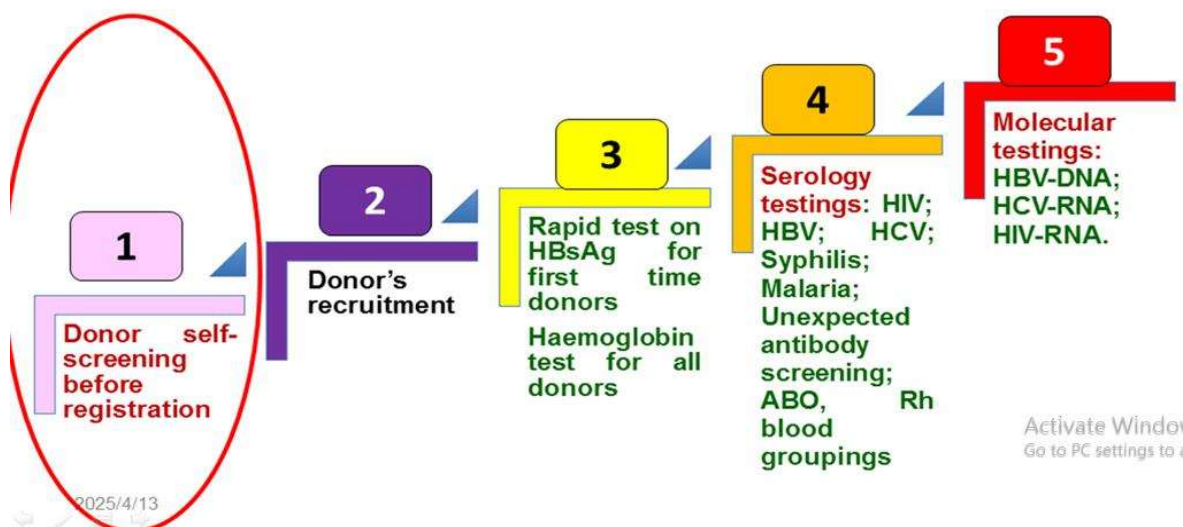


INTRODUCTION

- ✓ Collecting and distributing safe blood and blood components to over 60 hospitals in Ho Chi Minh City and the eastern southeastern provinces, serving a population of more than 10 million people.
- ✓ Each day, the center collects an average of 600 units of whole blood (350ml) and distributes approximately 500-600 blood product components.

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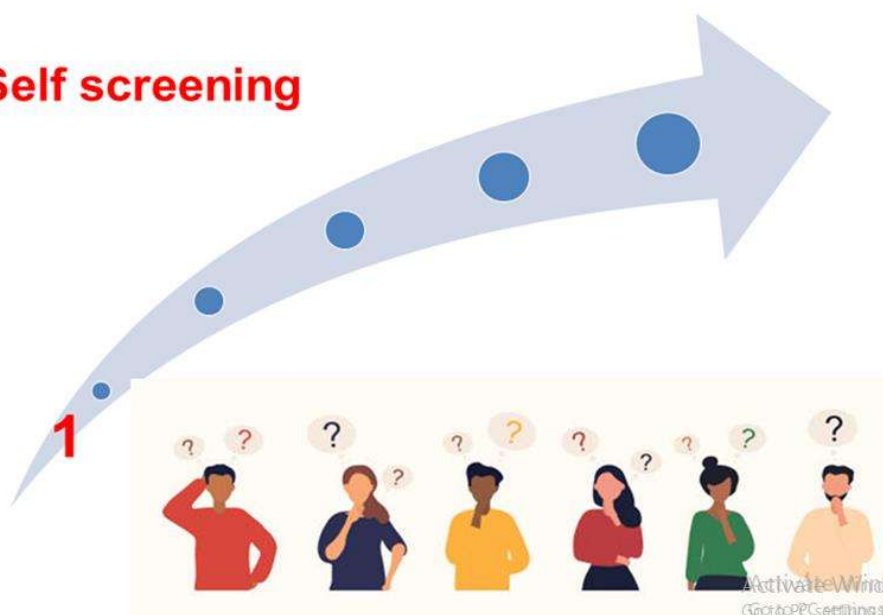
STRATEGY ON RECRUITING SAFE BLOOD DONORS



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Stage 1: Self screening



Sources of references : <https://www.istockphoto.com/vi/h%C3%ACnh-minh-h%E1%BB%8Da/ask-yourself>

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

DECORATION IN WINTER SEASON



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GIVING BLOOD DONATION STANDARD FOR DONORS SELF SCREENING



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PRIVATE SPACE FOR BLOOD DONORS TO ANSWER SCREENING QUESTIONS DURING THE BLOOD DONATION REGISTRATION



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SCREENING BASED ON BLOOD DONATION REGISTRATION FORM

CHO RAY HOSPITAL
CHO RAY BLOOD TRANSFUSION CENTER

INFORMED

BLOOD DONATION REGISTRATION FORM

Donation code: _____

FULL NAME (Capital letters): _____ Date of birth: ____/____/____ Sex: Male ☐ Female ☐
ID / Passport number: _____ Mobile phone: _____
Occupation: _____
Permanent address (as shown in ID Card, Passport): _____
Current address: _____

FOR BLOOD DONOR

1. Have you ever donated blood before? ☐ Yes ☐ No

2. Do you have any chronic diseases (epilepsy, neurological diseases, long/high blood pressure, jaundice, hepatitis B, C, respiratory/chronic diseases, cardiovascular diseases, kidney, chronic, cough, blood diseases, cancer, etc.)? ☐ Yes ☐ No
If you, kind of disease: _____
Additional drug use or alcohol? _____

3. In the last 12 months, have you recently got signs of symptoms:
• Surgery? Received blood and blood components? Malaria, Syphilis, Tuberculosis? ☐ Yes ☐ No
• Received a vaccine (rabies)? ☐ Yes ☐ No

4. In the last 6 months, have you recently got signs of symptoms:
• Unexplained weight loss (2 kg), diarrhea, enlarged lymph nodes
• Had body piercing, tattoo, acupuncture, ...? ☐ Yes ☐ No
• Had sex with a person who is heterosexual or bisexual? ☐ Yes ☐ No
• Had sex with anyone who has AIDS or is at high risk for HIV/hepatitis infection? ☐ Yes ☐ No

5. In the last 4 weeks, have you got recently signs of symptoms:
• Fever, rash on the skin, headache, fatigue, conjunctivitis, yellow eyes or in the area with Zika virus, unexpected sex with people infected with Zika virus? ☐ Yes ☐ No
• Received a vaccine hepatitis B, rubella, Mumps, typhoid, Cholera, meningitis, etc.? ☐ Yes ☐ No

6. In the last week, have you got recently signs of symptoms:
• Have flu, cold, sore throat, migraine? ☐ Yes ☐ No
• Drug use: Aspirin, Paracetamol, Tablet, Tobacco, ...? ☐ Yes ☐ No
• Received a vaccine hepatitis A, Tetanus, ...? ☐ Yes ☐ No

7. Are you disabled or August Orange victim? ☐ Yes ☐ No

8. Are you pregnant or breast feeding for child under 12 months age? ☐ Yes ☐ No

9. Are you within 1 week: _____

All donated blood units will be screened for HIV, HBV, HCV, syphilis and malaria according to current regulations.

I read, understand and answer truthfully all questions above and I am committed being responsible for correct information. If I discuss any information relating to the safety of donated blood units, I will contact with you to ensure the safety for my blood recipients. I agree that my blood units will be screened for syphilis, HIV, HCV, HTLV and others as regulated. I was informed about benefits as well as adverse reactions during and after blood donation. I feel healthy today and I am willing to donate blood to save lives.

Date: ____/____/____ (Signature and full name)

USE ONLY FOR MEDICAL STAFF

MEDICAL EXAMINER

Weight: ____ Kg
Pulse: ____ beats/min
Blood pressure: ____ mmHg
Hemoglobin: ____ g/dL
Quick test HbA1c: ____
Medical staff: _____

ADDITIONAL INFORMATION

Reason for donation: _____
Time: ____/____/____ Date: ____/____/____
Blood volume: ____ ml
Notes during blood collection: _____

Screening
blood
donors on
risk
behaviors
based on
Yes/No
questions

Commitments
for truly answers

CHO RAY HOSPITAL
CHO RAY BLOOD TRANSFUSION CENTER

INFORMED

BASIC INFORMATION ON BLOOD DONATION
(Please kindly read the following information before registration)

Cho Ray Blood Transfusion Center would like to thank you for your participation on blood donation.
For your safety as well as for those who will receive blood, take time to carefully read the following information:

- You need to bring your ID card and blood donation card (if any) for each blood donation registration.
- If you are suffering from acute or chronic medical conditions such as high blood pressure, diabetes, asthma, ... Please do not donate blood to ensure your health.
- If you have sex with many people, with people who inject drugs, do not donate blood to avoid spreading the disease to blood recipients.
- One day before donating blood, avoid alcohol and stay up late (need to get well sleep ≥ 6 hours).
- Before giving blood, you may have a snack and need to drink plenty of water (sweeten tea).
- The minimum duration time for each of whole blood donations is 12 weeks and platelet donation by cell separator is 2 weeks.

Kindly appreciate for your blood donation and look forward to receiving your contribution

Address: Cho Ray Blood Transfusion Center
201B Nguyen Chi Thanh street, Ward 12, District 5, Ho Chi Minh City
Phone: 028 39558885 or 08 238554137 - Extension: 1183 or 1421 or 1159

* We would like to invite you to DONATE YOUR BLOOD. Fill in all the information in registration form including your ID number, year of birth, address under ID, phone number for us write blood donation certificate and inform the blood donation result.

Blood donation under the guidance of the medical physician is not harmful, besides, there are many health benefit for each donor.

Please do not forget to bring your ID card for each of blood donation registration. Thank you!

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INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT

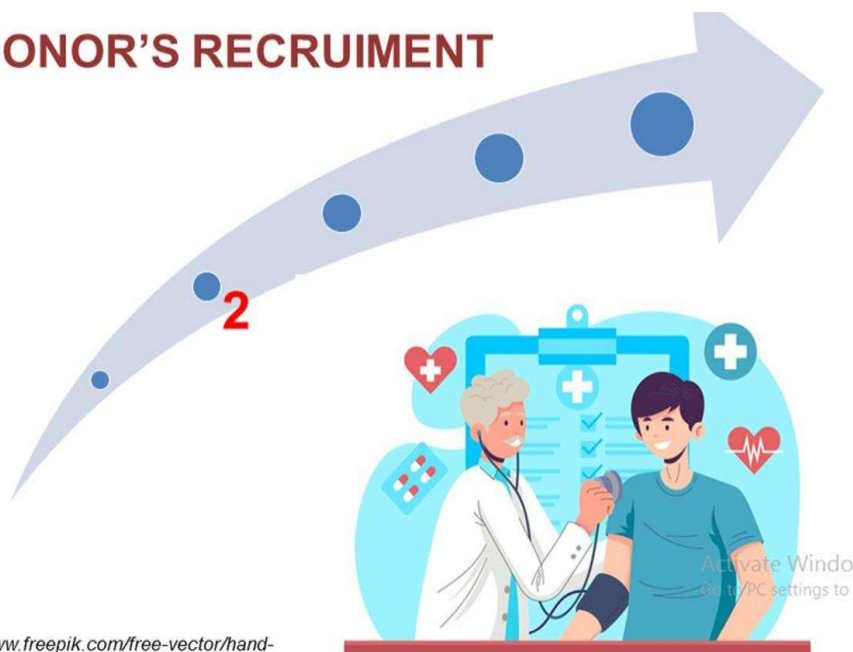
ONLINE BLOOD DONATION MANAGEMENT APPLICATION



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Stage 2: DONOR'S RECRUITMENT



Sources of references : https://www.freepik.com/free-vector/hand-drawn-patient-taking-medical-examination_12276384.htm

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SCREENING BASED ON BLOOD DONATION REGISTRATION FORM

CHO RAY HOSPITAL
CHO RAY BLOOD TRANSFUSION CENTER

INFORMED

BLOOD DONATION REGISTRATION FORM

Donation code: _____

FULL NAME (Capital letter): _____ Date of birth: ____/____/____ Sex: Male ☐ Female ☐

ID / Passport number: _____ Mobile phone: _____

Occupation: _____ Institution: _____

Permanent address (in choice in ID Card, Passport, ...): _____

Current address: _____

FOR BLOOD DONOR

1. Have you ever donated blood before? ☐ Yes ☐ No

2. Do you have any chronic diseases: psychiatric/neurological diseases, high blood pressure, jaundice/hepatitis B, C, respiratory/digestive diseases, cardiovascular diseases, kidney, chronic cough, blood diseases, cancer, etc...? ☐ Yes ☐ No

If you, kind of disease: _____

3. Are you taking any drug or alcohol? ☐ Yes ☐ No

4. In the last 12 months, have you recently got signs of symptoms:
- "Hepatitis" (swollen blood and blood components), Malaria, Syphilis, Tuberculosis?
- Received a vaccine rabies? ☐ Yes ☐ No

5. In the last 6 months, have you recently got signs of symptoms:
- Unexplained weight loss (10 kg), diarrhea, swollen lymph nodes
- Had a body piercing, tattoo, acupuncture, ...? ☐ Yes ☐ No

6. In the last week, have you got recently signs of symptoms:
- Have the cold, sore throat, gingivitis
- Dingy eye: Aspinia, Plavita, Talla, Follia, ...? ☐ Yes ☐ No

7. Are you disabled or Agent Orange victim? ☐ Yes ☐ No

8. Questions for female donor:
- Are you pregnant or breast feeding for child under 12 months age? ☐ Yes ☐ No

9. Signature within 1 week: _____ Date: ____/____/____

All donated blood units will be screened for HIV, HBV, HCV, syphilis and malarial infection in accordance with the national regulations.

I read, understand and answer truthfully all questions above and I am committed being responsible for personal information. If I discover any information relating to the safety of donated blood units, I will contact with you to ensure the safety for my blood recipient. I agree that my blood units will be screened for syphilis, HIV, HCV, HBV and others as requested. I am informed about benefits as well as adverse reactions during and after blood donation. I feel healthy today and I am willing to donate blood to save lives.

☒

USE ONLY FOR MEDICAL STAFF

MEDICAL EXAM
Weight: ____ Kg
Pulse: ____ beat
Blood pressure: ____/____ mmHg

PRE-DONATION TESTS
Hemoglobin: ☐ Pass ☐ Fail
Quick test HBsAg: _____
Medical staff: _____

ADDITIONAL INFORMATION
Tattoo: ☐ Yes ☐ No
Cancer: ☐ Yes ☐ No
Defect: _____
Medical physician: _____
FILLERIZATION: _____
Time: ____/____/____
Blood volume: _____ ml
Notes during blood collection: _____

Page: 1/2

Screening blood donors on risk behaviors based on Yes/No questions

Commitments for truly answers

BASIC INFORMATION ON BLOOD DONATION

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3. If you have sex with many people, with people who inject drugs, do not donate blood to avoid spreading the disease to blood recipients.
4. One day before donating blood, avoid alcohol and stay up late (need to get well sleep > 6 hours).
5. Before giving blood, you may have a snack and need to drink plenty of water (convenient tea).
6. The minimum duration time for each of whole blood donations is 12 weeks and platelet donation by cell separator is 2 weeks.

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* We would like invite you to DONATE YOUR BLOOD; Fill in all the information in registration form including your ID number, year of birth, address under ID, phone number for us write blood donation certificate and inform the blood donation result.



Blood donation under the guidance of the medical physician is not harmful; besides, there are many health benefit for each donor.

Please do not forget to bring your ID card for each of blood donation registration. Thank you!

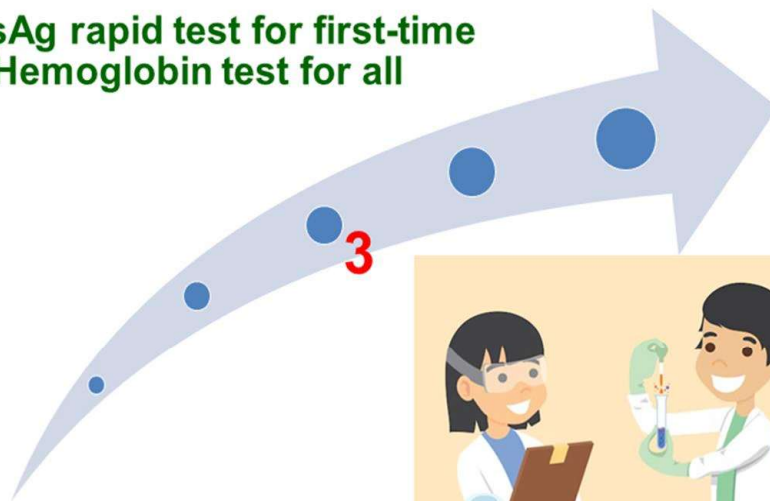
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Page: 2/2

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Stage 3: HBsAg rapid test for first-time donors and Hemoglobin test for all donors



Sources of references: <https://www.freepik.com/free-photos-vectors/medical-test>

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HBsAg rapid test for first-time donors and Hemoglobin test for all donors

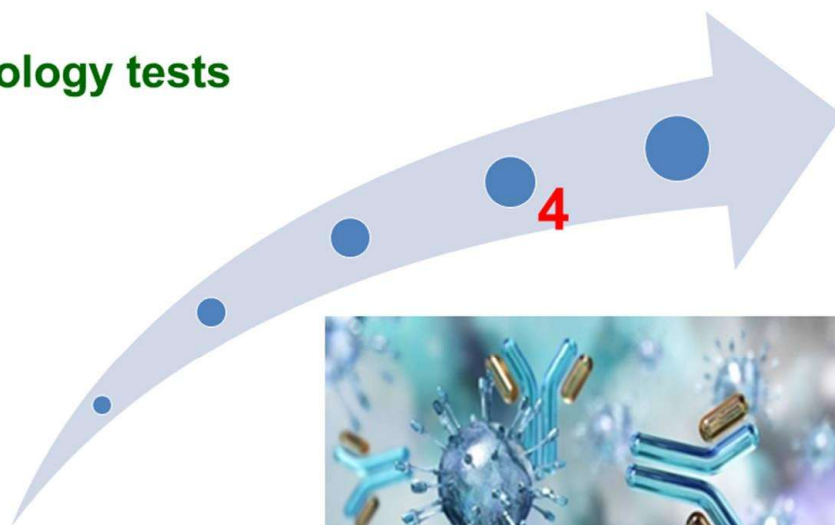
Approximately 2.5%* of potential blood donors do not meet the hemoglobin level requirement (<120g/l) to donate whole blood		Approximately 2.6%* of first-time blood donors tested reation for the rapid HBsAg test	
Hemoglobin test		HBsAg rapid test	Reaction

2025/4/13

Sources of references: <https://nursekey.com/assisting-in-the-analysis-of-blood/> and Cho Ray Blood Transfusion Center

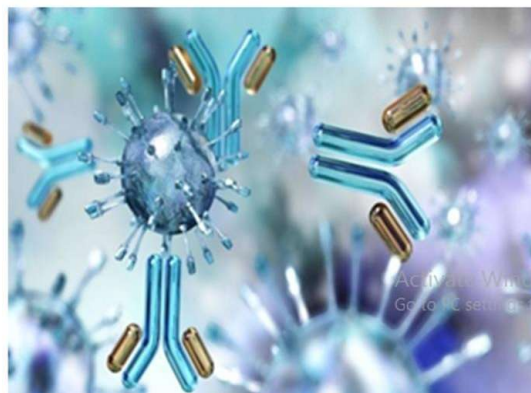
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Stage 4: Serology tests



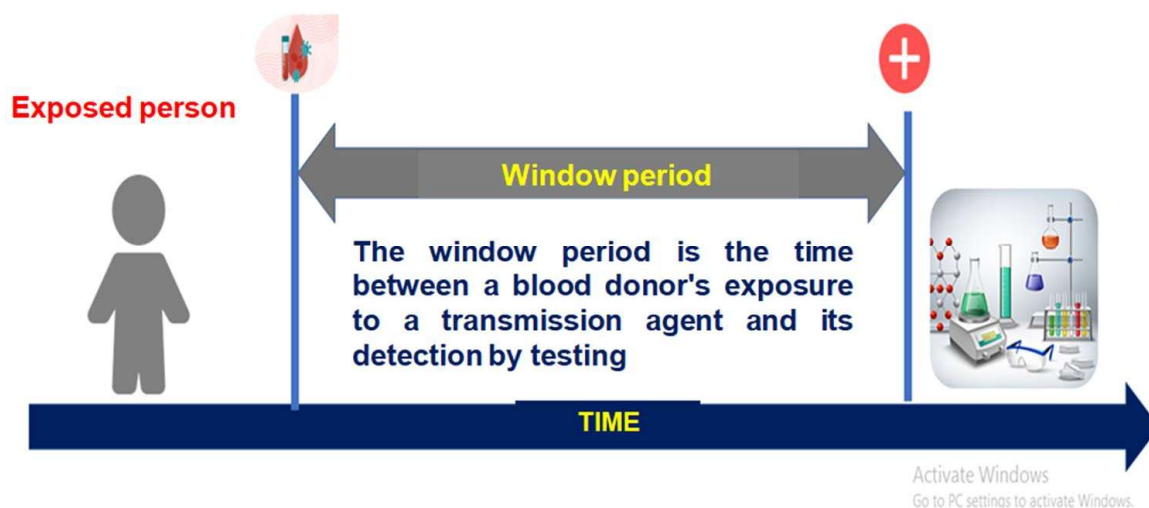
Sources of references:

: <https://www.morningcoach.com/blog/everything-should-be-in-balance/>;
<https://yinyangit.wordpress.com/2013/03/08/net-poco-la-g/question-mark/>;
<https://www.immunodiagnostic.fi/en/diagnostics/immunology-and-infectious-serology>;
<https://medicine.vale.edu/ahmed/sections/molecular-diagnostics/>



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WINDOW PERIOD FOR DETECTING TTIs AGENTS

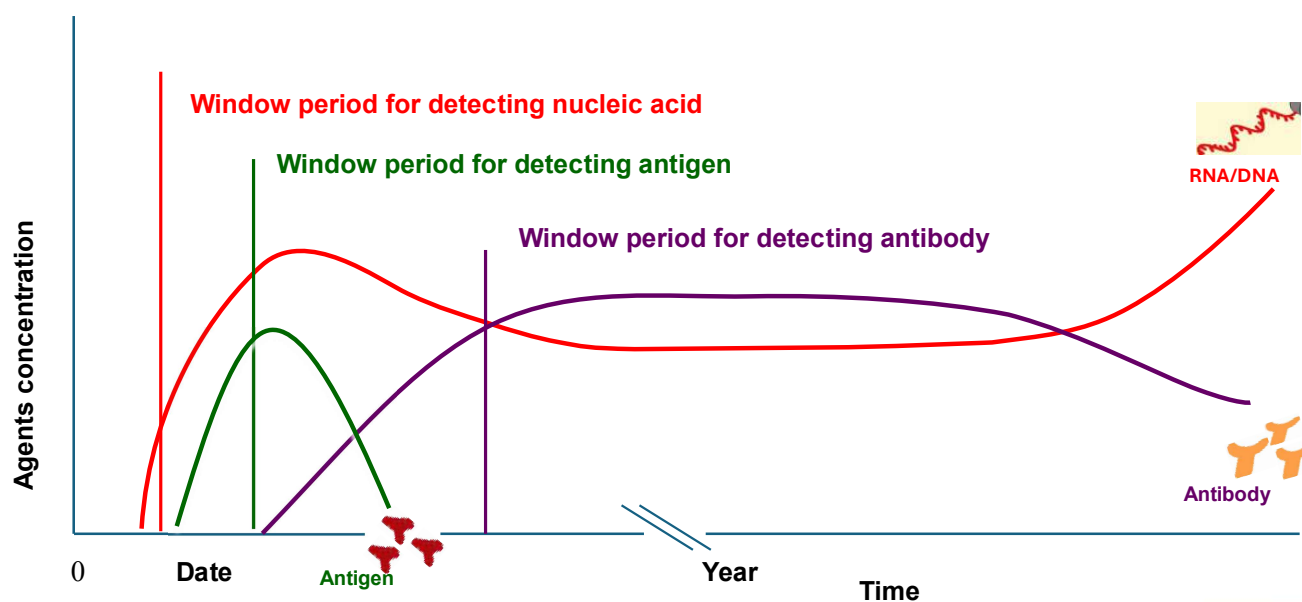


Nguồn hình ảnh minh họa và tài liệu tham khảo: <https://openclipart.org/detail/275133/person-generic>; <https://www.everydayhealth.com/hiv/aids/>; <https://pixabay.com/images/search/plus%20sign/>; <https://labvy.com/fr/8845184/Pentagon-v%20Laboratorium%20Sains%20di%20Sekolah%20dan%20Pernah%20Mereka%20dalam%20Membuat%20Keputusan%20Sains%20Sipat>; <https://www.vinmec.com/vie/bai-viet-thoi-ky-cua-so-trong-vet-nghiem-hiv-la-gi-vi>

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WINDOW PERIOD FOR DETECTING TTIs AGENTS



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WINDOW PERIOD FOR DETECTING TTIs AGENTS

Agents	HIV	HBV	HCV
Window period	HIV-RNA	HBV-DNA	HCV-RNA
Window period of Molecular method (Average day)**	Pool 6	Pool 6	Pool 6
	6,9	3,9	15,2
	ID	ID	ID
	4,7	2,8	8,6
Window period of serology method (Average day) approved by FDA for blood donor screening test	HIV Ag/Ab	HBsAg	Anti-HCV
	8,1	22,5	34

*Package insert-Cobas MPX; **GALEL, S. A et al., 2018. Sensitivity and specificity of a new automated system for the detection of hepatitis B virus, hepatitis C virus, and human immunodeficiency

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RECOMMENDED SENSITIVITY AND SPECIFICITY OF BLOOD DONOR SCREENING REAGENTS

World Health Organization (WHO)

Screening Donated Blood for Transfusion-Transmissible Infections



Recommendations

The sensitivity and specificity of all reagents used for blood donor screening should be as high as possible, and ideally no less than 99.5%.

Ministry of Health of Vietnam

Reagents for screening agents by ELISA/ Chemiluminescence methods

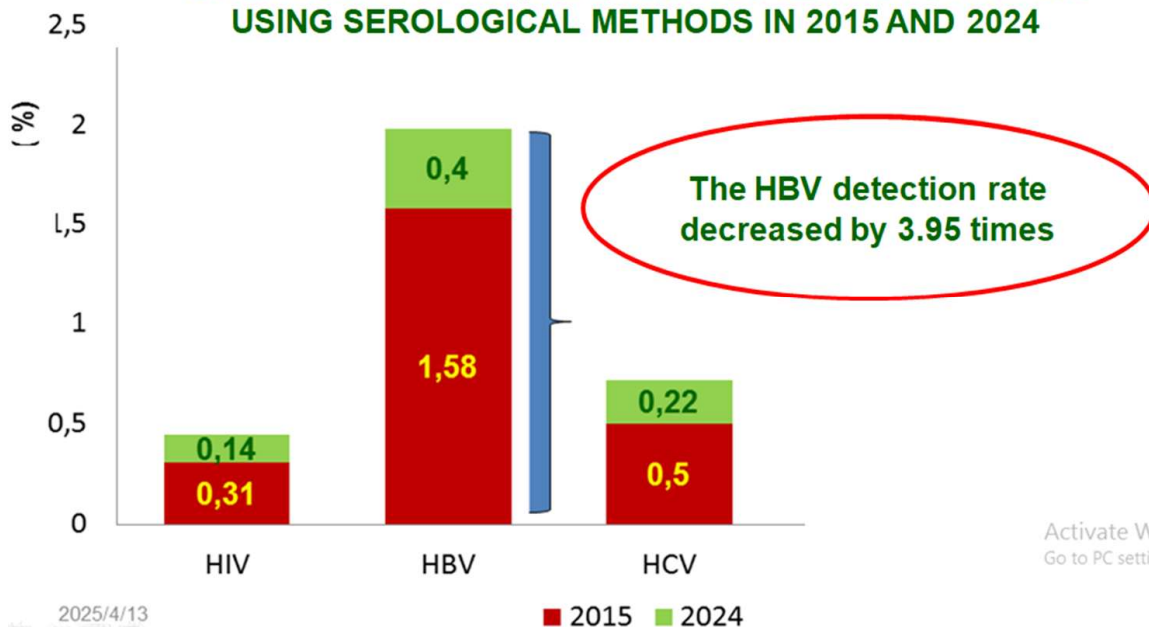
HBsAg: Limit of detection (LOD) is 0.5ng/ml

HIV: Detection of anti-HIV-1 antibodies (group M, O) and P24 antigen;

HCV: Able to detect weak positive reference samples.

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COMPARISON OF HIV, HBV, AND HCV DETECTION RATES USING SEROLOGICAL METHODS IN 2015 AND 2024



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Stage 5: Molecular method



Sources of references :

<https://www.morningcoach.com/blog/everything-should-be-in-balance/>
<https://yinyangit.wordpress.com/2013/03/08/net-poco-la-g/question-mark/>
<https://www.immunodiagnostic.fi/en/diagnostics/immunology-and-infectious-serology>
<https://medicine.vale.edu/ahmed/sections/molecular-diagnostics/>

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DETECTION RANGE ON MOLECULAR METHOD

Virus	Unit	Detection range*
HBV-DNA	IU/ml	1,4
HCV	IU/ml	4,0
HIV-1 group M	IU/ml	25,7
HIV-1 group O	Bản sao/ml	8,2
HIV-2	IU/ml	57,4

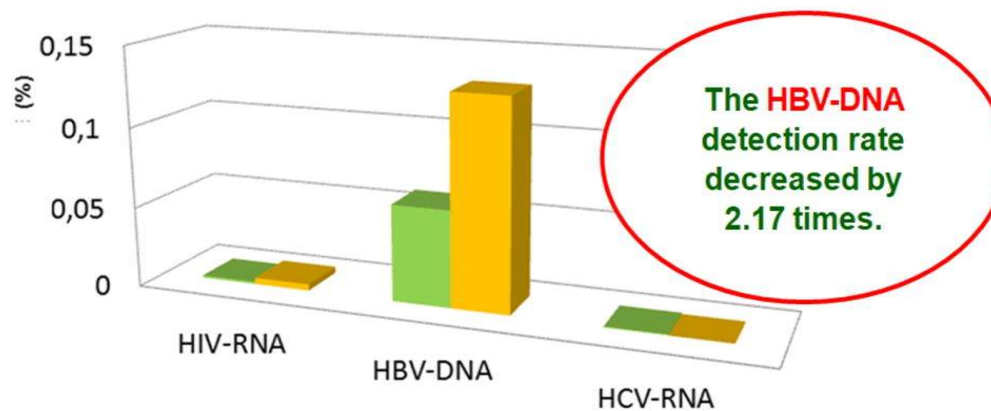
Activate Windows
Go to PC settings

Source: *Cobas® MPX. Package insert.

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COMPARISON OF HIV, HBV, AND HCV DETECTION RATES USING MOLECULAR METHODS IN 2015 AND 2024



2024
2015

HIV-RNA	HBV-DNA	HCV-RNA
0,0014	0,06	0,0007
0,004	0,13	0

Activate Windows
Go to PC settings

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HIV, HBV, HCV screening results among blood donors from 05/2015 to 09/2024

Agents	Results of blood donor screening (n=1,185,349)	
	Serology method	Molecular method
HBV	0.52%	0.067% ($\approx 1/1,498$)
HCV	0.17%	0.0003% ($\approx 1/390,418$)
HIV	0.13%	0.0009% ($\approx 1/106,478$)

796 HIV, HBV, and HCV infections were missed by serological methods. Molecular methods enable early detection of viral genetic

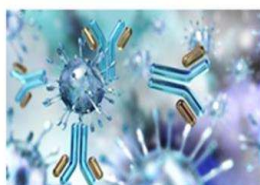
→ Shortening the window period

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Choosing a blood screening strategy

SEROLOGY

Important for
detecting
chronic
infections



MOLECULAR

Most effective in
detecting infections
in the transient and
early stages.
HBV detection in
both early and late
stages



COMBINE

source of picture: <https://www.morningcoach.com/blog/everything-you-need-to-know-about-serology/>
<https://vinyana.wordpress.com/2013/03/08/net-poco-la-question-mark/>
<https://www.immunodiagnostic.com/en/diagnostics/immunology-and-infectious-serology>
<https://medicine.vale.edu/labmed/sections/molecular-diagnostics/>

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CERTIFICATE OF PARTICIPATION IN THE NATIONAL EXTERNAL QUALITY ASSESSMENT FOR BLOOD DONOR SCREENING TESTS 2024

BỘ Y TẾ
VIỆN HUYẾT HỌC - TRUYỀN MÁU TRUNG ƯƠNG

CHƯƠNG TRÌNH NGOẠI KIỂM QUỐC GIA VỀ CHẤT LƯỢNG XÉT NGHIỆM SÀNG LỌC MÁU

CHỨNG NHẬN

Phòng xét nghiệm miễn dịch sàng lọc máu,
Trung tâm Truyền máu Chợ Rẫy - Bệnh viện Chợ Rẫy

Đạt yêu cầu của chương trình xét nghiệm
- NAT (HBV-ADN, HCV-ARN, HIV-ARN)
- Huyết thanh học: HBV, HCV, HIV, giang mai
năm 2024

GIÁM ĐỐC
TRUNG TÂM MÁU QUỐC GIA



PGS.TS. Trần Ngọc Quế

Hà Nội, ngày 15 tháng 01 năm 2025
VIỆN TRƯỞNG



PGS.TS. Nguyễn Hà Thanh

63/QĐ-HHTM ngày 15/01/2025

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INTERNATIONAL EXTERNAL QUALITY ASSESSMENT OF (NRL) IN 2024

ISO 15189:2022 CERTIFICATE

CERTIFICATE OF PARTICIPATION

This certifies that

Cho Ray Hospital

successfully participated in **NRL EQAS** in 2024

Hepatitis Serology
TORCH and EBV Serology
HBV Molecular
Multimer Blood Screening Serology
Multimer Blood Screening Molecular

Philippe Heyel
Dr Philippe Heyel

Director, NRL (National Serology Reference Laboratory) Unit 52
004 755 5402 4th floor ready Building 41 Victoria Parade 312001
VICTORIA 3005 AUSTRALIA

ỦY BAN TIÊU CHUẨN DO LƯỜNG CHẤT LƯỢNG QUỐC GIA (STAMEQ)
VĂN PHÒNG CÔNG NHẬN CHẤT LƯỢNG QUỐC GIA (BoA)



CHỨNG CHỈ CÔNG NHẬN

Phòng xét nghiệm:
PHÒNG XÉT NGHIỆM MIỄN DỊCH SÀNG LỌC
TRUNG TÂM TRUYỀN MÁU CHỢ RẪY
BỆNH VIỆN CHỢ RẪY

Địa điểm PCN:
201B Nguyễn Chí Thanh, Phường 12, Quận 5, Thành phố Hồ Chí Minh
đã được đánh giá và phù hợp với các yêu cầu của tiêu chuẩn

ISO 15189:2022
Lĩnh vực công nhận
VI SINH
Mã số
VILAS MED 040

Kèm theo Quyết định công nhận số: 163/QĐ-VPCNCLQG ngày 16/06/2025
Chứng chỉ có hiệu lực từ ngày: 16/06/2025 đến 16/06/2030
Ngày được công nhận lần đầu 27/04/2015

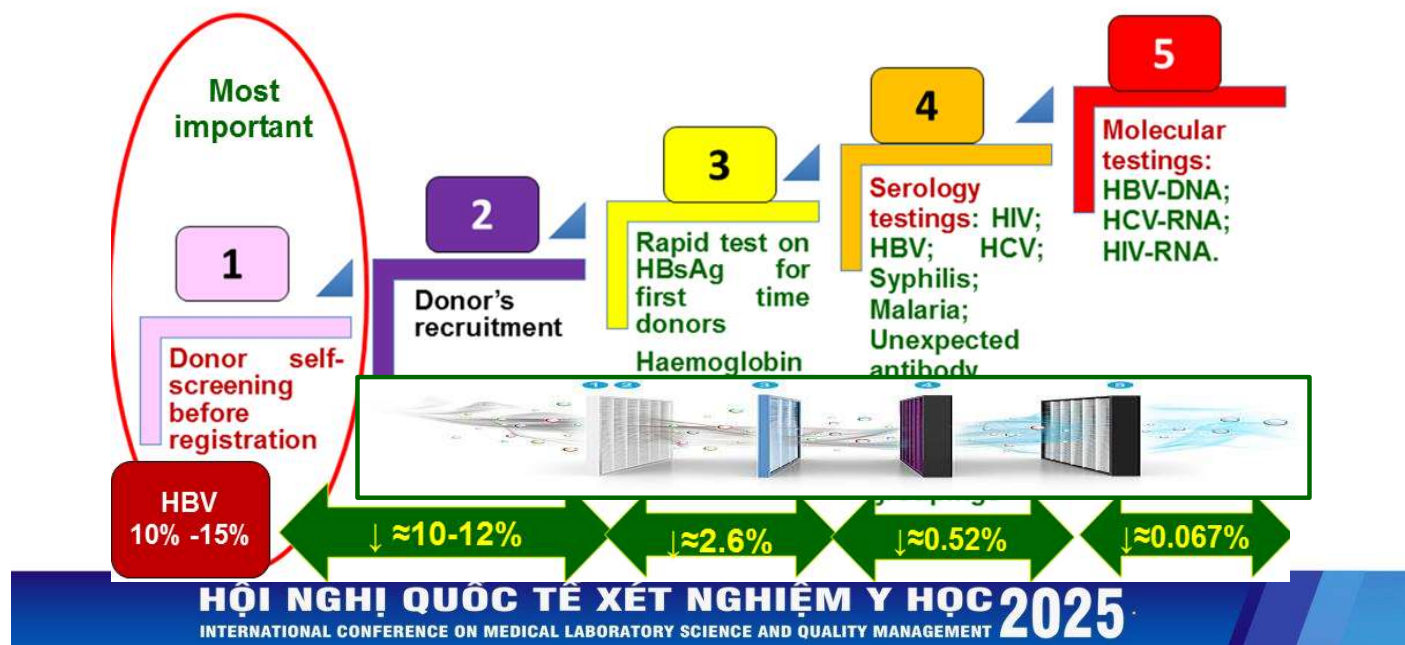
GIÁM ĐỐC
VĂN PHÒNG CÔNG NHẬN CHẤT LƯỢNG QUỐC GIA



TS. Trần Thị Thu Hà

HỘI NGHỊ QUỐC TẾ XÉT NGHIỆM Y HỌC 2025 INTERNATIONAL CONFERENCE ON MEDICAL LABORATORY SCIENCE AND QUALITY MANAGEMENT 2025

CONCLUSION



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DETERMINATION OF THE NEW QUANTITATION LIMIT OF THE METHOD OF BLOOD ETHANOL CONCENTRATION MEASUREMENT ON THE COBAS C503 ANALYZER

Ngo Kien Duc, PharmD, PhD

Head of Department of Biochemistry - Thong Nhat Hospital

Head of the Department of Biochemistry, Faculty of Pharmacy – University of Medicine and Pharmacy at Ho Chi Minh City

INTRODUCTION

- Ethanol is the main component in alcoholic beverages like wine and beer. In addition, ethanol is also present in fermented foods such as ripe fruit, sugar cane, bamboo shoot, and cassava,...
- Ethanol is classified as a stimulant and an addictive substance. → alcohol dependency
- Ethanol is one of the three leading causes of increased traffic accidents, accounting for 36.2% in males and 0.7% in females (WHO, 2014) → **"prohibiting the operation of vehicles when the alcohol concentration in blood or breath is present"**

INTRODUCTION

Law No. 44/2019/QH14 ON PREVENTION AND CONTROL OF HARMFUL EFFECTS OF ALCOHOL AND BEER; effective from January 1, 2020

- Article 5. Prohibited acts in the prevention and control of harmful effects of alcohol and beer
 - Clause 6. Operating a motor vehicle while **there is an alcohol concentration in the blood or breath.**

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INTRODUCTION

According to Decree No. 100/2019/ND-CP dated December 30, 2019

Chapter 2, Section 1, Article 5:

- Clause 6: Fine from 6,000,000VND to 8,000,000 VND
 - c) Operating a vehicle on the road while having an alcohol concentration in the blood but not exceeding 50 milligrams per 100 milliliters of blood, or not exceeding 0.25 milligrams per 1 liter of breath.
- Clause 8: Fine from 16,000,000 VND to 18,000,000 VND
 - d) Operating a vehicle on the road while having an alcohol concentration in the blood or breath exceeding 80 milligrams per 100 milliliters of blood, or exceeding 0.4 milligrams per 1 liter of breath
- Clause 10: Fine from 30,000,000 VND to 40,000,000 VND
 - a) Operating a vehicle on the road while having an alcohol concentration in the blood **exceeding 80 milligrams per 100 milliliters of blood**, or **exceeding 0.4 milligrams per 1 liter of breath.**

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INTRODUCTION

Decision No. 320/QĐ-BYT dated January 23, 2014 on the promulgation of the document **“Guidance on professional technical procedures in the Biochemistry sector”**

< 10,9 mmol/L (50 mg/dL)

Normal Values

10,9 – 21,7 mmol/L

Manifestation of red eyes, vomiting, slow reflexes, reduced responsiveness (or reduced acuity)

21,7 mmol/L

Clinical signs of central nervous system depression

86,8 mmol/L

May be life-threatening.

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INTRODUCTION

Alcohol concentration in blood and breath:

50 mg/dL BAC $\approx$ 0,25 mg/L BrAC

Sensitivity of the breath alcohol test:

0,1 mg/L BrAC $\approx$ 20 mg/dL BAC

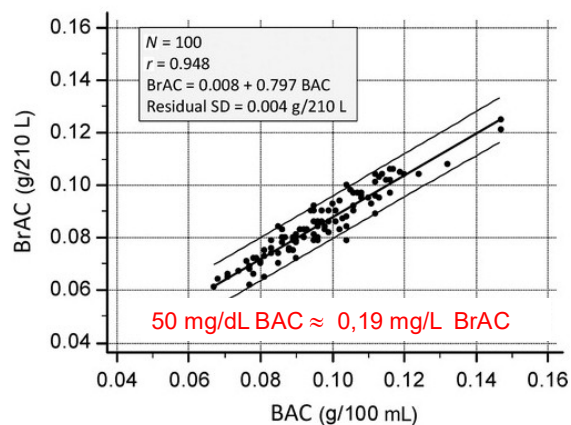
Limit of Quantitation (LoQ) cobas c503:

10,1 mg/dL BAC (Lower than the sensitivity of the breath alcohol test.)

SPECIFICATIONS

1. Indication of B.A.C.

- HIGH: > 0.50‰ or 0.05%BAC or 0.25mg/l BrAC
- LOW: 0.20~0.50‰ or 0.02~0.05%BAC or 0.10~0.25mg/l BrAC
- ZERO: < 0.20‰ or 0.02%BAC or 0.1mg/l BrAC



Alan Wayne Jones, Johnny Mack Cowan, Reflections on Variability in the Blood-Breath Ratio of Ethanol and its Importance When Evidential Breath-Alcohol Instruments are Used in Law Enforcement, *Forensic Sciences Research*, Volume 5, Issue 4, December 2020, Pages 300–308, <https://doi.org/10.1080/20961790.2020.1780720>

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INTRODUCTION

False Negative: No alcohol detected in the breath (< 20 mg/dL), but there is ethanol in the blood → Legal authorities require the laboratory to report the result.

- The laboratory can only determine ethanol concentrations of 10,1 mg/dL or higher
- When ethanol concentration is $< 10,1$ mg/dL: **Result is reported as “ < 10 mg/dL”** → **Did the concerned person violate the regulation?**
- **Who is involved:**
 - Consumed alcohol/beer a long time before (the test)
 - Consumed fermented foods containing alcohol

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INTRODUCTION



It is necessary to **extend the measuring range** on the Cobas c503 system to enable the measurement of **samples with ethanol concentrations below 10,1 mg/dL.**

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RESEARCH OBJECTIVES

To validate the method for quantitative determination of ethanol concentration in blood by alcohol dehydrogenase enzyme on the cobas c503 automated biochemical analyzer, and to **establish the new Limit of Quantitation (LOQ)**

LoQ: Limit of Quantitation

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MATERIALS

- Serum samples: contained in tubes containing micronized silica particles.
- Quality Control (QC) solution and Calibration solution.

Materials	Concentration (mg/dL)	Lot No.	Expiration date
QC 1 Solution	49,8	78200601	30/04/2025
QC 2 Solution	143	78200701	30/04/2025
Calibration solution	216	78200501	30/04/2025

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METHODS

- The Clinical and Laboratory Standards Institute (CLSI) is a leading global organization that develops laboratory standards, with more than 290 standards and guidelines published
- The method validation parameters were carried out in accordance with the following guidelines:
 - ✓ **CLSI EP17A:** Protocols for Determination of Limits of Detection and Limits of Quantitation.
 - ✓ **CLSI EP06:** Evaluation of the Linearity of Quantitative.
 - ✓ **CLSI EP15:** Evaluation of precision and estimation of bias.

Following CLSI guidelines helps laboratories improve reliability and ensures the comparability of results across different testing facilities.

METHODS

Validation parameters	Content	Note
Limit of Blank (LoB)	- Repeat the blank sample 60 times .	Verification: Repeat the blank sample 20 times.
Limit of Detection (LoD)	- Four low-concentration samples , tested 15 times each	Verification: Repeat the claimed LoD sample 20 times.
Limit of Quantitation (LoQ)	- Samples with concentrations $\geq$ LoD, tested 40 times each. - Requirement: the lowest concentration must have $TE_{PXN}\% \leq TEa\%$	Verification: Repeat the claimed LoQ sample 25 times.
Linearity	- Linear range: from LoQ to 216 mg/dL - Requirement: $0.995 < R \leq 1$ and $TE_{PXN}\% \leq TEa\%$	
Precision	- Three patient samples: each sample tested 5 times per day for 5 consecutive days (5×5). Requirement: $CVr\% \text{ and } CVWL\% \leq 20\%$.	
Trueness	- Two QC samples: each sample tested 5 times per day for 5 consecutive days (5×5). Requirement: the mean value must fall within the verified interval (VI).	

TEa: Total Allowable Error
TEa Alcohol blood < 20% (CLIA 2024)

<https://westgard.com/clia-a-quality/quality-requirements/2024-clia-requirements.html>

RESULT

Parameters	Result	Note
Limit of bank (LoB)	1,971 mg/dL	
Limit of detection (LoD)	3,426 mg/dL	
Limit of quantitation (LoQ)	5 mg/dL	$TE_{PXN} \% = 18,24\% < TEa \% = 20\%$.
Linearity	- Linear range: 5 - 216 mg/dL - R = 0,9997	The intercept is not significant ($\hat{y} = 1,0192x$)
Precision	All 3 patient samples meet requirements	
Trueness	Both QC samples meet the requirements	

DISCUSSION

- The re-determination of the **LoB, LoD và LoQ values are lower than the public ones** (The manufacturer announced that all three values are 10,1 mg/dL).
- The new LoQ confirmed is **5 mg/dL**

DISCUSSION

According to **Circulars 42/2024/TT-BYT**, now, the **Limit of Quantitation (LoQ)** of **Gas Chromatography method** applied to laboratory is **0,02% (equivalent to 15 mg/dL)**.

→ **The re-determination of LOQ** using the ADH enzyme method on the Cobas C503 is **5 mg/dL**, which is **significantly lower** than the current values.

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DISCUSSION

- **Experiment's result:** **LoQ = 5 mg/dL** → laboratory can quantify ethanol concentration in the range of **5 - 10 mg/dL**
- **The persistent problem:** concentrations below 5 mg/dL are consistently reported as "<5 mg/dL" ?
- **The question:** Is it necessary to accurately quantify concentrations below?

Compared to the normal blood ethanol concentration established by other countries and the Ministry of Health:

America: < 80 mg/dL

EU: < 50 mg/dL

Japan: 30 mg/dL

The Ministry of Health: < 50 mg/dL

Accurate quantification of concentrations below 5 mg/dL is unnecessary

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CONCLUSION VÀ PROPOSAL

CONCLUSION

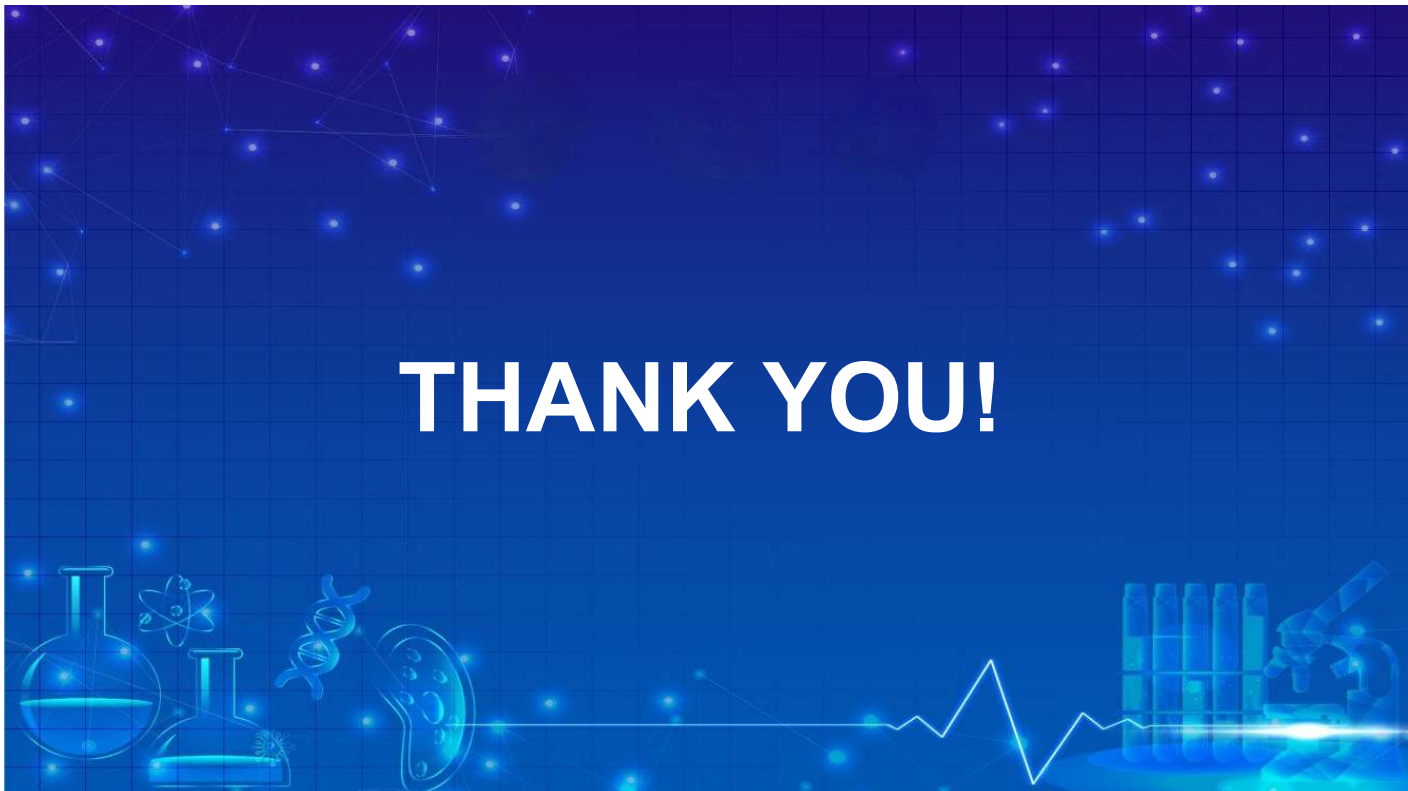
- The method for quantifying blood ethanol concentration using the ADH enzyme on the Cobas c503 automated biochemistry analyzer has met all validation parameters at the laboratory: LoB = 1,971 mg/dL, LoD = 3,426 mg/dL, LoQ = 5 mg/dL, linearity in the range 5 - 216 mg/dL, and precision and trueness meet CLSI requirements.

PROPOSAL

- The method for quantifying blood ethanol concentration using the ADH enzyme on the Cobas c503 can be applied to clinical practice with lower LoQ (5 mg/dL instead 10,1 mg/dL) and linearity in the range 5 - 216 mg/dL.
- Perform a correlation comparison with the Gas Chromatography (GC) method, which has higher sensitivity and specificity.

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THANK YOU!

RANDOX

HIL – thách thức tiền phân tích và
giải pháp kiểm soát ảnh hưởng

Bui Phuong Hanh



LỖI TIỀN PHÂN TÍCH

Phần lớn các lỗi trong phòng xét nghiệm lâm sàng đều **xuất hiện từ giai đoạn tiền phân tích**.
 Nguồn gốc gây ra **nhiều sai số nhất cho PXN**, do đó gây **rủi ro lớn nhất** đối với **mẫu bệnh nhân**.

Nguyên nhân hàng đầu của việc loại bỏ mẫu

(Getawa et al., 2023 (Practical laboratory Medicine, Vol 33))

⚠ Lỗi ghi nhãn	(7.31%)
⚠ Không đủ thể tích	(22.81%)
⚠ Tán huyết	(22.87%)
⚠ Mẫu bị vón cục	(32.23%)

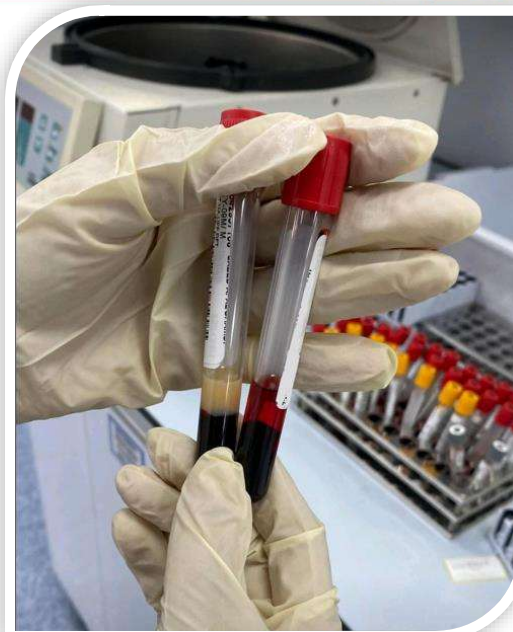
RANDOX

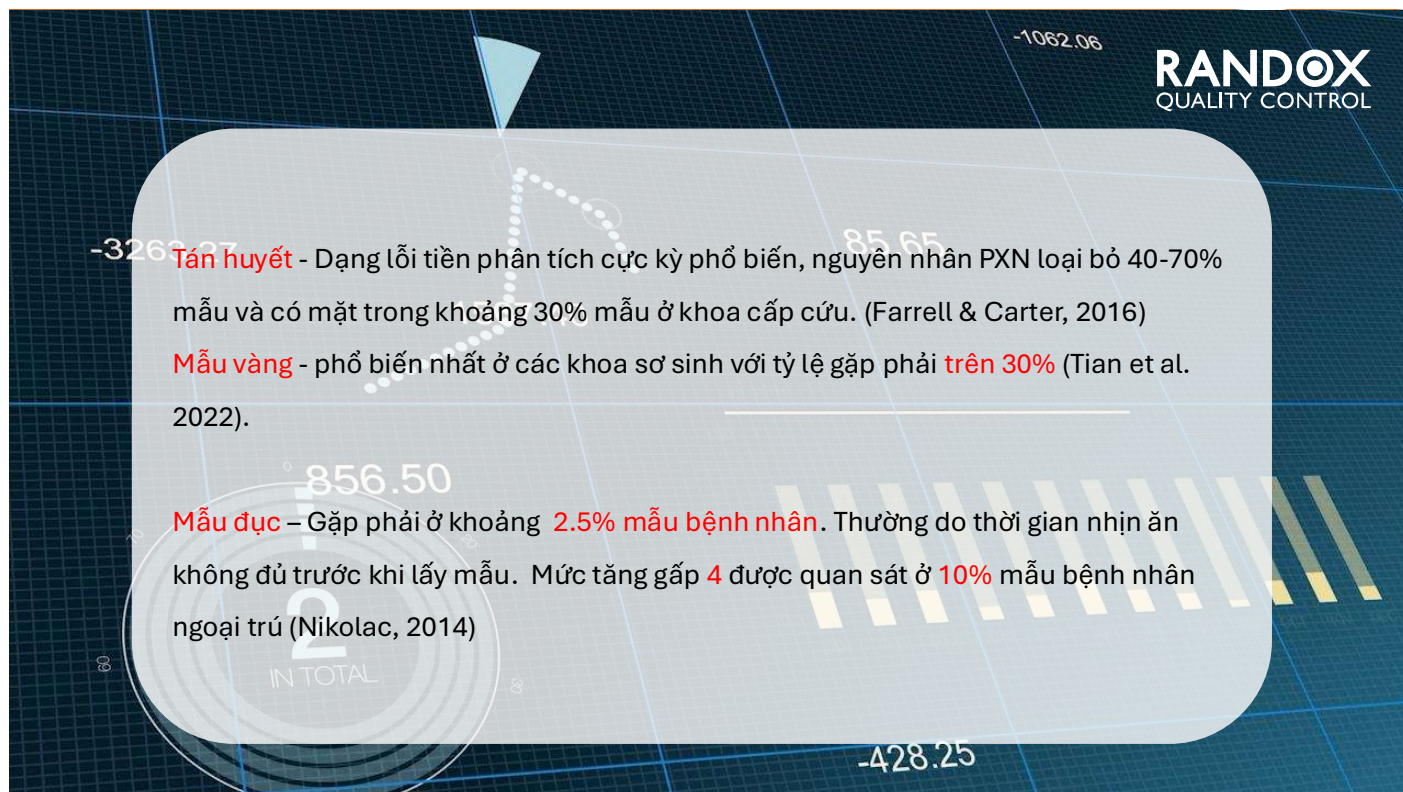
RANDOX
 QUALITY CONTROL

TẦM QUAN TRỌNG CỦA KIỂM SOÁT HIL

HIL thường không được kiểm soát bởi IQC hoặc chương trình EQA vì chúng thường không được coi là thông số phân tích.

Nhưng HIL được sử dụng để thẩm định kết quả xét nghiệm của các thông số khác hoặc để giám sát chất lượng mẫu nói chung. Nên ảnh hưởng trực tiếp đến kết quả xét nghiệm trên báo cáo.





Đánh giá các chỉ số huyết thanh



Phương pháp truyền thống
(Quan sát trực quan)



Phương pháp hiện đại
(Đánh giá tự động)

Mục tiêu: Đánh giá các giá trị SI thu được bằng cách kiểm tra trực quan so sánh với Cobas 6000 tự động. Xem xét nguy cơ đưa ra kết quả sai khi đánh giá SI do khả năng đánh giá trực quan.

Phương pháp: 1509 mẫu được kiểm tra trực quan bởi ba KTV được đào tạo, sau đó được phân tích lại bằng máy phân tích Roche Cobas 6000 để đo SI khách quan.

Results: Giá trị SI của HIL trong 1509 mẫu được phân tích trên Cobas 6000 được phân bố như sau: **Tán huyết (H) 993– 62%; mẫu vàng (I) 74-5%; Mẫu đục (L) 59 – 4%.** Khi đánh giá bằng cách kiểm tra trực quan, trung bình và trọng số kappa cho ba KTV được ghi nhận: **Tan máu (H) 20,67% – 0,21; mẫu vàng (I) 7,1%– 0,3421; Mẫu đục (L) 12,6% – 0,1258, thể hiện sự thiếu đồng thuận và nguy cơ diễn giải chủ quan.**

Reference: Getahun T et al., 2019, Ethiopia.

> EJIFCC. 2019 Oct 11;30(3):276-287. eCollection 2019 Oct.

Evaluation of Visual Serum Indices Measurements and Potential False Result Risks in Routine Clinical Chemistry Tests in Addis Ababa, Ethiopia

Tigist Getahun ¹, Anberber Alemu ¹, Firehiwot Mulgeta ¹, Merone Sileshi ¹, Abenezer Ayalew ¹, Wosene Habtu ¹, Zeleke Geto ¹, Fitsum Girma ¹, Feyissa Challa ¹, Mitse Wolde ²

Affiliations: + expand
PMID: 31695585 PMCID: PMC6803774

Abstract

Background: Serum indices (SI) including hemolyzed, lipemic, and icteric samples, affects the accuracy of test result. The aim of this study was to evaluate SI values done by visual inspections and potential false result risks by comparing with actual measurements done by Cobas 6000 Chemistry analyzer at Ethiopian Public Health Institute (EPHI), Addis Ababa, Ethiopia.

Methods: An observational, cross-sectional study was conducted from April to May 2017 on samples referred to Clinical Chemistry laboratory of EPHI, Ethiopia. These samples SI values, after visual inspection by three trained observers, was analyzed again on Roche Cobas 6000 analyzer (RCA). The generated data was analyzed by using weighted kappa methods on STAT statistical software version 20.

Results: From a total of 1509 samples, SI values identified by the RCA as hemolysis, icteric, and lipemic were 933 (62%), 74(5%) and 59(4%) respectively. The SI average weighted kappa between RCA and visual inspection were: 0.1870, 0.3421, and 0.1259 for hemolysis, icteric, and lipemic samples, respectively. Combined inter-observers variability among observers for hemolysis, icterus, and lipemic samples were 0.4758, 0.3258, and 0.3628 respectively. The best agreement among observers was in the case of hemolysis (0 grades), while the lowest agreement was observed in the case of icterus (+3 grades). In addition, test parameters, such as CK-MB (22%), and LDH (20%) were falsely accepted, whereas CT and Na+ (up to 25%) were falsely rejected tests by observers. On the other hand, results rejected by Cobas SI assessments included CK-MB (22%), LDH (20%), and BIL-D (4%).

Conclusion: Visual inspection of SI showed poorly agreement with automated system. Thus, there is genuine need for more training of Laboratory professionals on identification of SI, and as much as possible SI should be done by automated system to improve quality of test results.

Keywords: hemolysis; icteric; lipemic; serum indices.

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Yếu tố nhiều		Mức nhiều- đánh giá trực quan					Kết hợp
		0	+1	+2	+3	+4	
Kappa	Tán huyết	0.6600	0.3563	0.2619	0.1486	0.4847	0.4758
	Mẫu vàng	0.4643	0.1310	0.3238	0.1016	0.2692	0.3258
	Mẫu đục	0.5022	0.2265	0.2489	0.2067	0.2812	0.3628

Results:

Các thông số thử nghiệm đã được **chấp nhận sai** bởi quan sát trực quan trong khi bị từ chối bởi Cobas SI bao gồm **CK-MB (22%), LDH (20%) và BIL-D (4%)**, bị quan sát trực quan **từ chối sai** trong khi được chấp nhận bởi phân tích chỉ số huyết thanh cobas, bao gồm **CL- và Na+ (n = 178, 25%) và BIL-T (n = 17, 7%)**

> EJIFCC. 2019 Oct 11;30(3):276-287. eCollection 2019 Oct.

Evaluation of Visual Serum Indices Measurements and Potential False Result Risks in Routine Clinical Chemistry Tests in Addis Ababa, Ethiopia

Tigist Getahun ¹, Anberber Alemu ¹, Firehiwot Mulgeta ¹, Merone Sileshi ¹, Abenezer Ayalew ¹, Wosene Habtu ¹, Zeleke Geto ¹, Fitsum Girma ¹, Feyissa Challa ¹, Mitse Wolde ²

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Background: Serum indices (SI) including hemolyzed, lipemic, and icteric samples, affects the accuracy of test result. The aim of this study was to evaluate SI values done by visual inspections and potential false result risks by comparing with actual measurements done by Cobas 6000 Chemistry analyzer at Ethiopian Public Health Institute (EPHI), Addis Ababa, Ethiopia.

Methods: An observational, cross-sectional study was conducted from April to May 2017 on samples referred to Clinical Chemistry laboratory of EPHI, Ethiopia. These samples SI values, after visual inspection by three trained observers, was analyzed again on Roche Cobas 6000 analyzer (RCA). The generated data was analyzed by using weighted kappa methods on STAT statistical software version 20.

Results: From a total of 1509 samples, SI values identified by the RCA as hemolysis, icteric, and lipemic were 933 (62%), 74(5%) and 59(4%) respectively. The SI average weighted kappa between RCA and visual inspection were: 0.1870, 0.3421, and 0.1259 for hemolysis, icteric, and lipemic samples, respectively. Combined inter-observers variability among observers for hemolysis, icterus, and lipemic samples were 0.4758, 0.3258, and 0.3628 respectively. The best agreement among observers was in the case of hemolysis (0 grades), while the lowest agreement was observed in the case of icterus (+3 grades). In addition, test parameters, such as CK-MB (22%), and LDH (20%) were falsely accepted, whereas CT and Na+ (up to 25%) were falsely rejected tests by observers. On the other hand, results rejected by Cobas SI assessments included CK-MB (22%), LDH (20%), and BIL-D (4%).

Conclusion: Visual inspection of SI showed poorly agreement with automated system. Thus, there is genuine need for more training of Laboratory professionals on identification of SI, and as much as possible SI should be done by automated system to improve quality of test results.

Keywords: hemolysis; icteric; lipemic; serum indices.

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RIQAS

KẾT QUẢ NGOẠI KIỂM
CHỈ SỐ HUYẾT THANH

RIQAS 

CHƯƠNG TRÌNH CHỈ SỐ HUYẾT THANH (RQ9194)

Mỗi đợt: 3 mẫu x 1ml: 1 x Mẫu bình thường+ 2 x Mẫu thêm bị ảnh hưởng

Tần suất: chu kỳ kéo dài 12 tháng bắt đầu từ tháng 10,
tần suất 2 tháng 1 lần (Bi-monthly)

RANDOX 

Được đánh giá theo 2 phần:

1. Đánh giá chỉ số huyết thanh định lượng và/hoặc bán định lượng cho mỗi mẫu
2. Đánh giá định lượng các thông số hóa sinh cho từng mẫu theo nhu cầu

- Tần suất 2 tháng 1 lần
- Mỗi lần 3 x 1ml
1x mẫu bình thường,
2 mẫu để đánh giá 2 trong 3 Chỉ số Tan máu (Haemolytic), Vàng da (Icteric) hoặc Mỡ máu (Lipemic)

Các thông số hoá sinh

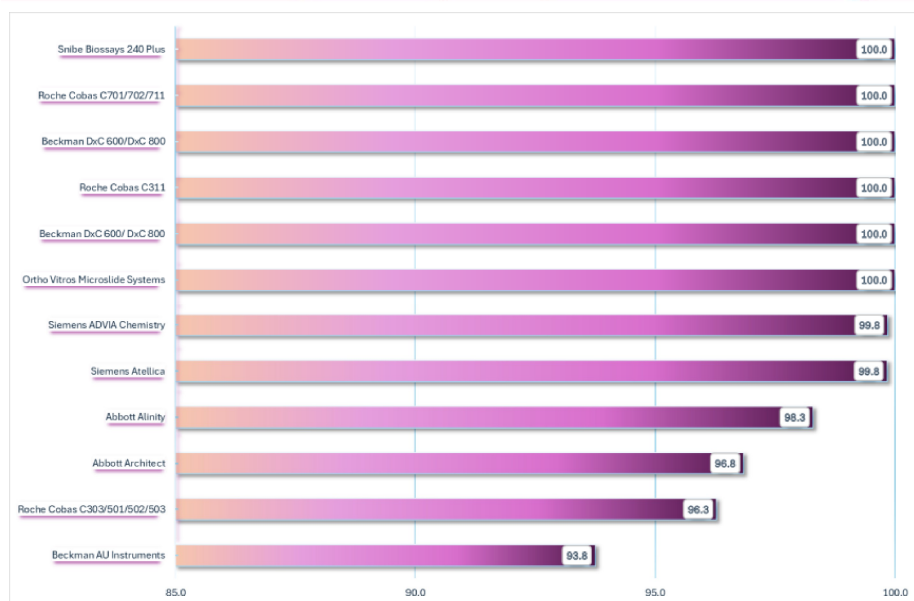
- | | | | | |
|----------------------|---------------|-----------|-------------|-------------------|
| • ALP | • Calcium | • GGT | • LDH | • Protein (Total) |
| • ALT | • Chloride | • Glucose | • Lipase | • Sodium |
| • AST | • Cholesterol | • HDL | • Magnesium | • Triglycerides |
| • Bilirubin (Direct) | • CK NAC | • Iron | • Phosphate | • Urea |
| • Bilirubin (Total) | • Creatinine | • Lactate | • Potassium | • Uric Acid |

SỰ KHÁC NHAU CỦA CÁC THIẾT BỊ HIL
Tổng quan đánh giá (EQA)

Các hệ thống thiết bị khác nhau so sánh với nhau như thế nào đối với từng chỉ số HIL?

Tất cả các đơn vị tham gia có ghi nhận cùng một phân loại HIL cho từng loại mẫu hay không?

MẪU KHÔNG BỔ SUNG YẾU TỐ NHIỀU



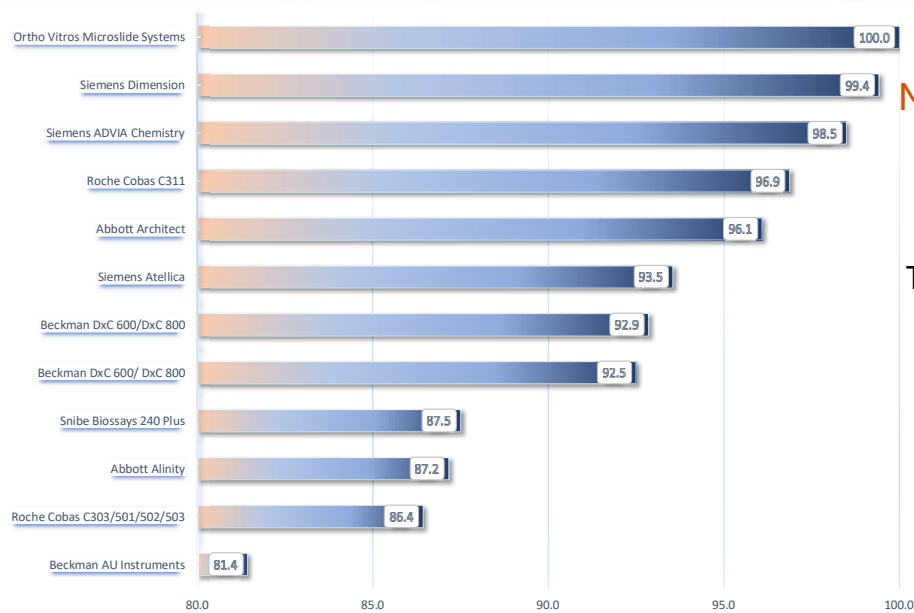
Mức độ đồng thuận trung bình giữa các nhóm kết quả

Tất cả các chỉ số: mẫu không bổ sung yếu tố nhiều

Chúng ta kỳ vọng rằng tất cả các đơn vị tham gia sẽ báo cáo các mẫu này là không có nhiều

RANDOX

MẪU CÓ BỔ SUNG YẾU TỐ NHIỀU



Mức độ đồng thuận trung bình giữa các nhóm kết quả

Tất cả các chỉ số: mẫu có bổ sung yếu tố nhiều

Mức độ tương đồng trung bình giảm, cho thấy hiệu suất phát hiện HIL khác nhau giữa các hệ thống

RANDOX



Với cả ba chỉ số HIL, có sự giảm mức độ tương đồng giữa các hệ thống trong việc xác định nồng độ HIL trong các mẫu

RANDOX



Sự thiếu thống nhất giữa các hệ thống nhấn mạnh tầm quan trọng của việc chạy mẫu nội kiểm trên các máy phân tích này nhằm đảm bảo rằng mẫu bệnh phẩm KHÔNG BỊ RỦI RO

RANDOX

KHÁC BIỆT GIỮA CÁC HỆ THỐNG PHÂN TÍCH

Vẫn còn tồn tại **những hạn chế quan trọng trong việc đo lường HIL** trên các **máy phân tích khác nhau từ các nhà sản xuất khác nhau** (Von Meyer et al., 2018 – EFLM)

Phương pháp đo lường

Phương pháp báo cáo dữ liệu các chất gây nhiễu

Định nghĩa các ngưỡng của mức độ nhiễu

Thiếu sự thống nhất về ngưỡng cut-off trong thực hành

RANDOX

RANDOX
QUALITY CONTROL

CÁC HƯỚNG DẪN QUỐC TẾ

- **ISO15189** “quy định rằng phòng xét nghiệm “...phải có quy trình được lập thành văn bản để xác định và xử lý các điểm không phù hợp trong bất kỳ khía cạnh nào của hệ thống quản lý chất lượng, bao gồm cả các **quy trình tiền phân tích...**”. Mục 5.4
- **CLSI-C56** khuyến nghị rằng **vật liệu kiểm soát chất lượng (QC) có nguồn gốc từ người** (được chuẩn bị theo các quy trình được mô tả trong hướng dẫn CLSI C56-A và EP07) **là phù hợp để sử dụng cho các chỉ số HIL.**
- **Liên đoàn Châu Âu về Hóa sinh Lâm sàng và Y học Phòng thí nghiệm (EFLM)** duy trì một nhóm chuyên trách về sai sót trong tiền phân tích, bắt đầu từ việc nhấn mạnh tầm quan trọng của giai đoạn này cho đến việc đưa ra **hướng dẫn cụ thể về các phương pháp kiểm soát chất lượng (QC)**

C56-A nêu rằng các phòng xét nghiệm nên xem xét việc **thẩm định phương pháp và kiểm soát chất lượng** để đánh giá các khía cạnh sau:

- **Các thông số HIL**, giống như mọi phép đo quang phổ khác, **có thể bị trôi dạt (drift) hoặc sai lệch** theo thời gian.
- **Không duy trì được độ ổn định trong phép đo** có thể dẫn đến **thay đổi các tiêu chí** chấp nhận hoặc loại bỏ mẫu bệnh phẩm.
- **Sự khác biệt giữa các máy phân tích** có thể gây ra sự không nhất quán trong tiêu chí chấp nhận hoặc loại bỏ mẫu.
- Xét đến tất cả các yếu tố trên, **việc áp dụng cách tiếp cận theo quy trình chất lượng đối với kiểm tra HIL là hết sức quan trọng.**

Bộ nội kiểm chỉ số huyết thanh (Serum Indices – SI) Randox Acusera được thiết kế để theo dõi phản ứng của thiết bị chẩn đoán in vitro (IVD) trong việc phát hiện các mẫu có hiện tượng tan máu (H), vàng da (I) và mỡ máu (L)

Vật liệu huyết thanh người, dạng đông khô, cung cấp đầy đủ các mức độ kiểm tra có ý nghĩa lâm sàng, bao gồm một mức âm tính (-) và ba mức dương tính (+, ++, +++), Các nghiên cứu kiểm tra cho thấy độ chụm tốt (CV% < 10%)

Analytes: Haemolysis (H) | Icterus (I) | Lipemia (L)

Description
Serum Indices Control

Size
4 x 5 ml

Cat No.
SI10448

RANDOX
QUALITY CONTROL



RANDOX

SERUM INDICES SETUP GUIDE
ABBOTT ALINITY



QUALITY CONTROL

RANDOX

SERUM INDICES SETUP GUIDE
ATELlica



QUALITY CONTROL

RANDOX

SERUM INDICES SETUP GUIDE
ROCHE



QUALITY CONTROL

RANDOX

Xin chân thành cảm ơn!



UltraE

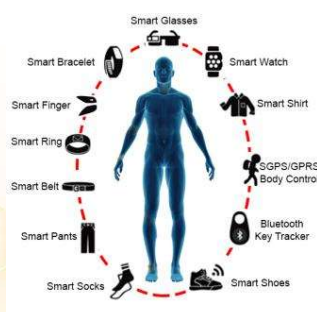
NÂNG CAO HIỆU QUẢ CHĂM SÓC SỨC KHỎE TRONG TƯƠNG LAI BẰNG HỆ THỐNG THIẾT BỊ ĐEO GIÚP THEO DÕI LIÊN TỤC CÁC CHỈ SỐ SINH HỌC



UltraE

Để Chăm Sóc Sức Khỏe Cá Nhân Tốt Hơn, Chúng Ta Cần Chẩn Đoán Đúng

**Chẩn đoán dựa trên các
dấu hiệu sinh tồn**



**Chẩn đoán dựa trên các
dấu hiệu sinh học**

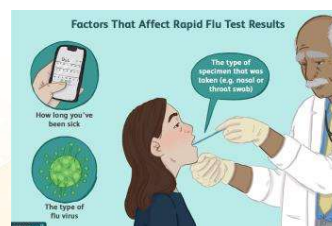


Sốt

Dấu hiệu sinh tồn
Đo nhiệt độ



Chẩn đoán sinh học
Nhiễm virus hoặc vi khuẩn



Phương pháp điều trị và thuốc
phù hợp cho bệnh nhân.

Suy Tim

Chẩn đoán dấu hiệu sinh tồn
ECG/ Huyết áp



Chẩn đoán sinh học
BNP/ proBNP/ Troponin I



Phương pháp điều trị và thuốc
phù hợp cho bệnh nhân.



Thiết Bị Theo Dõi Dấu Hiệu Sinh Tồn Đeo Tay/ Cầm Tay



Iphone Trở Thành Một Công Cụ Đo Lường (FDA Chấp Thuận)

Ứng dụng kèm phụ kiện

- AliveCor
- Welch Allyn iExaminer Adapter and Ophthalmoscope



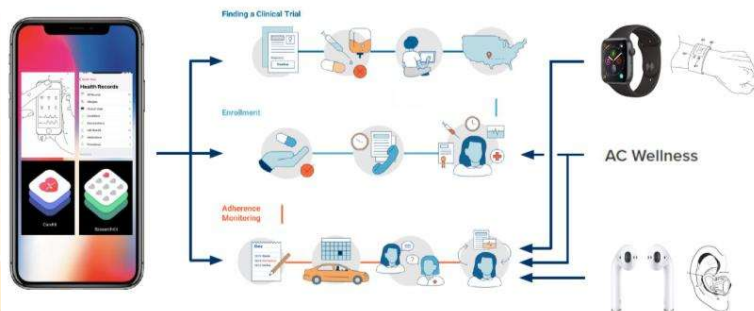
Thiết bị siêu âm cầm tay Butterfly iQ hay Pulsenmore có giá dưới 2.000\$



Apple Watch Và AirPods Được Dùng Để Theo Dõi Các Chỉ Số Sinh Tồn.

UNUSUAL SUSPECTS

Apple's unbundling of clinical trials





Thiết Bị Chẩn Đoán In Vitro



Với Bệnh Tiểu Đường Bệnh Nhân Đã Dùng Máy Đo Đường Huyết Hàng Thập Kỳ Nay.

Kiểm Soát Đường Huyết Hiệu Quả



Giờ Đây, Bệnh Nhân Tiểu Đường Đã Chuyển Sang Dùng CGM (Máy Đo Đường Huyết Liên Tục).

Continuous glucose monitoring

Possible display devices

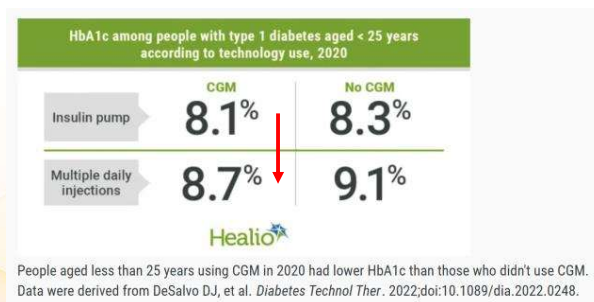
Insulin pump

Smart watch

Smartphone or handheld device

Cleveland Clinic © 2024

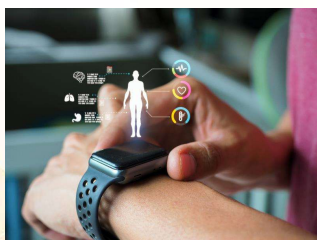
Sensor



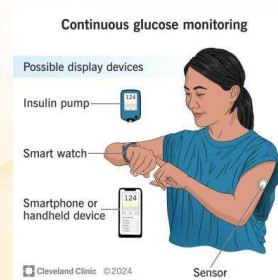
Hữu ích để giảm thiểu rủi ro

Giải Pháp Chăm Sóc Sức Khỏe Cá Nhân Tốt Nhất Kết Hợp Chẩn Đoán Qua Dấu Hiệu Sinh Tồn & Các Chỉ Số Sinh Học.

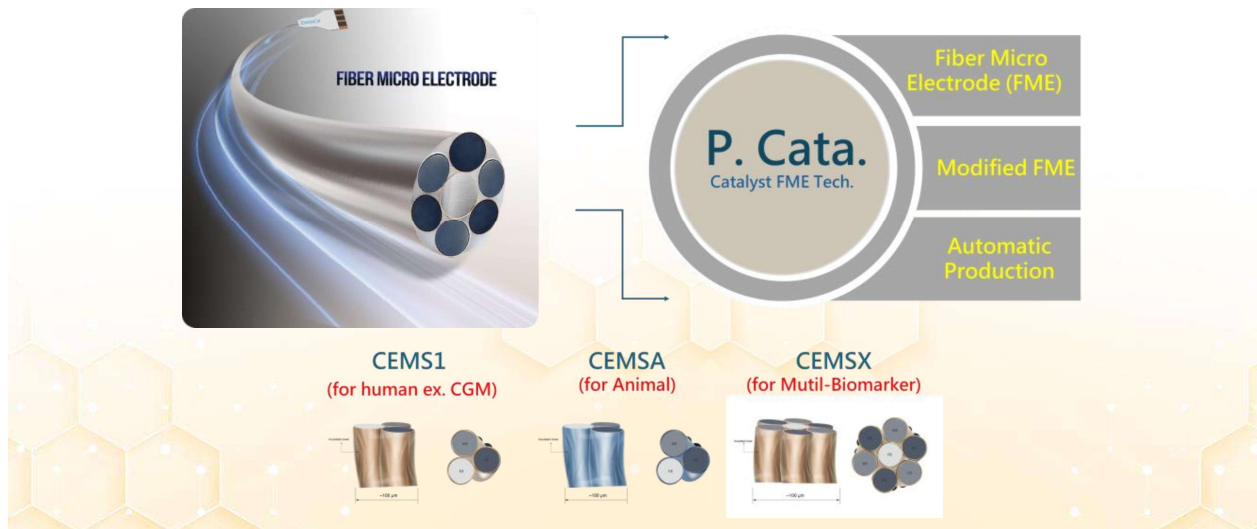
Chẩn đoán dấu hiệu sinh tồn Nhiều sản phẩm



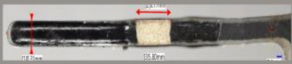
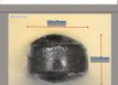
Chẩn đoán chỉ số sinh học Cần thêm sản phẩm



Hệ Thống Theo Dõi Sinh Học Liên Tục Mang Tính Đột Phá.



Hệ Thống Theo Dõi Chỉ Số Sinh Học Liên Tục Thế Hệ Mới

	Front side	Back side	Top
A brand (US L 2)	Width 0.380 mm 		
B brand (Taiwan IF)	Width 0.460 mm 		
S brand (China)	Width 0.300 mm 		
UltraE	Width 0.137 mm 	- Global Smallest Sensor System - Low Interference - Cost Effective	  Bare Biofilm coated

Không Chỉ Dừng Lại Ở Việc Theo Dõi Đường Huyết Liên Tục



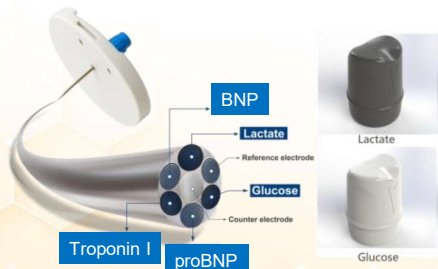
Suy Tim

Chẩn đoán dấu hiệu sinh tồn
ECG/ Huyết áp

Chẩn đoán sinh học
BNP/ proBNP/ Troponin I







Theo dõi liên tục nồng độ BNP/ proBNP/ Troponin I tại nhà để giảm thiểu nguy cơ



Công nghệ P. Cata Là Giải Pháp Tối Ưu Giúp Theo Dõi Dấu Hiệu Sinh Học Liên Tục Trong Chăm Sóc Sức Khỏe.



CẢM ƠN!



International Conference on Medical Laboratory Science and Quality
Management 2025: A 15-Year Journey of Development



Evaluation of Reagent Lot-to-Lot Variability According to CLSI EP26-A



November 15, 2025

Presenter: Le Huu Hoang

CLSI: Clinical and Laboratory Standards



Contents:

1

- Background – Quality Control Requirements

2

- CLSI EP 26 – A Guideline

3

- Conclusion



1

• Background



Definition: Lot-to-lot variability describes the differences in performance between production batches of the same reagent.

Causes: Variability arises from **changes** in raw **materials**, **manufacturing processes**, and **storage** or **transportation** conditions.

Impact: Even minor inconsistencies can affect test accuracy, **requiring evaluation of each new reagent lot before use.**

International Conference on Medical Laboratory Science and Quality Management 2025: A **15**Year Journey of Development

3



1

• Quality Control Requirements for Reagents



Verification is required whenever a complete reagent change occurs, unless the laboratory can demonstrate that the change in reagent lot number does not affect the reportable range used for patient test results.



A new reagent lot and/or shipment must be evaluated against the previous lot or an appropriate reference material before or at the time of being placed into use.

International Conference on Medical Laboratory Science and Quality Management 2025: A **15**Year Journey of Development

4



1

• Quality Control Requirements for Reagents



BỘ Y TẾ

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Số: 2429/QĐ - BYT

Hà Nội, ngày 12 tháng 6 năm 2017

QUYẾT ĐỊNH

Ban hành Tiêu chí đánh giá mức chất lượng phòng xét nghiệm y học

TCVN ISO 15189:2025

ISO 15189:2022

Xuất bản lần 2

CHƯƠNG VII. QUẢN LÝ MUA SẴM, TRANG THIẾT BỊ, VẬT TƯ,...24
HÓA CHẤT VÀ SINH PHẨM.....24

7.8. Nếu PXN không thực hiện lưu trữ hóa chất, sinh phẩm và vật tư tại PXN, thì PXN có thực hiện kiểm tra không gian và điều kiện nơi bảo quản				
7.9. Đối với mỗi loại kit xét nghiệm hoặc lô hóa chất sinh, phẩm mới nhận, PXN đánh giá chất lượng trước khi sử dụng				

6.6.3 Thuốc thử và vật tư tiêu hao – Kiểm tra chấp nhận

Từng thuốc thử hoặc công thức mới của các bộ kit xét nghiệm có sự thay đổi về thuốc thử hoặc quy trình, hoặc lô hoặc hàng mới, đều phải được kiểm tra xác nhận tính năng trước khi đưa vào sử dụng hoặc khi thích hợp, trước khi đưa ra kết quả.

Các vật tư tiêu hao có thể ảnh hưởng đến chất lượng của các xét nghiệm phải được kiểm tra xác nhận tính năng trước khi đưa vào sử dụng.

CHÚ THÍCH 1: Kết quả thực hiện IQC so sánh của lô thuốc thử mới và những lô trước đó có thể được sử dụng làm bằng chứng cho việc chấp nhận (xem 7.3.7.2). Mẫu của bệnh nhân được ưu tiên khi so sánh các lô thuốc thử khác nhau để tránh những vấn đề về tính tương đồng của vật liệu IQC.

CHÚ THÍCH 2: Đôi khi việc kiểm tra xác nhận có thể dựa trên giấy chứng nhận phân tích thuốc thử.

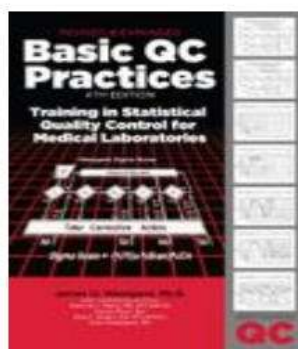
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5

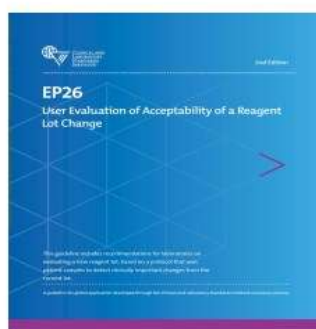


1

• Quality Control Requirements for Reagents



Tiếp cận theo Westgard



Tiếp cận theo CLSI



Tiếp cận theo tác giả khác

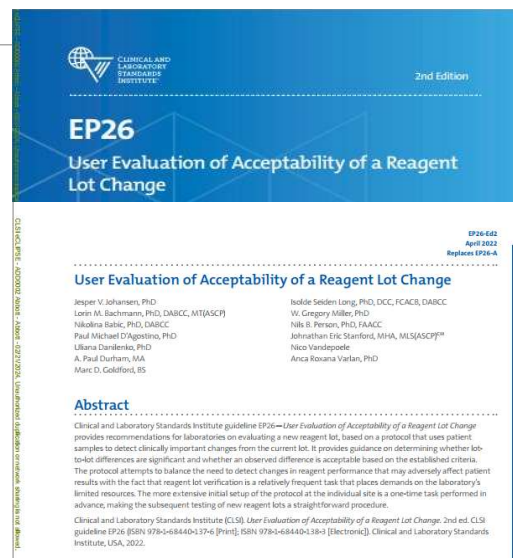
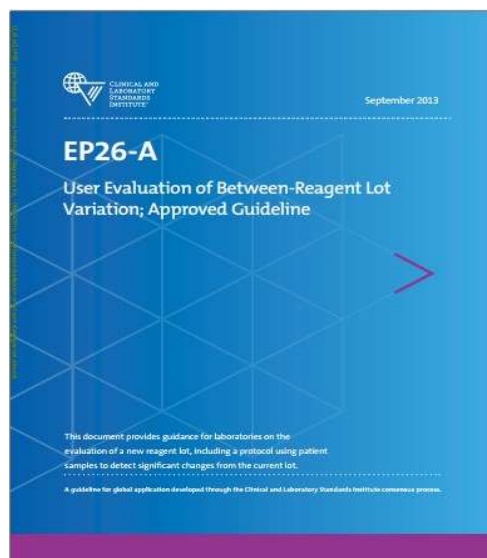
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6



2

• CLSI EP 26 – A Guideline



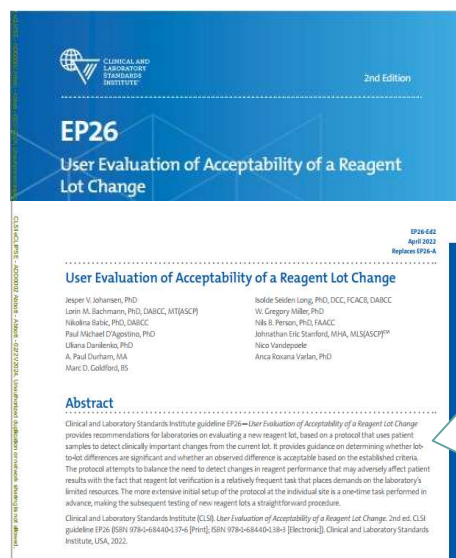
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7



2

• CLSI EP 26 – A Guideline



Recommendations for Clinical Laboratories:

- Evaluate each new reagent lot using a process that incorporates patient samples to detect clinically significant differences compared with the current lot.
- Determine whether the observed lot-to-lot differences are significant and whether such differences are acceptable based on established criteria.
- Balance the need to identify performance changes that may negatively affect patient results with the practical reality that reagent lot verification is a relatively routine task that must be performed using limited laboratory resources.
- Establishing a detailed initial setup of the verification procedure at each laboratory site is a one-time effort that will simplify future evaluations of new reagent lots.

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8



2

• CLSI EP 26 – A Guideline



Phase 1

Phase 2

- ☐ Assessing the acceptable limits for reagent lot-to-lot variation: test, concentration, and number of samples evaluated.
- ☐ Data collection and acceptance criteria.
- ☐ Performed once.

- ☐ Perform the evaluation according to the Phase 1 setup: select and test appropriate samples, and compare the differences between the old and new reagent lots based on the established acceptance criteria.
- ☐ Repeat this stage whenever a new reagent lot is introduced.

CLSI. User Evaluation of Acceptability of a Reagent Lot Change. 2nd ed. CLSI guideline EP26. 2022.

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9

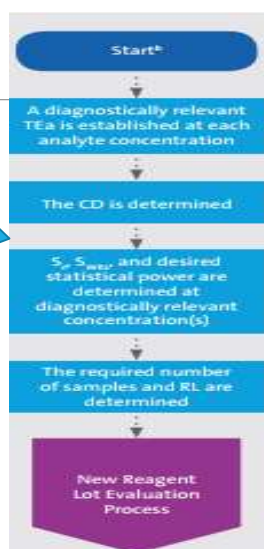


2

• CLSI EP 26 – A Guideline



Phase
1



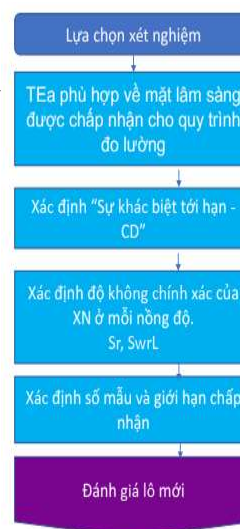
Parameters in Phase 1:

TEa: Total Allowable Error

CD-Critical Difference:

Sr: Precision

Swrl: Repeatability within the same reagent lot.



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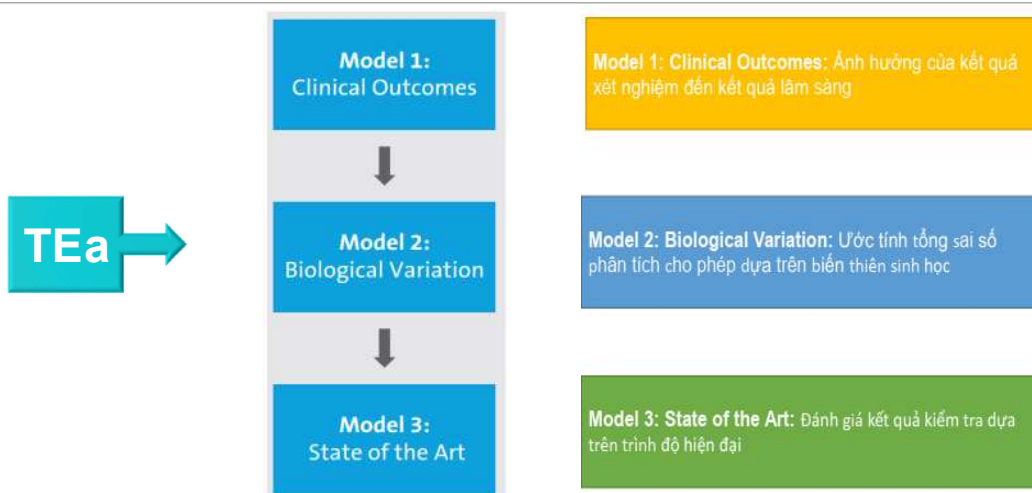


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Parameters in Phase 1:



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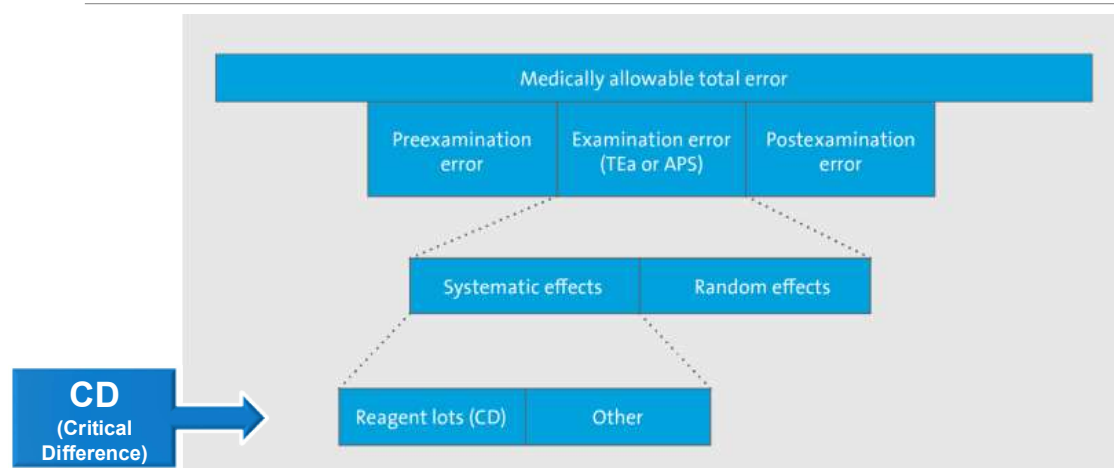
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Parameters in Phase 1:



CD
(Critical
Difference)

$$CD = TEa - 2 \cdot S_{wrl}$$

• Swrl (within–reagent lot imprecision):

The imprecision within a single reagent lot (including variability within a single run, between runs, and between days, without involving multiple lots), expressed as SD or CV (%). This parameter may correspond to the repeatability claimed by the manufacturer or obtained during method verification.

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Parameters in Phase 1:



Collecting S_r (repeatability CV) and S_{wrl} (within-lot CV) values
There are three sources for obtaining these data:

- Manufacturer's Instructions for Use (IFU).
- Laboratory QC results obtained from a single reagent lot.
- Results from method verification when the assay is first implemented or during periodic method revalidation.

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Parameters in Phase 1:

- **TEa**: Total allowable error
- **CD**: Critical difference (percentage or absolute)
- **S_r**: Short-term assay variability: repeatability SD or CV
- **S_{wrl}**: Long-term assay variability: within-lot SD or reproducibility CV
- **POWER**: Statistical power, the ability to detect a difference; minimum requirement is 80%

Calculated indices:

$$CD / S_{wrl}$$

$$S_r / S_{wrl}$$

Applied to determine the required number of samples and acceptance thresholds in Phase 2.

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2

CLSI EP 26 – A Guideline

Determining the Required Sample Size and Acceptance Thresholds

Table A1-A3 (EP26 CLSI)

		RL for Mean Difference									
		0.90 • CD		0.80 • CD		0.70 • CD		0.60 • CD		0.55 • CD	
CD/S _{wrl}	S _r /S _{wrl}	Power	N	Power	N	Power	N	Power	N	Power	N
1.5	1.00	0.594	5	0.698	6	0.800	7	0.910	10	0.951	12
1.5	0.95	0.588	7	0.692	11	0.800	20	0.904	114	—	—

Rejection threshold

Statistical power / ability to detect lot differences

Required sample size

1. Locate CD/S_{wrl}
2. Locate S_r/S_{wrl}
3. Move to the Power cell and stop at Power ≥ 0.8 (80%); the corresponding N is the required number of samples.
4. X•CD corresponds to the rejection limit.

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Determining the Required Sample Size and Acceptance Thresholds



Example:

For Assay A, at a single concentration level:

$CD/S_{wRL} = 3.0$

$S_r/S_{wRL} = 1.0$

Using Table A1 (for assays with one concentration level):

⇒ The laboratory needs to test **3 patient samples**, providing **92.9% power** to detect a difference at the threshold of $0.6 \times CD$.

Table A1: RL for Mean Difference

CD/S _{wRL}	S _r /S _{wRL}	0.90 × CD		0.80 × CD		0.70 × CD		0.60 × CD		0.55 × CD	
		Power	N	Power	N	Power	N	Power	N	Power	N
2.0	1.00	0.597	3	0.714	4	0.802	4	0.917	6	0.954	7
2.0	0.95	0.589	3	0.691	4	0.803	6	0.909	11	0.948	16
2.0	0.90	0.589	4	0.690	6	0.801	13	—	—	—	—
2.0	0.85	0.589	6	0.688	13	—	—	—	—	—	—
2.0	0.80	0.587	11	—	—	—	—	—	—	—	—
2.0	0.75	—	—	—	—	—	—	—	—	—	—
2.5	1.00	0.599	2	0.691	2	0.821	3	0.921	4	0.962	5
2.5	0.95	0.594	2	0.712	3	0.800	3	0.910	5	0.953	7
2.5	0.90	0.591	2	0.699	3	0.801	4	0.905	8	0.946	15
2.5	0.85	0.588	2	0.688	3	0.800	6	0.904	48	—	—
2.5	0.80	0.592	3	0.688	4	0.800	17	—	—	—	—
2.5	0.75	0.588	3	0.688	7	—	—	—	—	—	—
2.5	0.70	0.588	4	0.688	47	—	—	—	—	—	—
2.5	0.60	0.586	20	—	—	—	—	—	—	—	—
2.5	0.50	—	—	—	—	—	—	—	—	—	—
3.0	1.00	0.618	2	0.726	2	0.818	2	0.929	3	0.951	4
3.0	0.95	0.613	2	0.717	2	0.805	2	0.919	3	0.953	3
3.0	0.90	0.608	2	0.709	2	0.826	3	0.919	4	0.946	5
3.0	0.85	0.605	2	0.702	2	0.812	3	0.919	6	0.947	10

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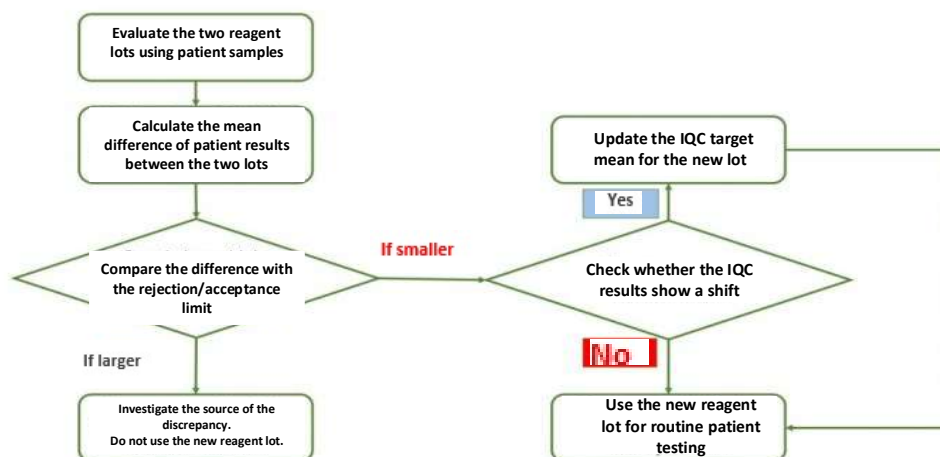


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Phase 2



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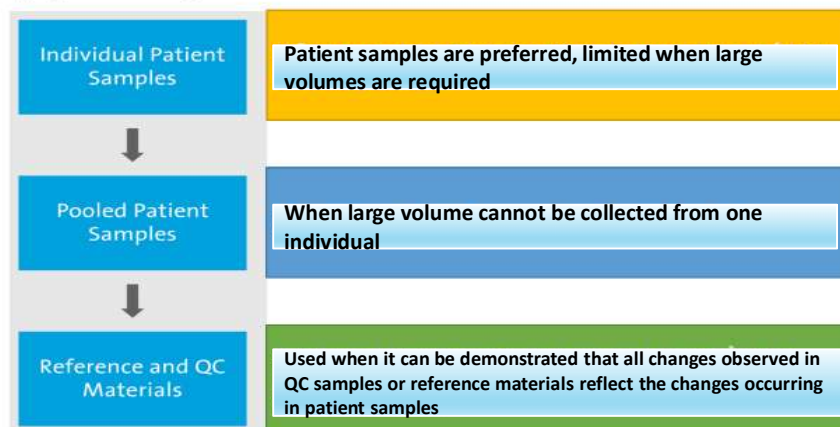


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Samples Used for Evaluating a New Reagent Lot:



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• CLSI EP 26 – A Guideline

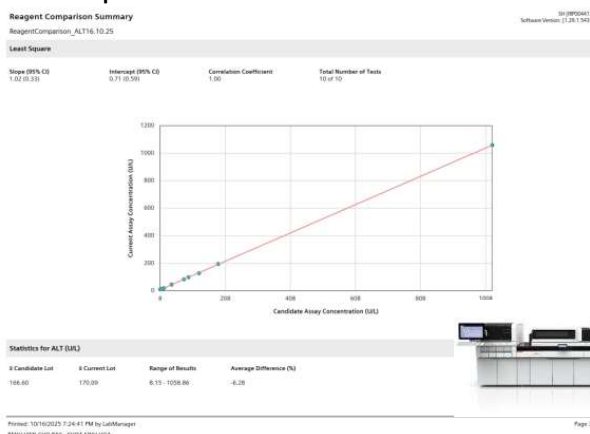


Example

Sample	Current Lot Result (IU/L)	New Lot Result (IU/L)	Difference	Rejection Limit (0.7*CD)
1	165	160	-5	
2	158	162	4	
3	168	170	2	
Mean	163.67	164	0.33	0.35

Conclusion: The mean difference is $0.33 < 0.35 \Rightarrow$ The new reagent lot is accepted for use

Results report



CLSI. User Evaluation of Acceptability of a Reagent Lot Change. 2nd ed. CLSI guideline EP26. 2022.

Ví dụ:

Mẫu	Kết quả lô hiện tại, IU/L	Kết quả lô mới, IU/L	Sự khác biệt	Giới hạn từ chối 0.7*CD
1	165	160	-5	
2	158	162	4	
3	168	170	2	
TB	491	492	0.33	0.35

KL: Sự khác biệt trung bình: $0.33 < 0.35 \Rightarrow$ Lô mới được chấp thuận sử dụng

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• Conclusion



Verification of reagent lot-to-lot changes is mandatory to ensure that test results remain stable and medically equivalent over time.

Reagent lot verification using patient data is the most reliable method for detecting systematic differences between lots, which may be missed by routine quality control.

Minimizing the risk of instrument errors and ensuring continuous laboratory quality.

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**My sincere appreciation to all Professors,
Teachers, and Colleagues!**

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ỨNG DỤNG XÉT NGHIỆM DỊ ỨNG ĐA DỊ NGUYÊN TRONG ĐỊNH HƯỚNG CHẨN ĐOÁN VÀ QUẢN LÝ BỆNH DỊ ỨNG TẠI VIỆT NAM

TP. Hồ Chí Minh, 11/2025

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Nội dung



1. Đặt Vấn Đề
2. Dữ liệu thực tế tại Việt Nam
3. Xét Nghiệm Dị Ứng Đa Dị Nguyên
4. Ứng dụng trong lâm sàng

1. Đặt Vấn Đề



➤ Thực trạng bệnh dị ứng

Trên Thế Giới :

- 10 – 40%

Theo tổ chức dị ứng thế giới (WAO, 2020)

Tại Việt Nam :

- 20% – 25% tại thành phố
- 20% tại nông thôn

Theo TTDUMDLS BV Bạch Mai (2020)



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1. Đặt Vấn Đề



➤ Thách thức trong chẩn đoán

- Chẩn đoán dựa vào lâm sàng và tiền sử phơi nhiễm
- Test lấy da (skin prick test, SPT)
- Bệnh nhân nhạy cảm với đa dị nguyên

→ Công cụ xét nghiệm khách quan, toàn diện hơn



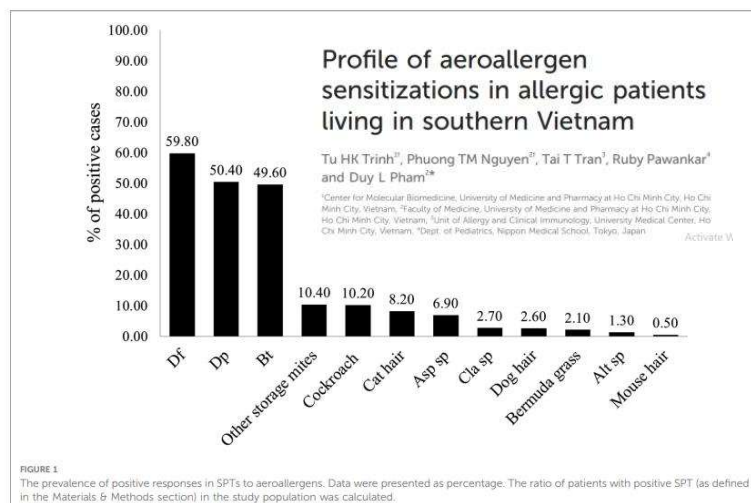
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2. Dữ Liệu Thực Tế Tại Việt Nam

➤ DỊ NGUYÊN NÀO THƯỜNG GẶP Ở VIỆT NAM?

- Nhóm dị nguyên hô hấp phổ biến nhất : mạt bụi nhà (Df, Dp, Bt), mạt kho, gián, lông thú, nấm mốc, cỏ...



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2. Dữ Liệu Thực Tế Tại Việt Nam

➤ DỊ NGUYÊN NÀO THƯỜNG GẶP Ở VIỆT NAM?

- Ở trẻ viêm da cơ địa: đạm sữa bò, trứng (lòng trắng > lòng đỏ), thịt bò, đậu phộng,...
- Ở người lớn: hải sản (giáp xác > cá), thịt bò,...

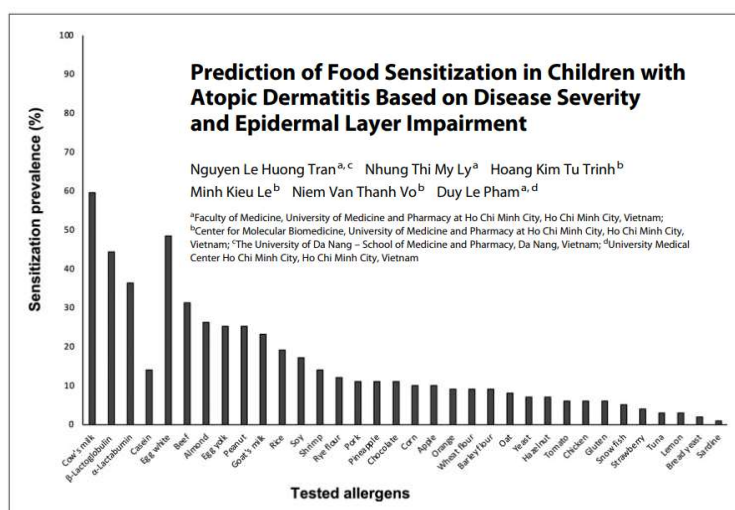


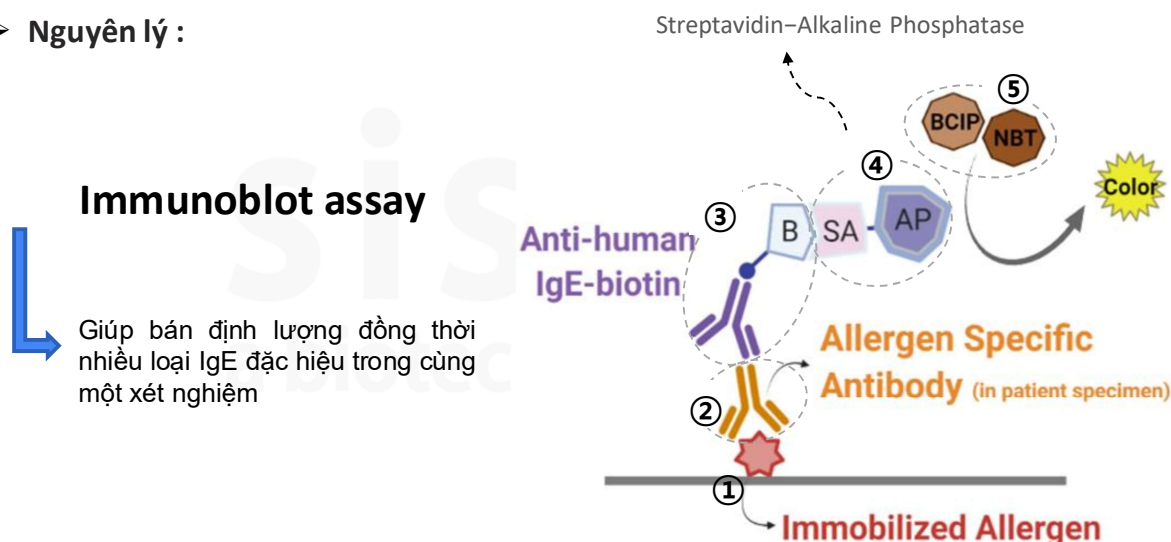
Fig. 1. Prevalence of sensitization to FAs in the study subjects.

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3. Xét nghiệm dị ứng đa dị nguyên

➤ Nguyên lý :



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3. Xét nghiệm dị ứng đa dị nguyên

➤ So sánh với SPT

	Test lấy da, test áp da (SPT)	Immunoblot
Cách thực hiện	Test trực tiếp trên bề mặt cánh tay thông qua một chất gây dị ứng cụ thể	Test bằng huyết thanh hoặc huyết tương, thông qua các loại hóa chất xét nghiệm
Kết quả	Kết quả chủ quan : Kết quả dương tính được biểu thị bằng một nốt sần , một cục u màu trắng nổi lên được bao quanh bởi một vòng da mẩn đỏ nhỏ.	Kết quả khách quan kết quả thể hiện trong biểu mẫu báo cáo
Ưu và nhược điểm	Kết quả ngay lập tức Độ nhạy cao (Không dành cho trẻ sơ sinh,khoảng 50%-60% đều cho kết quả “dương tính giả”) không phải lúc nào cũng là một yếu tố dự đoán chính xác	Dễ chịu, không có nguy cơ sốc phản vệ Độ đặc hiệu cao Không bị ảnh hưởng bởi thuốc, như thuốc kháng histamin Có thể xét nghiệm nhiều chất gây dị ứng khác nhau khi cần thiết
Thời gian test	Khoảng 40 phút cho 20 dị nguyên	3h – 4h cho hơn 100 dị nguyên
Giá cả	Thấp	Trung bình - cao
Độ rủi ro	Cao	Thấp

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3. Xét nghiệm dị ứng đa dị nguyên



➤ Sugentech - Giải pháp xét nghiệm dị ứng tự động



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3. Xét nghiệm dị ứng đa dị nguyên



Bộ xét nghiệm hô hấp (50 dị nguyên)



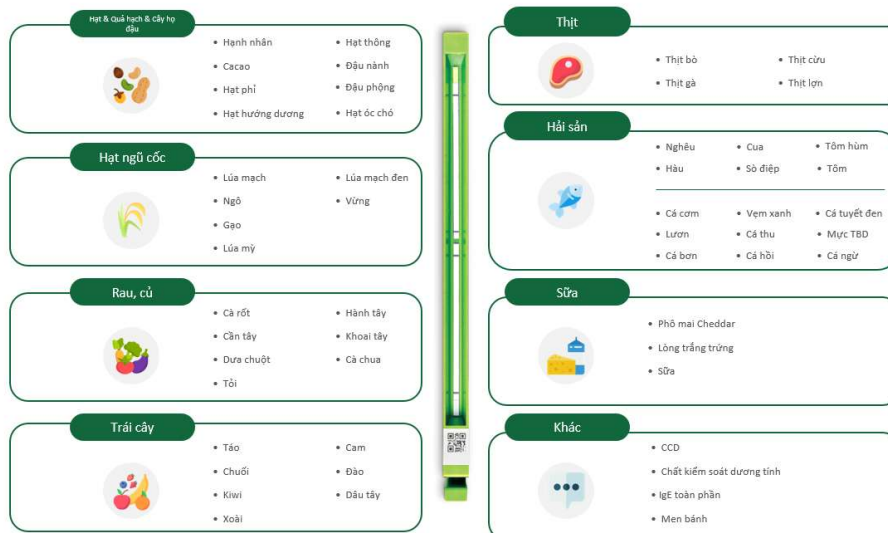
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3. Xét nghiệm dị ứng đa dị nguyên

Bộ xét nghiệm thực phẩm (52 dị nguyên)

- Hiệu quả chi phí / tiết kiệm cho bệnh nhân
- Linh hoạt trong chỉ định lâm sàng



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3. Xét nghiệm dị ứng đa dị nguyên

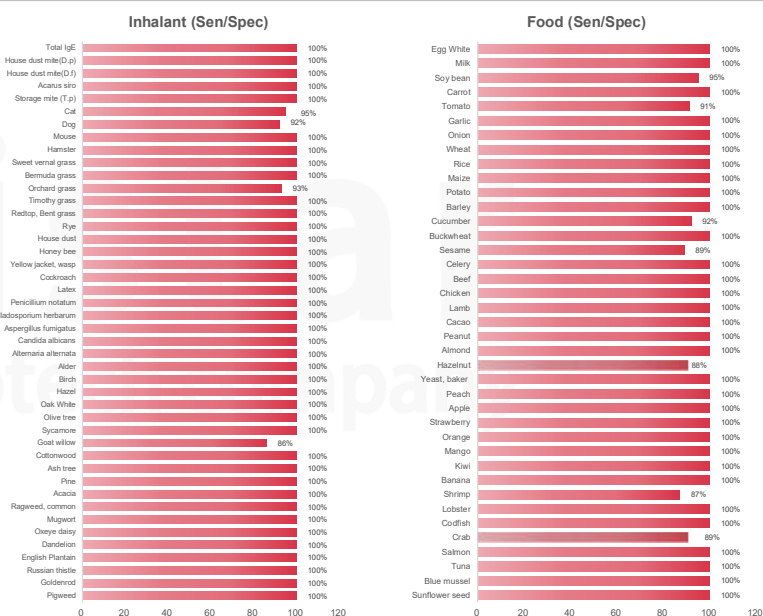


Thiết bị chẩn đoán: **Phadia ImmunoCAP – Tiêu chuẩn vàng**

Dị nguyên: 83 loại
Số mẫu nghiên cứu : 120 mẫu

Tương quan

98.30(%)



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4. Ứng dụng trong lâm sàng



4. Ứng dụng trong lâm sàng

➤ Ứng dụng trong một số nhóm bệnh dị ứng: *

Bệnh lý	Vai trò	Nguồn khuyến cáo / tài liệu tham khảo
Hen suyễn	Giúp xác định yếu tố khởi phát triệu chứng hen suyễn	GINA 2023 – Global Initiative for Asthma: “Identification of sensitizing allergens is recommended for management and selection of allergen immunotherapy.”
Viêm mũi dị ứng	Hỗ trợ chỉ định sử dụng giải mẫn cảm	ARIA 2019 – Allergic Rhinitis and its Impact on Asthma guidelines: “Allergen identification is essential before initiating allergen immunotherapy.”
Dị ứng thức ăn đáp ứng qua IgE	Hỗ trợ chẩn đoán. Đánh giá trước điều trị giải mẫn cảm	EAACI 2017 – Food Allergy Guidelines: “Measurement of specific IgE is recommended for diagnosis and for consideration of immunotherapy (Grade B evidence).”
Viêm da cơ địa	Hỗ trợ chẩn đoán dị nguyên thức ăn có liên quan	Consensus-based European guidelines for treatment of atopic eczema 2018: “Allergen-specific IgE testing can help identify relevant triggers, especially in moderate to severe AD.”
Sốc phản vệ	Hỗ trợ chẩn đoán	WAO 2020 – World Allergy Organization Guidelines for Anaphylaxis: “Specific IgE testing should be performed to identify the responsible allergen after recovery.”

Kết luận



- **Xét nghiệm dị ứng đa dị nguyên** là công cụ hiện đại, giúp xác định chính xác các dị nguyên gây bệnh.
- **Mạt bụi nhà, gián, nấm mốc và hải sản** là nhóm dị nguyên phổ biến nhất tại Việt Nam, chiếm tỷ lệ nhạy cảm cao nhất ở cả trẻ em và người lớn.
- **Ứng dụng xét nghiệm này** giúp bác sĩ định hướng điều trị chính xác, hỗ trợ lựa chọn liệu pháp giải mẫn cảm và theo dõi hiệu quả điều trị lâu dài.
- **Mở rộng xét nghiệm dị ứng đa dị nguyên** tại các tuyến y tế là xu hướng tất yếu, góp phần nâng cao chất lượng chẩn đoán và quản lý bệnh dị ứng tại Việt Nam.

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False Rejection: Challenges and Practical Solutions in Clinical Laboratories

Tran Thanh Vinh MD. PhD.



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Content

1. What is a False rejection?
2. Causes of False rejection
3. How to confirm a False rejection?
4. How to minimize False rejection?
5. Key messages

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False rejection in IQC and EQAS

What is a False rejection?

Have an **out-of-control** flag
from a control (iQC/eQA)



Wrong with the method

No detector is perfect!

$$\sim \\ FR > 0$$

→ False rejection

When a laboratory's testing process is operating in its stable in-control state and a QC rule is evaluated, there is a chance that the QC rule will reject → **False rejection**

<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

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False rejection in IQC and EQAS

What is a False rejection?

- **Probability of false rejections (P_{fr})**
 - $P_{fr} = 0.01$ (1%) ~ one false rejection for every 100 QC runs
 - depends on no. of QC concentrations, total no. of QC results, and QC rule(s) used
 - predicted either mathematically, by computer simulation, or by empirical evaluation of retrospective laboratory data
- **Average run length for false rejection (ARL_{fr}):** number of times a control solution will be analyzed before a false rejection occurs
 - $ARL_{fr} = 1/P_{fr}$
 - $P_{fr} = 0.01$ (1%) ~ $ARL_{fr} = 100$ ~ on average, 370 measurements before a false rejection is observed
 - **Longer ARL_{fr} is better!!!**

<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

CLSI. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions. 4th ed. CLSI guideline C24. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

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False rejection in IQC and EQAS

Impact of False Rejection on Laboratory Operations



- Response to a QC false rejection caused a **delay in reporting results** that affected decisions regarding patient management.
- Increased rate of QC rule failures causing an increased amount of troubleshooting, repeated measurements for patient specimens, and additional work involved in following up on QC rule failures → **reduces efficiency and increases operational costs**

CLSI. *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions*. 4th ed. CLSI guideline C24. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

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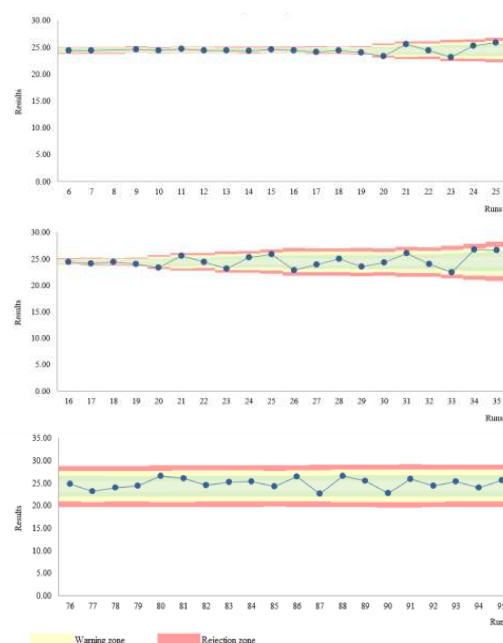
False rejection in IQC and EQAS

Causes of False rejection in IQC

IQC

Too narrow control limits

- **SD inadequately estimated:** use short-term QC data, not include longer-term sources of variability in lab
 - **Control limits calculated improperly:** use 2SD, even 1SD limits to exclude QC data
- 2SD limits: high false rejections of **9%** with 2 controls ~ one FR for average 10 runs (three control per run up to 14% false rejection)



<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

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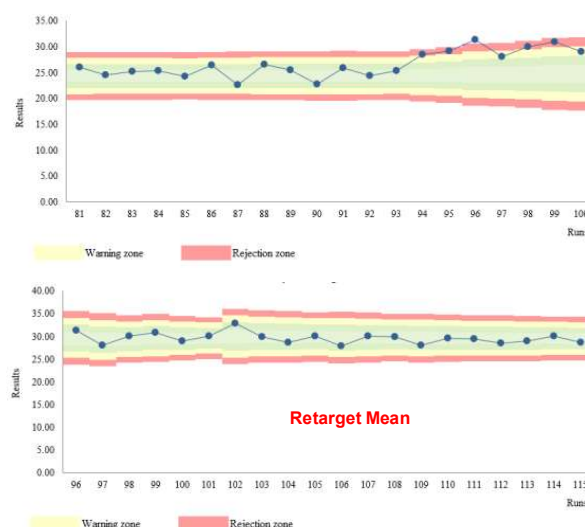
False rejection in IQC and EQAS

Causes of False rejection in IQC

IQC

Target value is no longer appropriate

- **Shifted mean:** caused by reagent lots change, maintenance activities, QC material stability,... but not a true value for patient specimen → Need to adjust target value (mean)



<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

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False rejection in IQC and EQAS

Causes of False rejection in IQC

IQC

Inappropriate QC rules

QC rules / multirules	P_{fr}
1_{2s}	~ 5% (N=1) ~ 9% (N=2) ~ 14% (N=3)
1_{3s}	~ 0.27% (N=1)
$1_{2s}/1_{3s}/2_{2s}/R_{4s}/4_{1s}/10_x$	~ 3%–4% (N=2) ~ 3%–7% (N=3)
$1_{3s}/2_{2s}/R_{4s}/4_{1s}/10_x$	~ 1–2% (N=1)
$1_{3s}/2_{2s}/R_{4s}$	~ 0.8 – 1% (N=1)

- **A non-zero P_{fr} always exists** for any QC rule or multirule, determined by rule design and number of control measurements (N) in each run.
- **Use only 1_{2s} rule** get high false rejection rates, 9% (N=2) and 14% (N=3)

<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

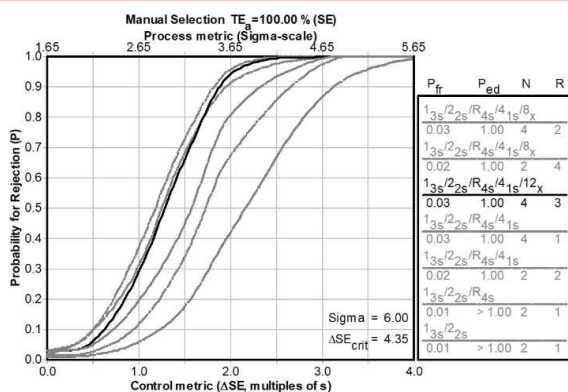
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False rejection in IQC and EQAS

Causes of False rejection in IQC

IQC

Inappropriate QC rules



- **Using more QC rules than necessary** when test performance not require → increases false rejections without improving quality

○ **Example:** At Sigma = 6, only a 1_{3s} rule is needed to reject a run (P_{ed} = 100%).

→ Each additional rule above **not boost error detection** but **increase 1% false rejection**

<https://westgard.com/essays/basic-qc-practices/weaning-off-warning-rules.html>

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False rejection in IQC and EQAS

Causes of False rejection in IQC

EQC

Errors not related to testing process on patient samples

- **Wrong method/instrument or measurement unit registered** lead to inclusion of result in wrong method/equipment group and affect both evaluation of group(s) as well as evaluation of lab own result and performance assessment.
- **Samples improperly stored, reconstituted, or processed** lead to poor test results but not related to test performance.
- **Transcript errors:** record or report a wrong result, wrong unit...

<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>
Kristensen GB, Meijer P. Interpretation of EQAS results and EQA-based trouble shooting. Biochem Med (Zagreb). 2017 Feb 15;27(1):49-62.

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False rejection in IQC and EQAS

Causes of False rejection in IQC

EQC

Error in statistical results of peer group

- **Wrong group of consensus-based PT/EQA:** not a true value for the specimen. And many methods are neither standardized nor harmonized, there is no real agreement on what the “right” value should be → AV of total group is not representative for lab’s method.
- **Unsuitable statistical method for data distribution/group size** e.g. due to a non-normal distribution of results caused by different reagent lots.
- **PT/EQAS sample stability not ensured:** affect statistical results of peer group → incorrectly classify laboratories performance.

<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

Kristensen GB, Mejer P. Interpretation of EQAS results and EQA-based trouble shooting. Biochem Med (Zagreb). 2017 Feb 15;27(1):49-62.

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False rejection in IQC and EQAS

Causes of False rejection in IQC

EQC

Error in statistical results of peer group

- Incorrect method registration
- Inter-vial precision of EQAS sample outside acceptable limit

<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

Kristensen GB, Mejer P. Interpretation of EQAS results and EQA-based trouble shooting. Biochem Med (Zagreb). 2017 Feb 15;27(1):49-62.

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False rejection in IQC and EQAS

Causes of False rejection in IQC

IQC

EQC

Non-commutability of IQC/EQAS samples

- **Matrix effects:** IQC/EQAS material NOT commutable for lab specific method, i.e not identical as a real patient sample

→ when result is “out”, but not reflective of real status of method.

<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

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False rejection in IQC and EQAS

How to confirm False rejections?

IQC

Re-run the control sample

- Take a new vial of same control material and re-run it by a different technician
- If re-run **PASS** → likely **FALSE** or caused by a random event affecting only that one measurement (e.g., pipetting error, small air bubble) or compromised QC material (QC material evaporated or improperly stored, QC material nearing expiration, wrong QC level analyzed...) → Initial patient batch can be released.
- If re-run **FAIL** again or **OK but near limits of acceptable range** → a **genuine problem** and patient results should not be released until cause is identified and corrected → follow the laboratory's standard corrective action plan for out-of-control IQC results

Evaluate the QC rule being used

- Check if rejection was based on a **warning rule** or a **rejection rule**
- If a warning, watch for a trend with future controls, but don't automatically reject patient results

Review the Levey-Jennings chart.

- Look for any suspicious **trends or shifts** leading up to the failed QC point.
- If failed point is a sudden outlier with no preceding pattern, more likely a random error
- If a noticeable drift away from mean, rejection is more likely true, indicating a gradual problem.

Assess impact on patient results

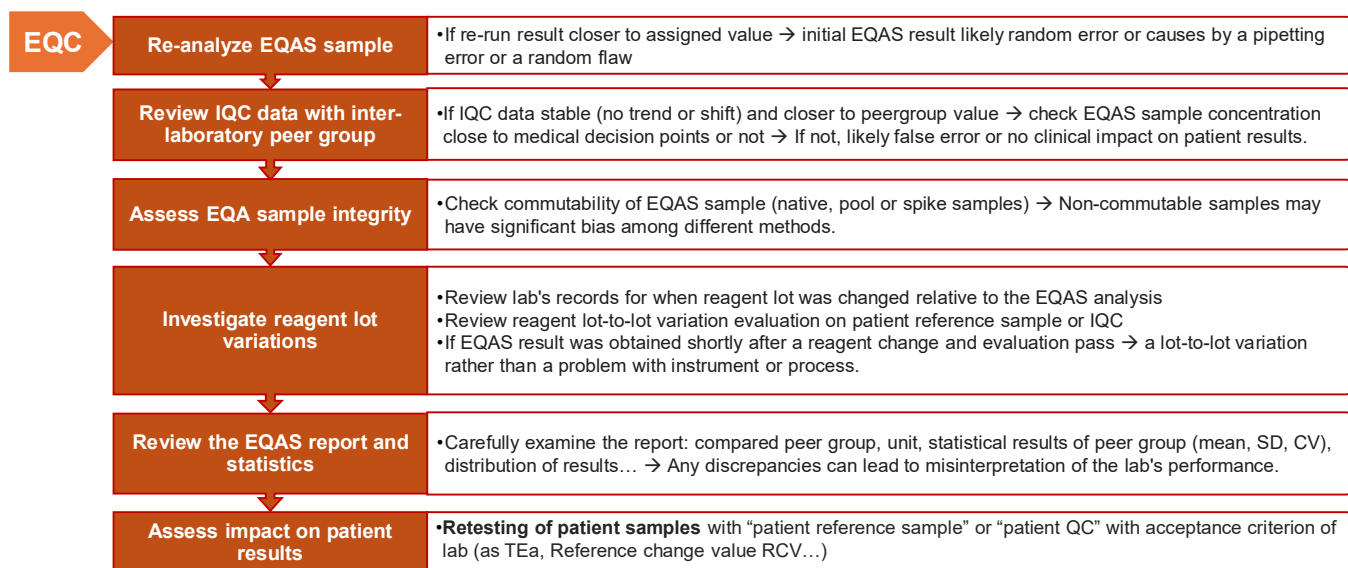
- **Retesting of patient samples** with “patient reference sample” or “patient QC”
- Evaluate bias before and after out-of-control run with acceptance criterion of lab (as TEa, Reference change value RCV...)

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False rejection in IQC and EQAS

How to confirm False rejections?



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False rejection in IQC and EQAS

How to minimize False rejection?

IQC

Determine control limits that represent stable analytical performance

Control limits

- **Determine stable SD:** Compute cumulative SD over first several months to ensure longer-term sources of variability are included in data, e.g. different calibration cycles, different reagent bottles or lots, preventive maintenance, component replacement, and environmental factors.
- **Adjusting target value** during the life of the lot of quality control material if influenced by changes in conditions that not affect patient results, such as reagent lot changes, some maintenance procedures, or deterioration of measurand...
- Review periodically and after critical events as calibration, instrument maintenance or replacement of parts, change of reagents lot... to update control limits if necessary.

CLSI. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions. 4th ed. CLSI guideline C24. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

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False rejection in IQC and EQAS

How to minimize False rejection?

IQC

Set Performance Goals for Lab QC strategies: $P_{ed} \geq 90\%$ and $P_{fr} \leq 5\%$

- Probability of false rejection as low as possible (preferable 1% or less)
- Balance desire for a low false rejection rate with required error detection

QC strategy

Use Sigma or OPSpec chart to select QC rules

- Calculate Sigma values to evaluate test performance
- Determine QC rules as test performance and goals of QC plan

<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

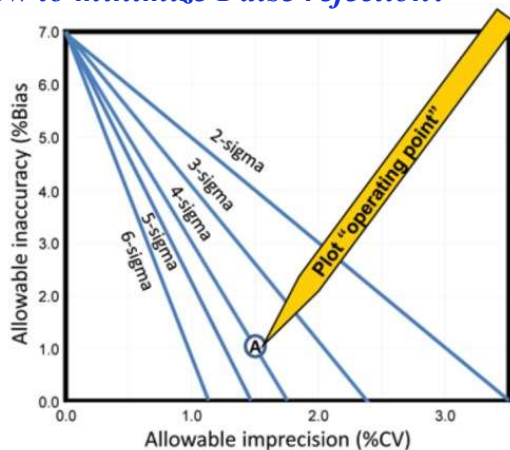
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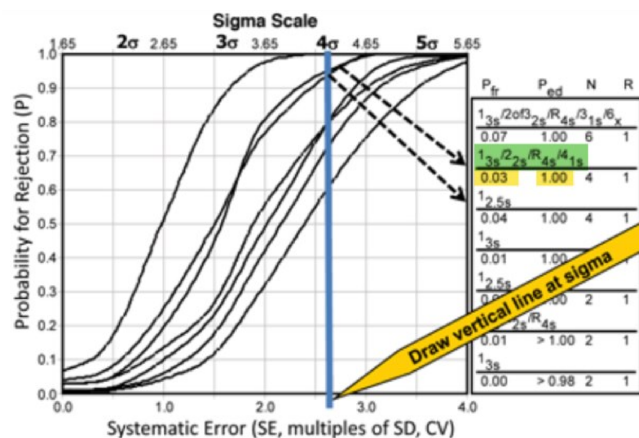
False rejection in IQC and EQAS

How to minimize False rejection?

IQC



Method decision chart



Sigma SQC selection graph

Westgard, J.O., & Westgard, S.A. (2013, September 1). Total Analytic Error: From Concept to Application. Journal of Applied Laboratory Medicine. <https://myadm.org/cdn/articles/2013/september/total-analytic-error>

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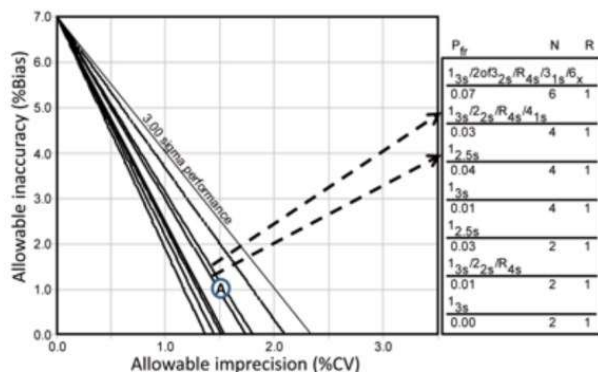
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False rejection in IQC and EQAS

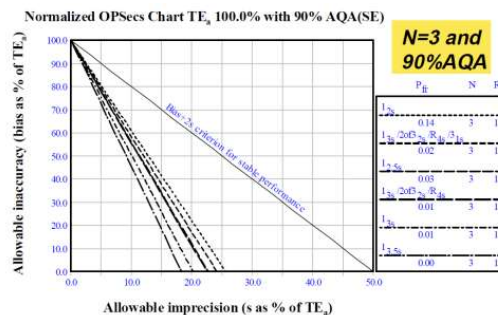
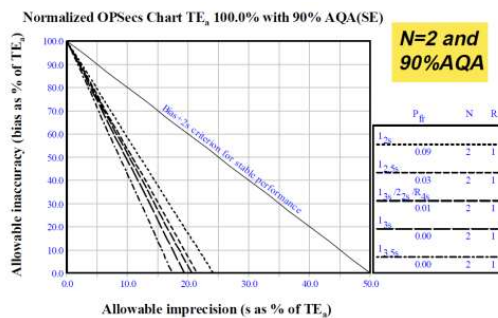
How to minimize False rejection?

IQC

QC strategy



Normalized method decision and OPSpecs charts



Westgard, J.O., & Westgard, S.A. (2013, September 1). Total Analytic Error: From Concept to Application. Journal of Applied Laboratory Medicine. <https://myadm.org/clin/articles/2013/september/total-analytic-error>

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False rejection in IQC and EQAS

How to minimize False rejection?

IQC

Chiến lược QC

Select QC rules and QC frequency (Run size) based on a patient risk model

- Probability of error detection → **Patient risk factor** (MaxE(Nuf)): number of erroneous patient results in the run will be a maximum of 1 if an error condition goes undetected
- **Severe of harm** to the patient is if the failure goes undetected

WESTGARD QC

QC Frequency Calculator

Number of Levels/Tests: 2

Analyst: JOW

Date: 07/29/2021

Analyzer: CLSI C24-E04 Example

Test: Calcium

Units: mg/dL

Critical Decision Level, Xc: 10.20

Quality Requirement, TEa: 0.612

Bias observed: 0.00

Precision observed: 0.143

Calculated Sigma-metric: 4.28

Patient Risk Sigma: 4.28

Patient Risk Factor: 1

Maximum Run Size: 1000

Calculate Results | Clear Form

Candidate SQC Procedures

Procedure	Run Size 1	Run Size 2
$1_{3s}/2_{\sigma}3_{\sigma}/R_{4s}/4_{\sigma}1_{\sigma}$ ($P_E=0.03$)	472	210
1_{3s} , $N=4$ ($P_E=0.01$)	134	66
$1_{3s}/2_{\sigma}3_{\sigma}/R_{4s}/3_{\sigma}1_{\sigma}$ ($P_E=0.02$)	305	144
1_{3s} , $N=3$ ($P_E=0.01$)	82	42
$1_{3s}/2_{\sigma}3_{\sigma}/R_{4s}$, $N=2$ ($P_E=0.01$)	75	39
1_{3s} , $N=2$ ($P_E=0.00$)	54	30
$1_{3.5s}$, $N=2$ ($P_E=0.00$)	13	7
$1_{2.5s}$, $N=1$ ($P_E=0.05$)	101	61
$1_{2.5s}$, $N=1$ ($P_E=0.01$)	36	22
1_{3s} , $N=1$ ($P_E=0.00$)	13	8



<https://westgard.com/resources/resources/qc-frequency-calculator.html>

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False rejection in IQC and EQAS

How to minimize False rejection?

IQC

Select QC rules and QC frequency (Run size) based on a patient risk model

QC strategy



Risk-based QC Parameters: Multi Rule Scheme

Select/Add QC rules: 1-3s/2-2s/4-1s/R-4s
Number of QC observation: 1

TEa (%) or MAU (%): 10.00
Imprecision (%CV): 2.00
Bias (%): 0.10

Expected number of patient samples between planned QCs (E(NB)): 200

Severity of harm category of the measurand: Negligible

☐ Calculate MRS based on custom patient risk factor



Risk based QC Parameters

Parameter	Value
Probability of false rejection (%)	0.55
Sigma-metric value	4.95
Systematic error (%) at MaxE(Nuf)	7.0
MaxE(Nuf)	4.03
Max run size	248



<https://westgard.com/resources/resources/qc-frequency-calculator.html>

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False rejection in IQC and EQAS

How to minimize False rejection?

IQC

Periodically reviewing method performance

QC strategy

- Periodically reviewing method performance (e.g. Sigma values) to adjust QC strategy with maximize error detection and minimize false rejection

<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

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False rejection in IQC and EQAS

How to minimize False rejection?

EQC

Minimize non-testing errors in EQAS

- Select appropriate EQAS programs and ensure correct registration.
- Standardized procedures for all aspects of EQAS handling, from the moment kit arrives to final reporting of results.
- Designate specific staffs to be responsible for coordinating all EQAS activities.
- Implement a two-person check for critical steps, particularly for data entry and result review, to catch transcription errors.
- Create a checklist to ensure all steps are followed, including proper sample handling, storage, and result submission.

<https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>

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False rejection in IQC and EQAS

How to minimize False rejection?

Other

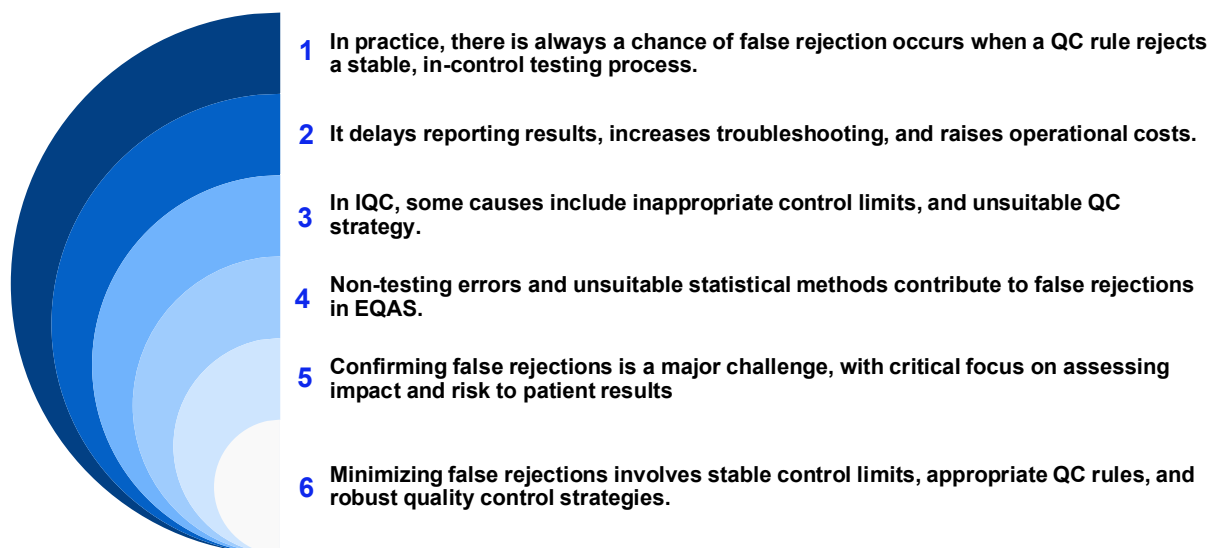
Additional tools for Lab Quality System

- **Inter-laboratory QC:** review peer group QC values for new lots of reagent, calibrator, assay reformulations → supplementing PT/EQA programs, guarantee testing reliability every day and help to investigate a failed or questionable PT/EQA result.
 - **Patient-based Real Time QC:** detect errors in patient results data → eliminates matrix effects, reduce QC frequency
- By combining tools, build a comprehensive and robust quality control strategy that significantly minimizes false rejections

CLSI. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions. 4th ed. CLSI guideline C24. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

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Key messages



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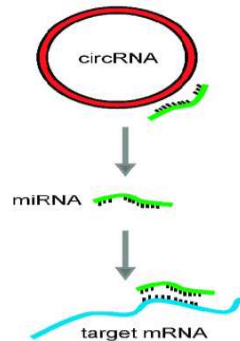
References

- Westgard, S. (2011, November). *Is QC quality compromised?* <https://westgard.com/essays/basic-qc-practices/qc-quality-compromised.html>
- Westgard, S. (2025, March). *When it is time to Wean yourself off Warning Rules?* <https://westgard.com/essays/basic-qc-practices/weaning-off-warning-rules.html>
- CLSI. *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions*. 4th ed. CLSI guideline C24. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.
- Giannoli, J.-M., Vassault, A., Carobene, A., Perret Liaudet, A., Blasutig, I. M., Dabla, P. K., Lin, J., Thomas, A., Tesser Poloni, J. A., Meng, Q. H., & Amann, E. P. (2025). *Ensuring internal quality control practices in medical Laboratories: IFCC recommendations for practical applications based on ISO 15189:2022*. *Clinica Chimica Acta*, 571, 120240. <https://doi.org/10.1016/j.cca.2025.120240>
- Kristensen GB, Meijer P. *Interpretation of EQAS results and EQA-based trouble shooting*. *Biochem Med (Zagreb)*. 2017 Feb 15;27(1):49-62.

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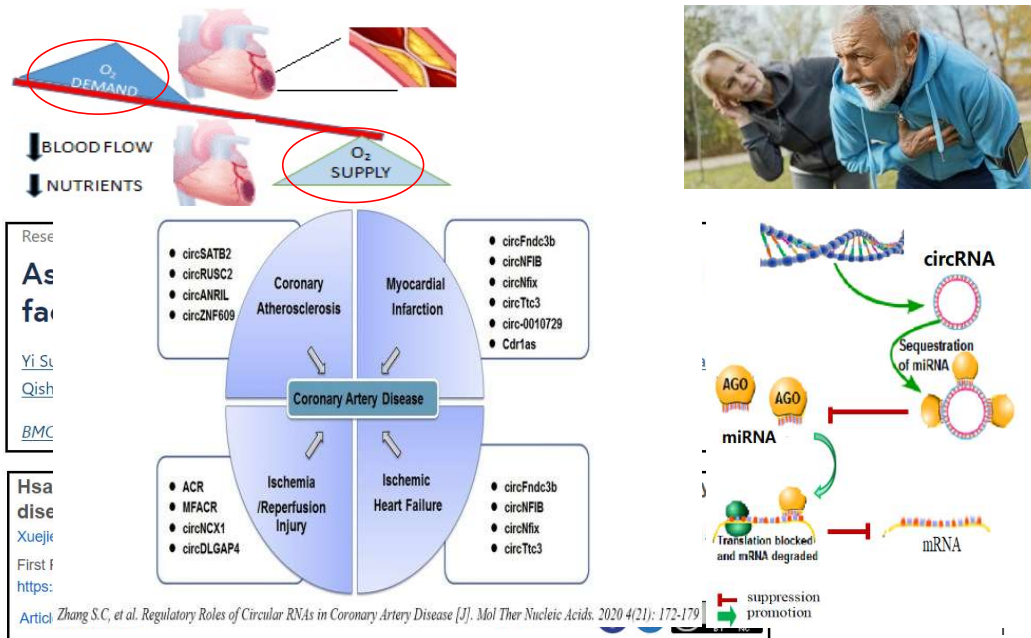


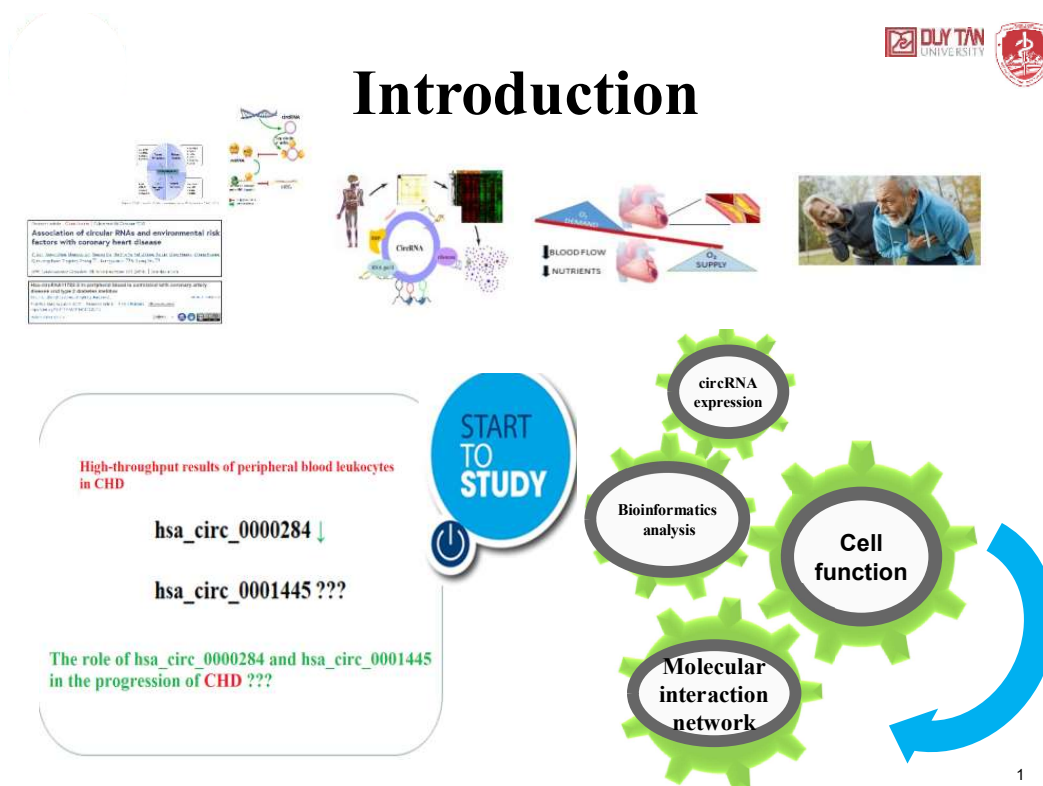
Hsa_circRNA_0000284 acts as a ceRNA to participate in coronary heart disease progression by sponging **miRNA-338-3p** via regulating the expression of **ETS1**



Reporter: Dr. Dinh Phong Son
Co-author: Dr. Tran Chau My Thanh
Duy Tan University

Introduction





Materials and methods

Study population

Selection Criteria

- **CHD group:** The presence of significant stenosis in at least one of the three major coronary arteries or one of their major branches showing $\geq 50\%$ stenosis (with a diameter ≥ 2 mm) on coronary angiography.
- **Control group:** They were confirmed to be in a healthy condition during a routine physical evaluation performed at the same time as the evaluations of CHD patients. The controls did not have a history or signs of coronary atherosclerosis or microvascular diseases.

Exclusion Criteria

- Patients with uncontrolled hypertension, diabetes mellitus, liver or kidney dysfunction, malignancy, endocrine diseases, acute or chronic inflammatory systemic disease, autoimmune diseases, as well as those with a history of percutaneous coronary intervention, prior CHD or coronary artery by pass grafting were excluded from the study.

Methods

1. Samples
2. Total RNA extraction
3. Reverse transcription
4. Quantitative PCR analysis
5. Cell culture
6. CCK-8 analysis
7. Reactive oxygen species analysis
8. Cell cycle analysis
9. Cell aging analysis
10. CRISPR/Cas9
11. CircRNA overexpression and silencing
12. Bioinformatics analysis
13. Fluorescence in situ hybridization
14. MiRNA mimic and inhibitor
15. Luciferase assay
16. Western blotting
17. Statistical analysis



Results

- 1 Hsa_circRNA_0000284 expression and its association with CHD risk factors
- 2 Hsa_circRNA_0000284 expression in cells exposed to inflammatory and oxidative stress
- 3 Effects of hsa_circRNA_0000284 on cell function
- 4 Prediction of hsa_circRNA_0000284/miRNA/mRNA/protein network
- 5 Impacts of hsa_circRNA_0000284 on hub gene expression in vivo and in vitro

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Result 1

Hsa_circRNA_0000284 expression and its association with CHD risk factors

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1-1 CircRNA expression in Peripheral blood leukocytes (PBLs)



Table 1 circRNAs expression in CHD patients and healthy controls

circRNA	Control (n=126)	CHD (n=94)	P
hsa_circ_0000284	0.218 ± 0.079	0.161 ± 0.059	<0.001
hsa_circ_0001445	1.079 ± 0.453	0.640 ± 0.254	<0.001

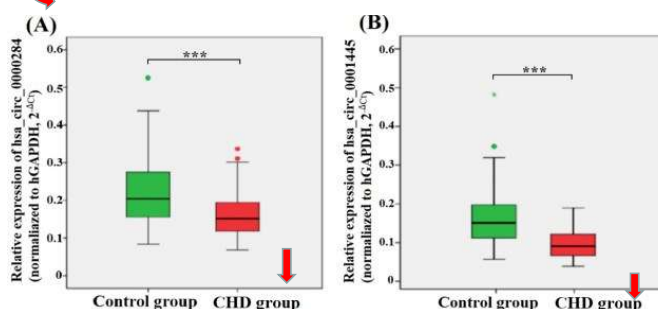


Fig.1 circRNAs expression in CHD patients and healthy controls
(A) hsa_circ_0000284; (B) hsa_circ_0001445; *P < 0.001

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1-2 Correlation between circRNA expression and cardiovascular risk factors



Table 2 Object information

Clinical Characteristics	Control	CHD	p
Age	60.746 ± 8.817	65.957 ± 9.780	<0.001
(Male/Female)	61/65	58/36	0.051

Table 3 The correlation coefficient between hsa_circ_0000284, hsa_circ_0001445 and paraclinical Characteristics

paraclinical Characteristics	hsa_circ_0000284		hsa_circ_0001445	
	r	p	r	p
Age	-0.258	<0.001	-0.290	<0.001
WBC(10 ⁹ /L)	-0.169	0.012		
NEUTR(10 ⁹ /L)	-0.185	0.006	-0.137	0.043
RBC(10 ¹² /L)			0.142	0.036
HGB(g/L)	0.159	0.019	0.181	0.007
T-Cho(mmol/L)	0.283	<0.001	0.249	<0.001
HDL-C (mmol/L)	0.292	<0.001	0.284	<0.001
LDL-C (mmol/L)	0.305	<0.001	0.293	<0.001
ALT(U/L)	0.064	0.400	-0.021	0.781
GGT(U/L)	-0.105	0.132	-0.102	0.143
GLU(mmol/L)	0.037	0.588	0.063	0.356
T-Cho(mmol/L)	0.283	<0.001	0.249	<0.001
HDL-C (mmol/L)	0.292	<0.001	0.284	<0.001
LDL-C (mmol/L)	0.305	<0.001	0.293	<0.001

Table 4 Logistic regression analysis with

circRNA ID	Model 1	
	OR (95% IC)	P
hsa_circ_0000284	0.341 (0.194 - 0.599)	<0
hsa_circ_0001445	0.175 (0.096 - 0.319)	<0

1-3 CircRNA as a potential molecular marker for CHD

Fig.2 hsa_circ_0000284

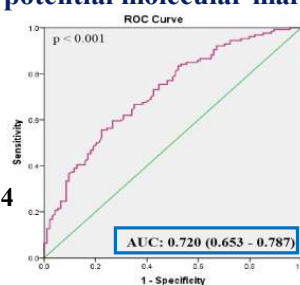
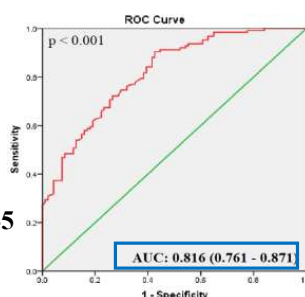


Fig.3 hsa_circ_0001445



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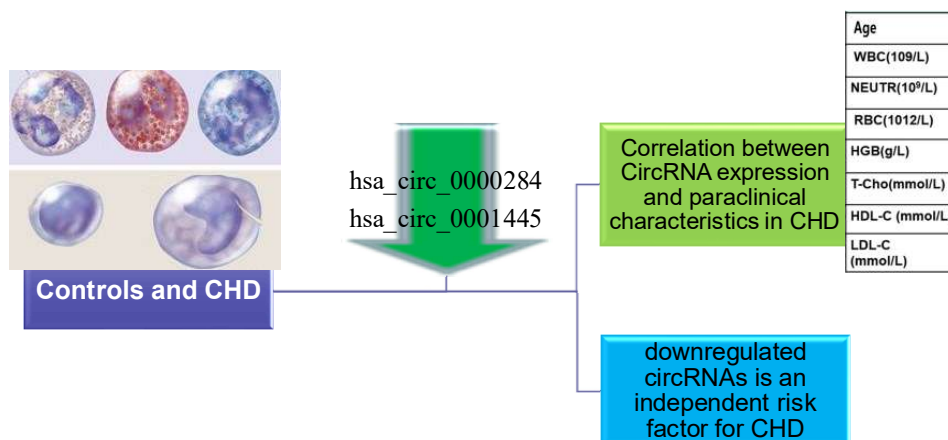


Fig.4 Chapter 1 conclusion

Discussion 1

Expression of hsa_circ_0000284 and hsa_circ_0001445 are associated with CHD.

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Result 2

Hsa_circRNA_0000284 expression in cells exposed to inflammatory and oxidative stress

2-1 CCK-8 analysis

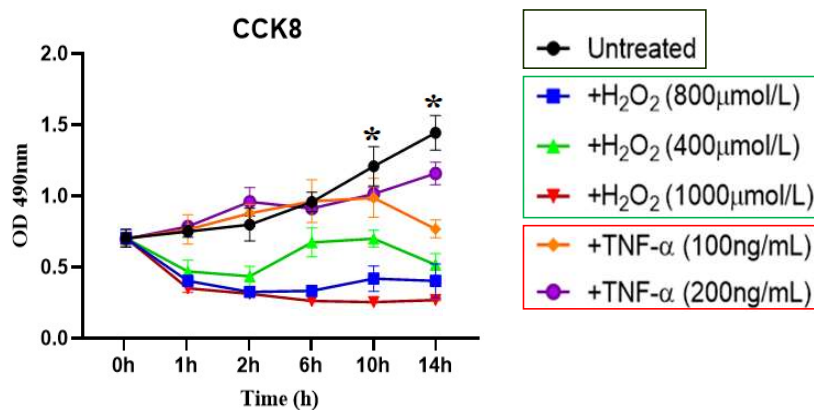


Fig.5 Effect H₂O₂, TNF-α on the proliferation ability of EA-hy926 cells

2-2 Reactive oxygen species (ROS) analysis

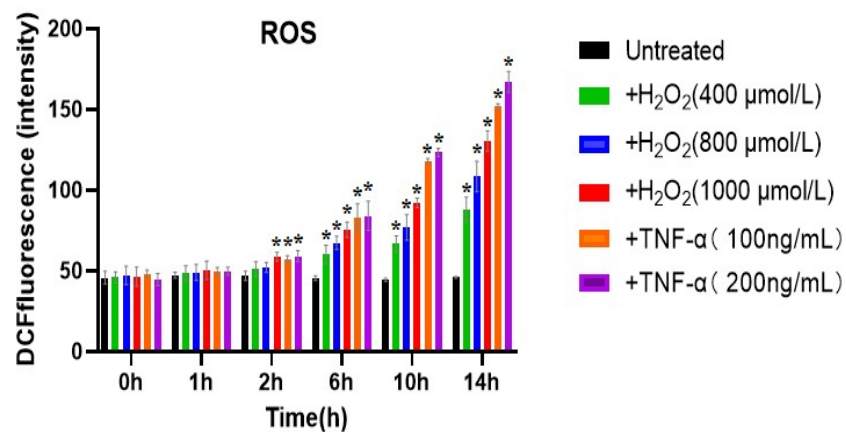


Fig.6 Effect of H₂O₂ and TNF-α on the level of reactive oxygen species in EA-hy926 cells (P< 0.05)

2-3 EA-hy926 Cell Morphology

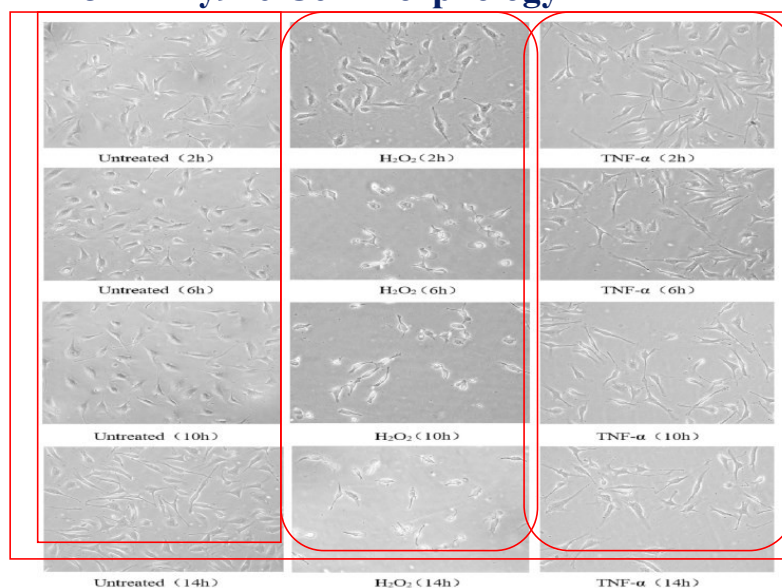


Fig.7 The effect of H₂O₂ and TNF-α on the morphology of EA-hy926 cells (200x)

2-4 Effects of H₂O₂, TNF- α on cell cycle progression

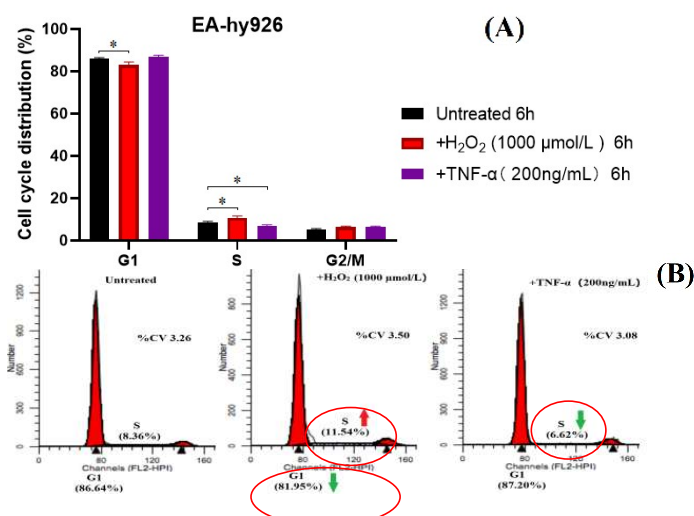


Fig.8 Cell cycle changes induced by H₂O₂ and TNF- α
 (A) Statistics in cell cycle analysis (*P < 0.05), (B) Flow cytometry results

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2-5 Effects of H₂O₂, TNF- α on cell aging

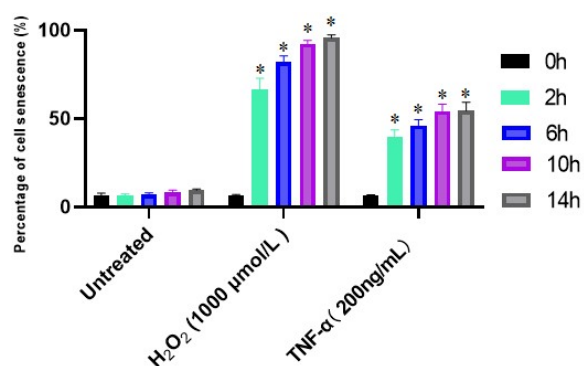


Fig.9 Senescent rate of cells under oxidative and inflammatory injury (*P < 0.05)

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2-6 hsa_circ_0000284 expression over time in EA-hy926 cells treated with H₂O₂ and TNF- α

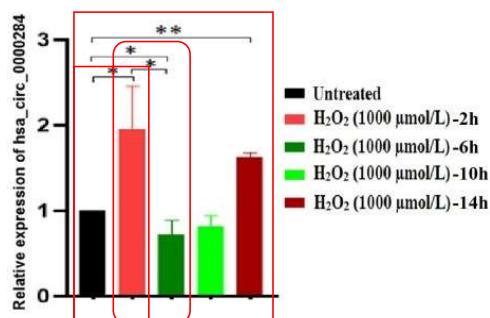


Fig.10 Effect of H₂O₂ on expression of hsa_circ_0000284 (*P < 0.05)

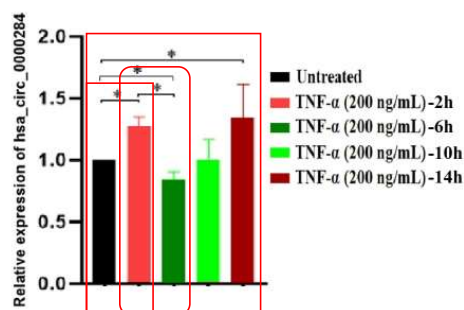
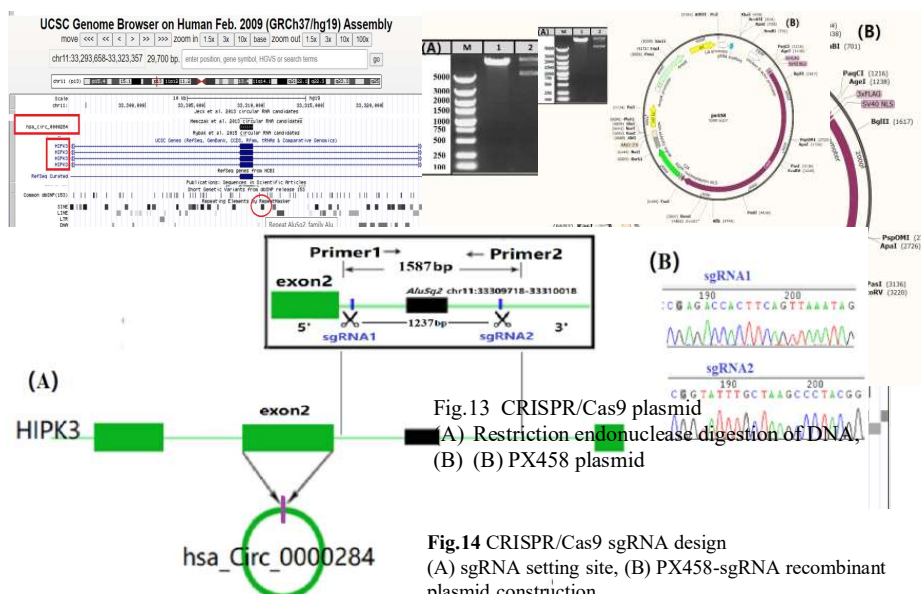


Fig.11 Effect of TNF- α on expression of hsa_circ_0000284 (*P < 0.05)

2-7 CRISPR/Cas9 knockout Alu element



2-7 CRISPR/Cas9 knockout Alu element

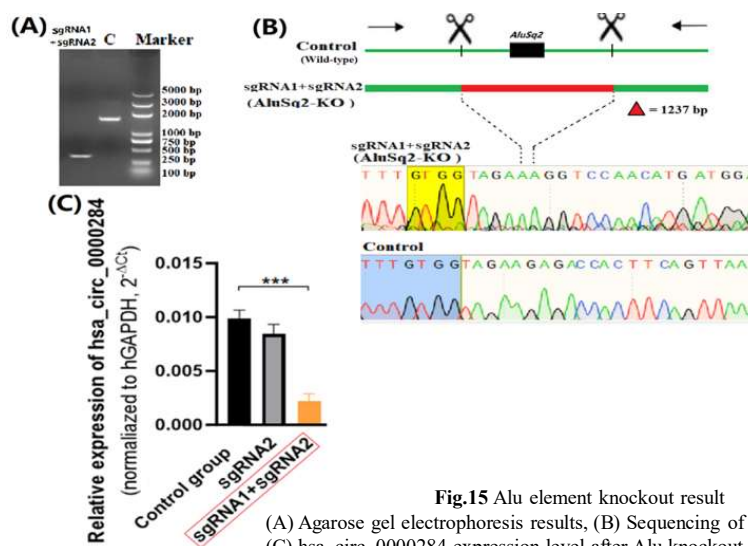


Fig.15 Alu element knockout result

(A) Agarose gel electrophoresis results, (B) Sequencing of PCR Products, (C) hsa_circ_0000284 expression level after Alu knockout (***P < 0.001)

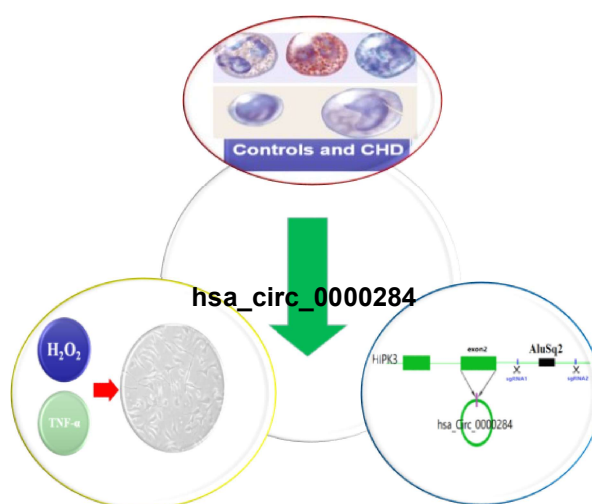


Fig.16 Chapter 3 conclusion

Discussion 2

hsa_circ_0000284 may participate in the oxidative stress and inflammatory injury associated with endothelial cell dysfunction in the development of CHD.

Result 3

Effects of hsa_circRNA_0000284 on cell function



3-1 CCK-8

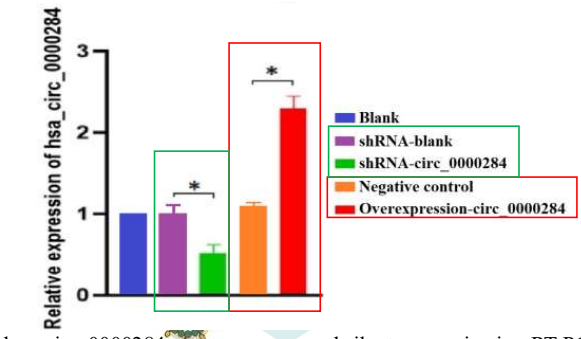


Fig.18 hsa_circ_0000284 overexpression and silent expression in qRT-PCR detection results (*P < 0.05)

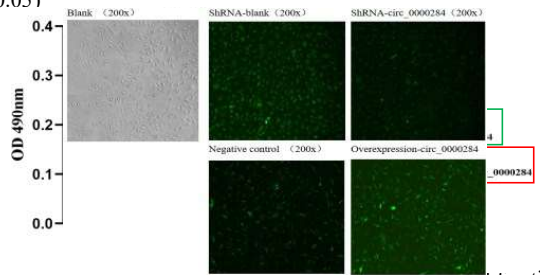


Fig.19 Effect of overexpression and silence of hsa_circ_0000284 on the proliferation ability of EA-hy926 cells (*P < 0.05) Fig.17 Fluorescence of EA-hy926 cells after transfection

3-2 Flow cytometry analysis

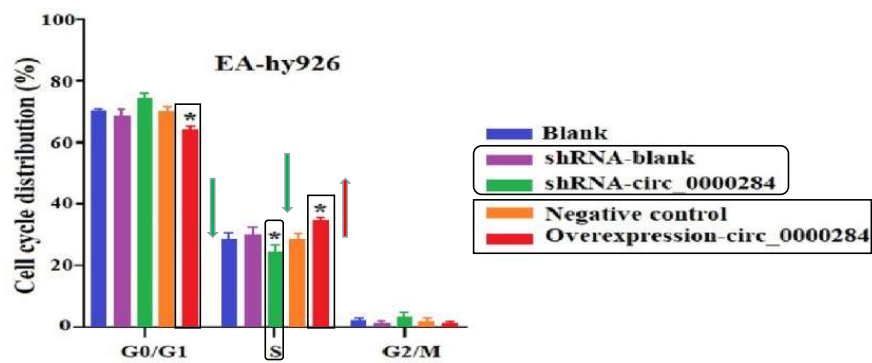
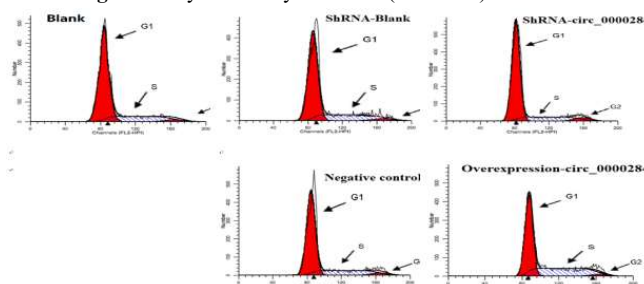


Fig.20 EA-hy926 cell cycle results (*P < 0.05)



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3-3 Effects of overexpression and silencing of hsa_circ_0000284 on apoptosis

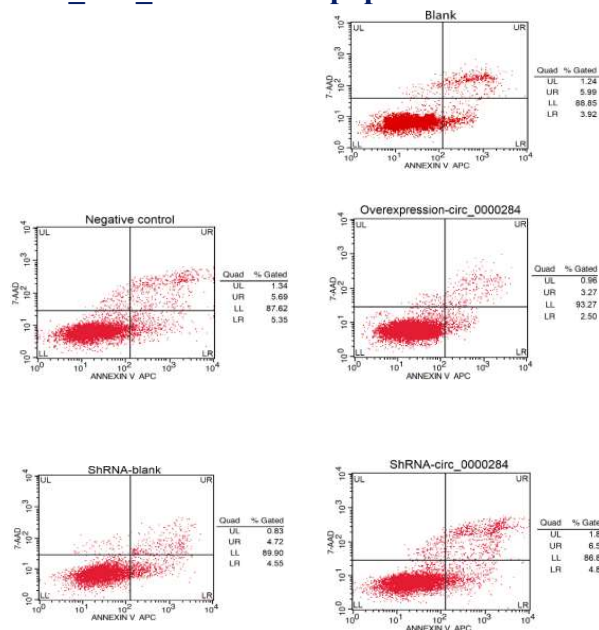


Fig.21 The effect of overexpression of hsa_circ_0000284 on apoptosis in EA-hy926 (*P < 0.05)

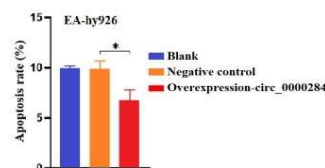
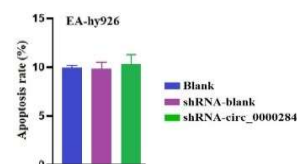
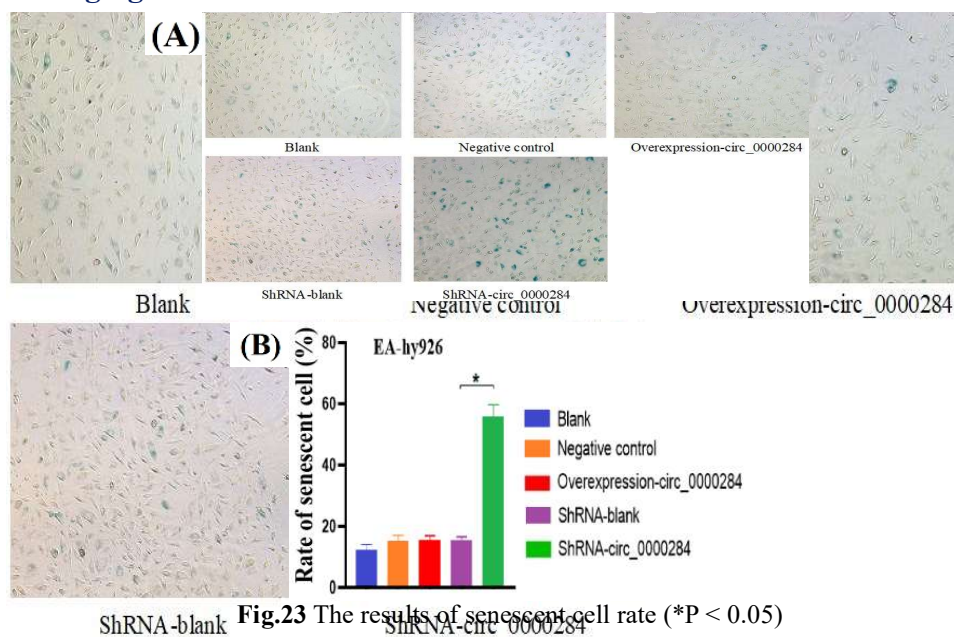


Fig.22 The effect of silent of hsa_circ_0000284 on apoptosis in EA-hy926



3-4 Effects of overexpression and silencing of hsa_circ_0000284 on aging



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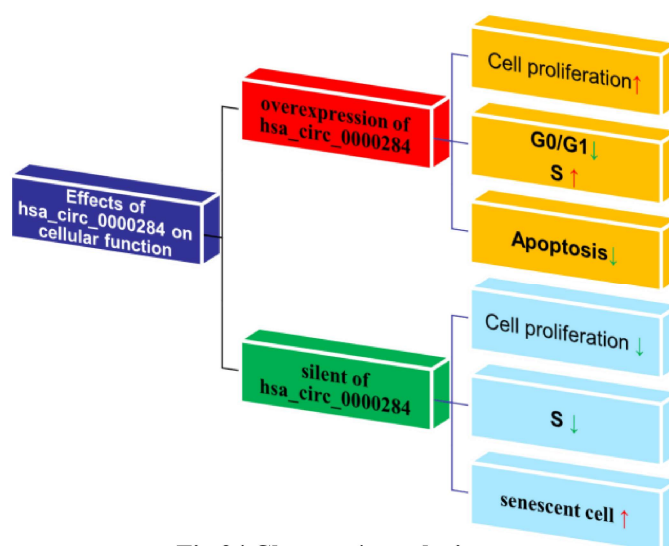


Fig.24 Chapter 4 conclusion

Discussion 3

Downregulated expression of hsa_circ_0000284 may lead to injury and apoptosis of vascular endothelial cells, thus promoting the occurrence and development of CHD.

Result 4

Prediction of
hsa_circRNA_0000284/miRNA/mRNA/protein
network

4-1 Predicted hsa_circ_0000284-miRNA interaction network

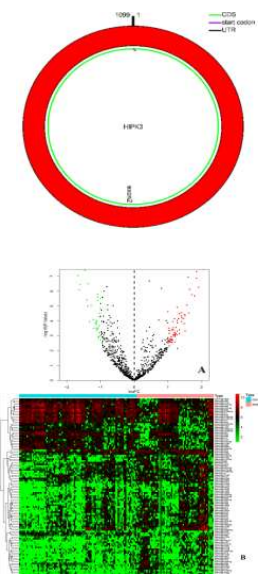


Table 5 Prediction target miRNA of hsa_circ_0000284

Database	Results
circBank	97 miRNA
Circinteractome	42 miRNA

hsa-miR-382-5p
hsa-miR-508-3p
hsa-miR-1283
hsa-miR-338-3p
hsa-miR-653-5p
hsa-miR-1178-3p
hsa-miR-1250-5p
hsa-miR-558
hsa-miR-637
hsa-miR-1290
hsa-miR-1825
hsa-miR-330-5p
hsa-miR-375-3p
hsa-miR-199b-5p
hsa-miR-302d-5p

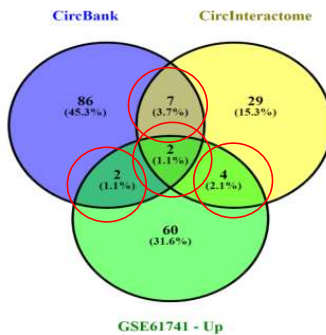


Fig.26 The intersection of database/dataset for hsa_circ_0000284

Fig.25 Expression of miRNAs in GSE61741

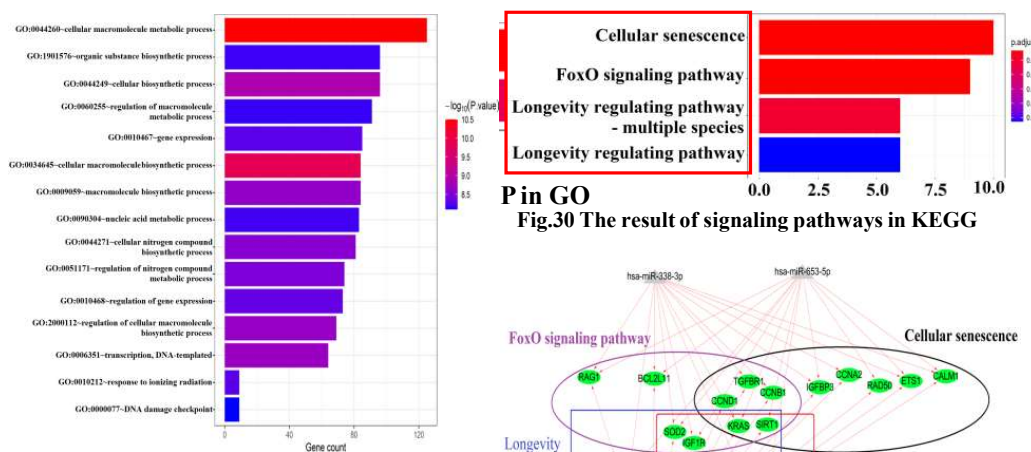
A Venn diagram illustrating the overlap of differentially expressed genes across three datasets: MirWalk2 (blue circle), Mirtarbase (yellow circle), and GSE56885-DOWN (green circle). The diagram shows the number of genes in each region and the percentage of the total (198) they represent.

Region	Count	Percentage
MirWalk2 only	573	19.8%
Mirtarbase only	1435	49.5%
GSE56885-DOWN only	670	23.1%
MirWalk2 & Mirtarbase	123	4.2%
MirWalk2 & GSE56885-DOWN	22	0.9%
Mirtarbase & GSE56885-DOWN	70	2.4%
All three datasets	4	0.1%

Figure 2 is a network diagram illustrating the interaction between hsa-miR-2002-2-5p and various target genes. The central node is hsa-miR-2002-2-5p, represented by an orange diamond. It is connected to numerous target genes, represented by circles of varying sizes and colors (pink, green, blue, yellow). The connections are labeled with gene names and miRNA names. The network is complex, with many nodes and edges, indicating a large number of potential targets for hsa-miR-2002-2-5p.

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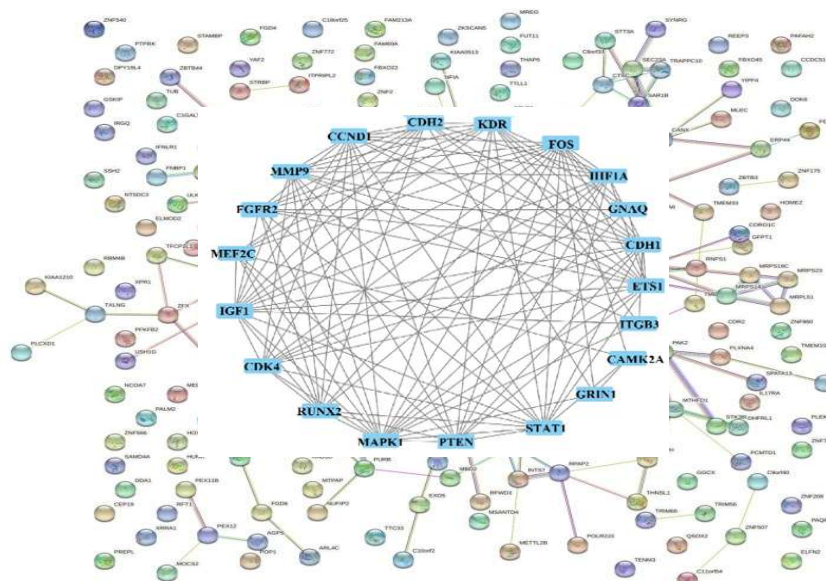


Pin GO

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4-4 Protein-protein interaction network

Fig.32 Protein-protein interactions of 219 potential genes



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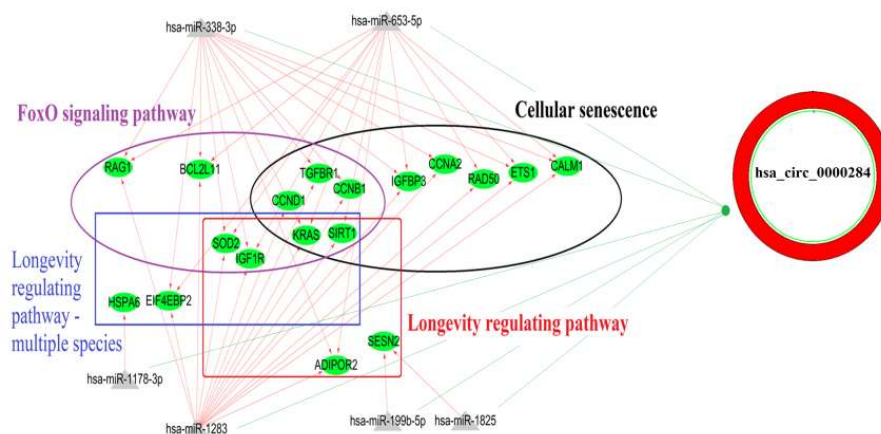


Fig.34 Chapter 2 conclusion

Discussion 4

hsa_circ_0000284 is involved in genes in the FoxO molecular signaling pathway, cellular senescence, and lifespan regulation.

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Result 5

Impacts of hsa_circRNA_0000284 on hub gene expression in vivo and in vitro

5-1 Expression of hsa-miR-338-3p in PBLs

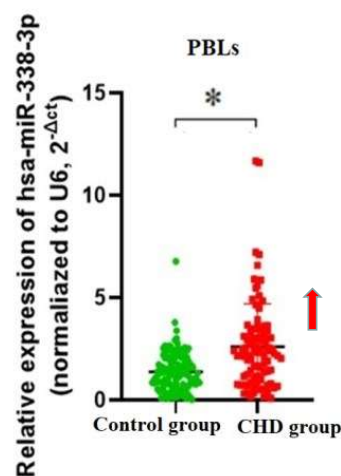


Fig.35 hsa-miR-338-3p expression from CHD patients and healthy controls

5-2 Correlation analysis between hsa_circ_0000284 and hsa-miR-338-3p expression

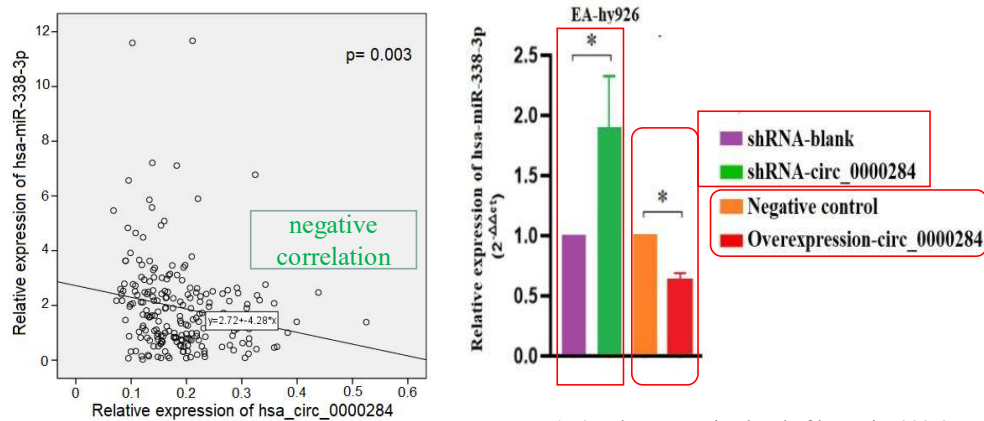


Fig.36 Correlation analysis between hsa_circ_0000284 and hsa-miR-338-3p expression in PBLs

Fig.37 The expression level of hsa-miR-338-3p (*P < 0.05)

5-3 Predicted binding sites of hsa_circ_0000284 and hsa-miR-338-3p

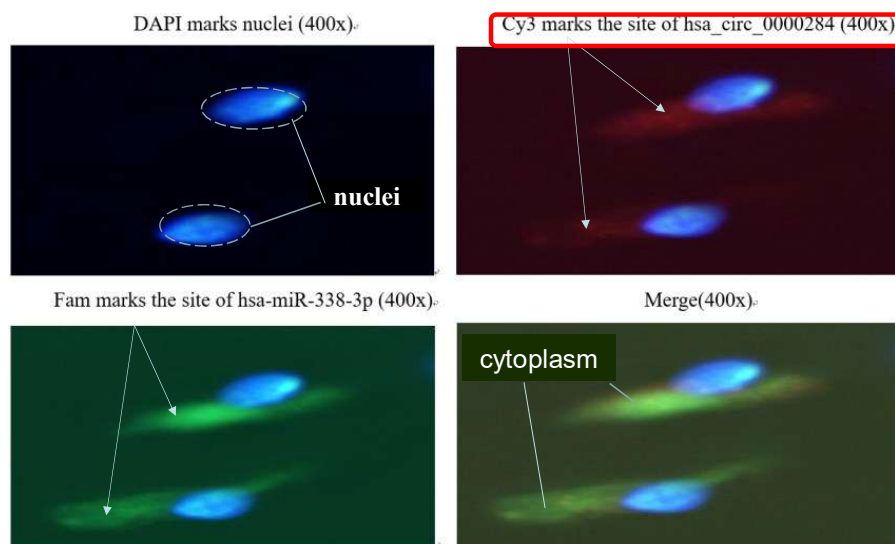


Fig.38 The results of hsa_circ_0000284 and hsa-miR-338-3p with the FISH test

5-4 hsa_circ_0000284 and hsa-miR-338-3p in luciferase assay

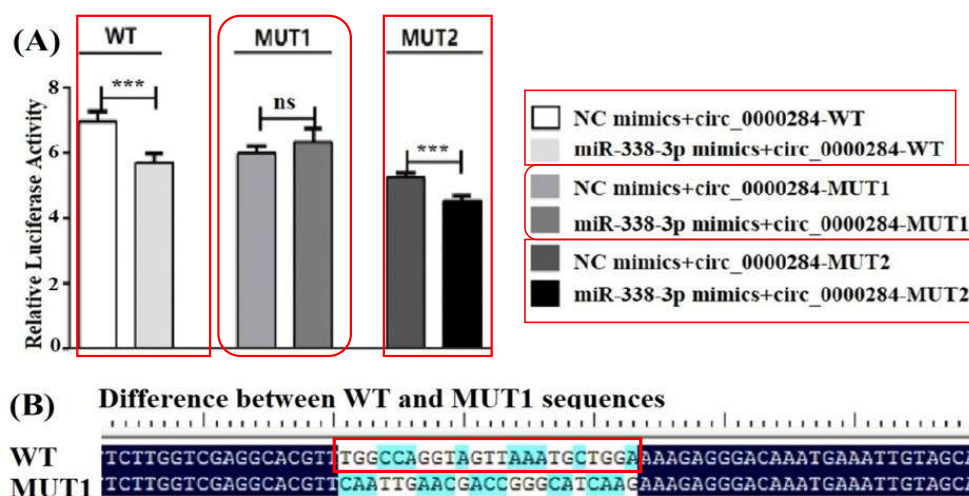


Fig.39 Dual luciferase reporter assay

(A) The targeted binding of hsa-miR-338-3p to MRE1 and MRE2 (** $P < 0.001$),

(B) Difference between WT and MUT1

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5-6 ETS1 expression in PBLs and correlation analysis with hsa-miR-338-3p

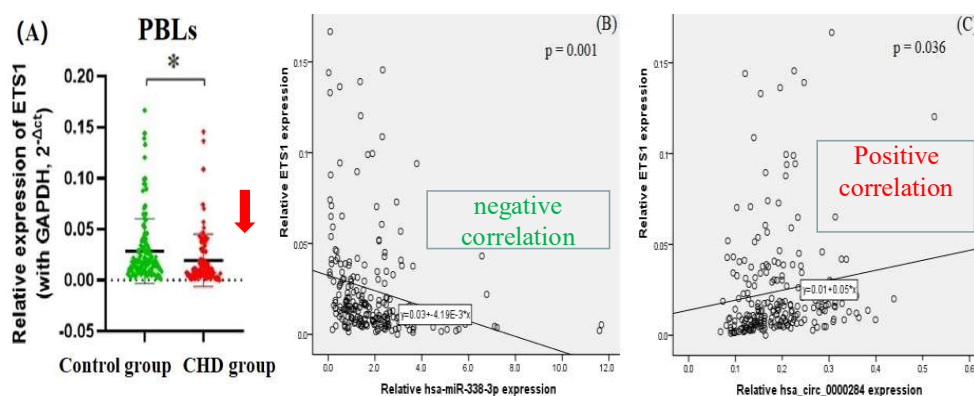


Fig.40 The expression level of ETS1

(A) The expression level of ETS1 in PBLs ($n = 220$) (* $P < 0.05$),

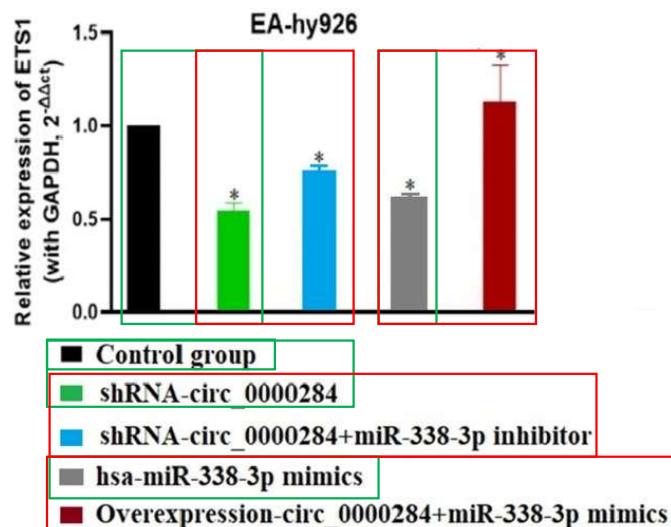
(B) The expression levels of ETS1 and hsa-miR-338-3p,

(C) The expression levels of ETS1 and hsa_circ_0000284

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Fig.41 The expression of ETS1 (*P < 0.05)



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	predicted pairing of target region (top) and miRNA (bottom)		seed match
Position 3469-3494 of ETS1 3' UTR	5'	...GUUUUUUUUAGUAGCUGAUCUGGC...	7mer-m8
hsa-miR-338		: :	
	3'	AGUUGUUUUUAGUAGUACGACCU	
Position 3485-3511 of ETS1 3' UTR	5'	...UGCUGGCA-CAUCAUU-UUGCUGAG...	7mer-1A
hsa-miR-338		: :	
	3'	AGUUGUUUUUAGUAGUACGACCU	

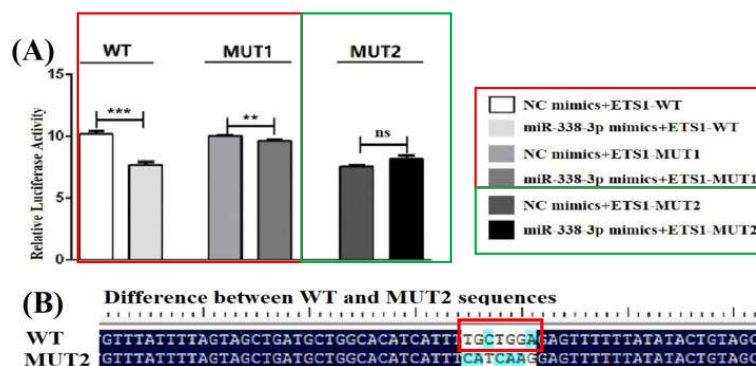


Fig.42 Dual luciferase reporter assay (A)The targeted binding relationship between hsa-miR-338-3p and ETS1 (***P < 0.001) . (B)Difference between WT and MUT2

5-9 ETS1 protein in WB assay

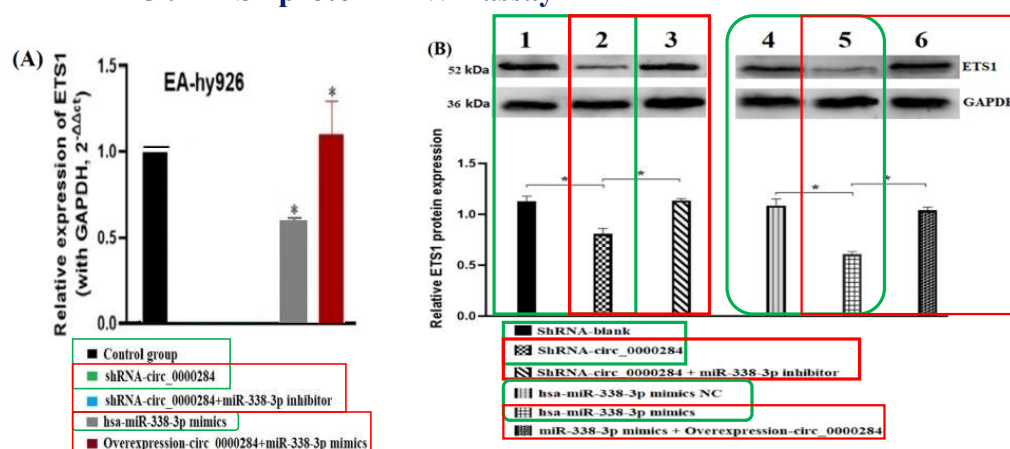


Fig.43 Relationship between gene and protein (A) ETS1 gene expression; (B) ETS1 protein expression

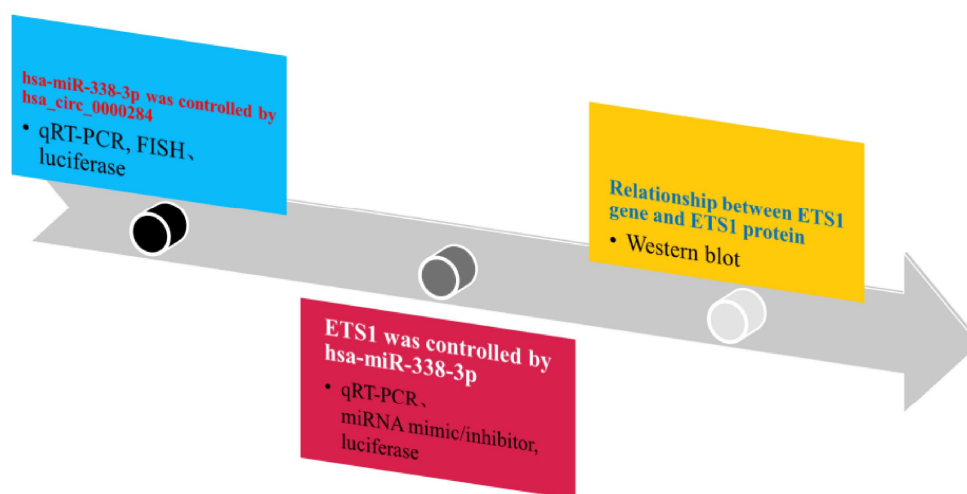


Fig.44 Chapter 5 conclusion

Discussion 5

hsa_circ_0000284 acts as a sponge of miR-338-3p to regulate ETS1 expression.

Multidrug-resistant *Edwardsiella tarda* and *Proteus vulgaris* Wound Coinfection: A Case Report

MÀO THẠCH SƠN , M.D.
TRIỀU AN HOSPITAL

INTRODUCTION

CASE REPORT

DISCUSSION

TAKE-HOME MESSAGE

INTRODUCTION

- Multidrug resistant (MDR) bacteria are a major public health concern
- More than 2.8 million case MDR in US, accounting for 35,000 deaths
- In VietNam.....

1. van Duin D, Paterson DL. Multidrug Resistant Bacteria in the Community: An Update. *Infect Dis Clin North Am.* 2020;34(4):709-722. doi:10.1016/j.idc.2020.08.002

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INTRODUCTION

- *Edwardsiella tarda* is a nonfermenting gram-negative bacillus belonging to the Enterobacteriaceae family
- It causes infections particularly in fish and reptiles.
- Rarely associated with infections in humans, 0.0073% in the Japanese population to 1% in Panamanians
- Few human cases reported worldwide

2. Onogawa T, Terayama T, Zenyoji H, Amano Y, Suzuki K. Distribution of *Edwardsiella tarda* and hydrogen sulfide-producing *Escherichia coli* in healthy persons. 3. *Kansenshogaku Zasshi* 1976;50:10-17

3. Kourany M, Vasquez MA, Saenz R. *Edwardsiellosis in human and animals in Panamá: clinical and epidemiological characteristics.* *Am J Trop Med Hyg* 1977;26:1183-1190

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INTRODUCTION

- *Proteus vulgaris* is an opportunistic Gram-negative pathogen.
- Commonly found in wounds, urine, hospital environments.
- Produces urease, hemolysin, fimbriae.
- Increasing multidrug resistance among clinical isolates reported.
- Early identification crucial for infection control and treatment.

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INTRODUCTION

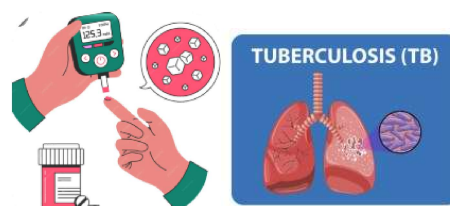
- Managing MDR wound infections requires multidisciplinary **collaboration**.
- **Clinicians**
- **Microbiologists**
- **Pharmacists**
- Team discussion ensures timely adjustment of treatment plans.
- Collaboration improves outcomes and limits antibiotic resistance spread.



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CASE REPORT

- 56-year-old male, fish vendor
- He has diabetes on insulin and oral drugs. Recovered from tuberculosis
- Foot injury from the fin of a bocourti fish, skin abrasion 5x6 cm
- After 2 days mild fever; wound: swollen, painful, pus discharging.



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CASE REPORT

- Laboratory tests elevated WBC count (16,450/mm³); N (12,220/mm³, 74.3%)
- HbA1c was 8.56%
- Purulent collected a sample for bacterial culture



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CASE REPORT

- IV vancomycin 1 g and cefoxitin 2 g every 12 hours
- Surgical debridement
- Glycemic control by endocrinologist
- Daily dressing



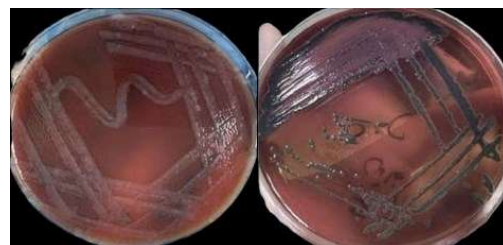
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CASE REPORT

- Culture results, which were based on colony morphology assessment indicated coinfection with *E. tarda* and *P. vulgaris*.



E. tarda



P. vulgaris.

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CASE REPORT

- Antibiogramme results of two strains of *E. tarda* and *P. vulgaris*
- IV 1g ceftazidime every 8 h
- IM 80 mg gentamicin every 12 h

Antibiotic	<i>Edwardsiella tarda</i>	<i>Proteus vulgaris</i>
Ampicilin	R	R
Ceftazidime	S	S
Colistin	R	R
Meropenem	S	S
Trimethoprim-Sulamethozazole	R	R
Ampicillin-Sulbactam	I	S
Ceftazidime-Avibactam	S	S
Ertapenem	S	S
Minocycline	S	R
Cefazolin	R	R
Ceftriaxone	R	R
Gentamicin	S	S
Piperacillin-Tazobactam	S	S
Amikacin	R	-
Cefepime	R	S
Ciprofloxacin	R	R
Imipenem	S	R
Tigecycline	I	R

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CASE REPORT

- VAC system was applied, 2 time
- Wound showed granulation tissue formation



After the first VAC placement



After the second VAC placement

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CASE REPORT

- 2nd surgery, split thickness skin grafting
- Complete healing after 2 weeks.



After 1 w



After 2 w

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CASE REPORT

CASE REPORT

J Mycol Infect 2025; 30(2): 66–70
pISSN:3058–423X, eISSN:3058–4302
<https://dx.doi.org/10.17966/JMI.2025.30.2.66>

JMI

Multidrug-resistant *Edwardsiella tarda* and *Proteus vulgaris* Wound Coinfection: a Case Report of a Fish Vendor

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¹Trieu An Hospital, Ho Chi Minh City, Vietnam

²University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam



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DISCUSSION

Treatment and Clinical

- Combined debridement, VAC, and antibiotics therapy.
- VAC reduced edema, improved perfusion flow, stimulate granulation tissue.
- Ceftazidime, gentamicin guided by antibiogram results.
- Gentamicin stopped after infection control .



Illustrative image

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DISCUSSION

- Gastroenteritis is the most commonly described manifestation of *E. tarda* infection
- Extraintestinal diseases such as **bacteremia, meningitis, cholecystitis, cholangitis, and peritonitis** have been reported
- About 23% involve skin and soft tissue after aquatic injuries
- Overall mortality is **44.6%**

Pham K, Wu Y, Turett G, et al. *Edwardsiella tarda*, a rare human pathogen isolated from a perihepatic abscess: Implications of transient versus long term colonization of the gastrointestinal tract. *IDCases*. 2021;26:e01283. doi:10.1016/j.idcr.2021.e01283
Hirai Y, Asahata-Tago S, Ainoda Y, Fujita T, Kikuchi K. *Edwardsiella tarda* Bacteremia. A Rare but Fatal Water- and Foodborne Infection: Review of the Literature and Clinical Cases from a Single Centre. *Can J Infect Dis Med Microbiol*. 2015;26(6):702615. doi:10.1155/2015/702615

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DISCUSSION

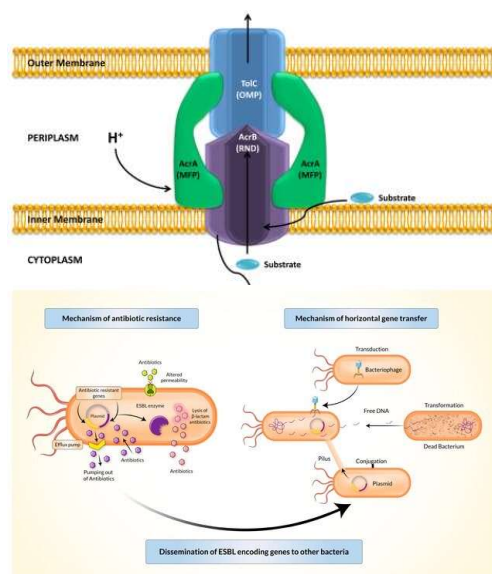
Transmission Pathways and Risk Factors

- Infection follows trauma exposed to freshwater or fish
- Entry occurs through open wounds or mucosal surfaces
- Risk factors include diabetes, liver disease, and malignancy
- **Diabetes** impairs immune defense and delays wound healing

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DISCUSSION

- *E. tarda* infections show rising multidrug resistance globally
- Resistance linked to β -lactamase and efflux pump genes.
- Horizontal gene transfer enhances resistance among Enterobacteriaceae.
- Antibiotic misuse in aquaculture drives genetic selection.



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DISCUSSION

- *Proteus vulgaris* found in 7% of wound isolates. *
- It appears in bloodstream infections with notable incidence.
- This pathogen exhibits increasing multidrug-resistance trends
- Infections often occur in immunocompromised or hospitalised patients.

Incidence of Proteus species in wound infections and their sensitivity pattern in the University of Benin Teaching Hospital | Request PDF. ResearchGate. October 12, 2013. Accessed October 28, 2025.

Ayoub M, Nazir A. Prevalence and Antimicrobial Susceptibility of Proteus Species Isolated from wound infections in a Tertiary Care Hospital in Kashmir Valley. J Med Life Sci. 2025;7(4):636-641. doi:10.21608/jmals.2025.405331.1061

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DISCUSSION

Biotechnology

- Nanotechnology improves antibiotic delivery and wound healing.
- Synthetic biology designs novel antimicrobial peptides and enzymes
- Personalized medicine tailors antibiotic therapy to genetic profiles.
- Combining diagnostics and biotechnology optimizes clinical outcomes.

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TAKE-HOME MESSAGE



Multidrug-resistant (MDR) bacteria have become a major global problem. Managing MDR wound infections requires multidisciplinary **collaboration**



Coinfection with *E. tarda* and *P. vulgaris* can lead to severe wound infection; early debridement and appropriate antibiotics are key to recovery



Combining debridement, antibiotics, VAC, and biotechnology may offer an effective wound infection treatment approach

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REFERENCE

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DIRECT ANTIBIOTIC SUSCEPTIBILITY TESTING FROM POSITIVE BLOOD CULTURE BOTTLES: EVIDENCE AND CLINICAL PROSPECTS

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OUTLINE

- 1, Introduction:** The crisis of waiting time in the treatment of bloodstream infections
- 2, Research Methodology:** Evaluation design of dAST at Thong Nhat General Hospital
- 3, Research Findings:** Analysis of three key pillars: Speed, Accuracy, and Cost
- 4, Discussion & Conclusion:** Clinical implications and recommendations

1. Introduction

The Time Crisis in Sepsis Treatment

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Challenge: Sepsis



Definition: Acute, severe infection due to bacteria circulating in the blood, causing a systemic inflammatory response.



Mortality Rate: Very high, ranging from 20% to 50%, particularly severe in septic shock cases.



Dual Problem: The high mortality rate and the rapid increase of multi-drug resistant bacteria (MRSA, CRE, ESBL).

CDC, 2018

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Race Against Time



"Golden Hour" in Sepsis: Early and APPROPRIATE antibiotic treatment is the key factor determining the patient's survival.



Kumar (2006) Study: Each hour of delay in administering effective antibiotics increases the risk of death by 7.6% in patients with septic shock.

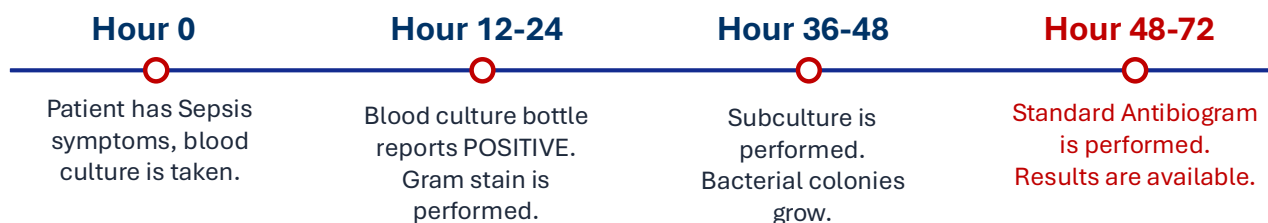


Problem: Physicians are forced to use broad-spectrum antibiotics "based on experience" because they cannot wait for the Antibigram results.

Kumar A, et al, Crit Care Med, 2006, PMID: 16625125

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The Bottleneck: Traditional Antibigram Process



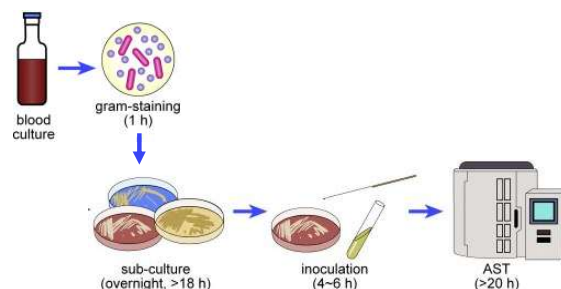
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Standard Procedure (Time-consuming)

Steps of the Standard Procedure

The standard (reference) procedure requires **02 overnight incubation steps**:

- ✓ **Subculture:** Subculture from the positive blood culture bottle onto agar plates (BA, MC), (Takes **18-24 hours**)
- ✓ **AST (Antimicrobial Susceptibility Testing):** From the grown colonies, prepare a 0.5 McFarland suspension, perform AST (disk diffusion or automated system), (Takes **16-24 hours**)



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2. Method

Solution: Direct Antimicrobial Susceptibility Testing (dAST)

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Solution: Direct Antimicrobial Susceptibility Testing (dAST)



Concept

Perform **direct AST** from the positive blood culture broth, **SKIPPING** the 18-24 hour subculture step.



Rationale

CLSI (USA) and **EUCAST (Europe)** have both provided **official guidance** for dAST methods using disk diffusion.



Goal

Evaluate the **effectiveness (speed, accuracy, cost)** of the 02 dAST methods at Thong Nhat General Hospital.

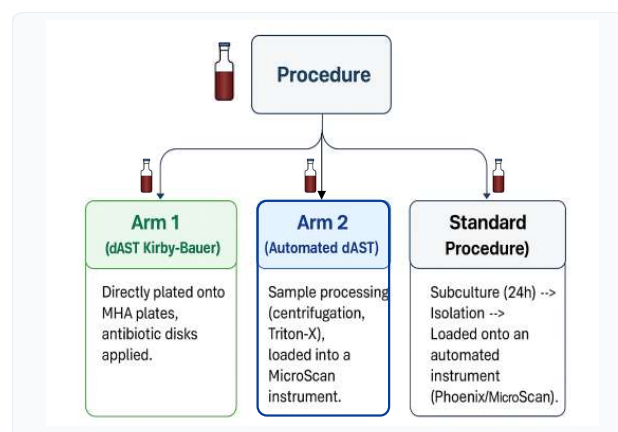
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Overall Study Flowchart

Procedure

From **1 positive blood culture bottle**, the sample is simultaneously divided into **3 arms**:

- ✓ **Arm 1 (dAST Kirby-Bauer):** Directly plated onto MHA plates, antibiotic disks applied.
- ✓ **Arm 2 (Automated dAST):** Sample processing (centrifugation, Triton-X), loaded into a MicroScan instrument.
- ✓ **Arm 3 (Standard Procedure):** Subculture (24h) --> Isolation --> Loaded onto an automated instrument (Phoenix/MicroScan).



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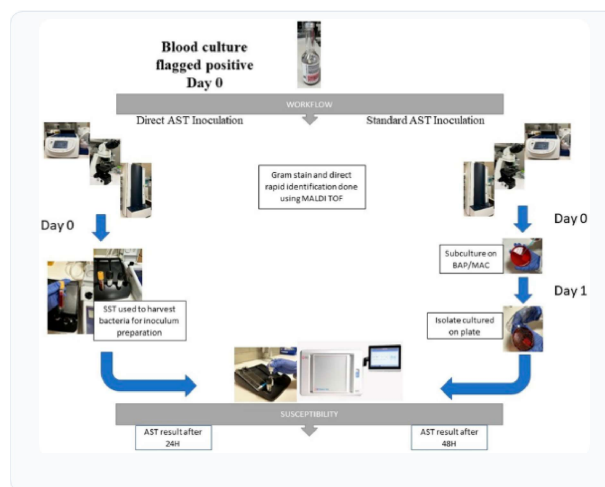
Arm 1 (02 researches)

Method 1: dAST (Kirby-Bauer)

Based on CLSI & EUCAST

The technique is standardized based on **international** guidelines

- ✓ **Gram Negative (CLSI):** Drop 4 drops of positive blood broth onto the MHA plate, spread evenly, apply antibiotic disks.
- ✓ **Gram Positive (EUCAST):** Drop 125µl of positive blood broth onto the MHA plate, spread evenly, apply antibiotic disks.
- ✓ **Reading Results:** After 8-10 hours and 16-18 hours.



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Arm 2 (01 research)

Method 2: dAST (Automation)

Sample Processing

To be loaded into the automated instrument, the blood broth must be processed to **remove red blood cells and protein.**

- ✓ Aspirate 9.5ml blood + 0.2ml Triton X-100 (to lyse RBCs)
- ✓ Centrifuge at 1,400g for 10 minutes
- ✓ Collect the bacterial layer from the surface, prepare a 0.5 McFarland suspension
- ✓ Load into the **MicroScan** panel



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Arm 2 (01 research)

Method 2: dAST (Automation)

MicroScan WalkAway

The MicroScan system uses 96-well panels (trays) containing **diluted and dehydrated antibiotics**.

- ✓ Panel **Neg** type 63: For **Gram-negative bacilli**
- ✓ Panel **Pos** type 33: For **Gram-positive cocci**
- ✓ The automated instrument incubates and reads MIC results



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(Target: 90\%\$)

Evaluation Criteria (According to CLSI)

- 
Category Agreement (CA): Agreement (S/I/R) between dAST and Standard Procedure
(Target: $\geq 90\%$)
- 
Major Error (ME): dAST = R, Standard Procedure = S (False resistance report)
(Target: $\leq 3\%$)
- 
Very Major Error (VME): dAST = S, Standard Procedure = R, (False susceptibility report - most dangerous)
(Target: $\leq 3\%$)
- 
Standard according to FDA (2009) & CLSI M52

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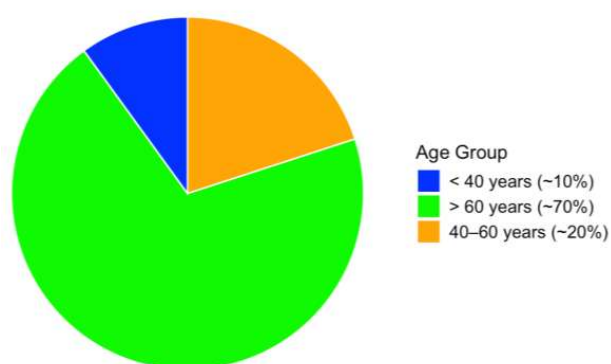
3. Results

Part 1: Epidemiological Characteristics & Pathogens

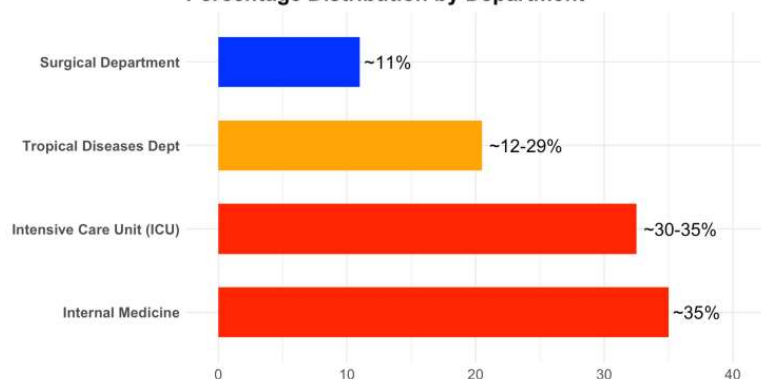
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Characteristics

Age Distribution of Patients



Percentage Distribution by Department



- ❖ The incidence of HAIs increases significantly with age ($p < 0.001$).
- ❖ Elderly individuals are the highest-risk group.

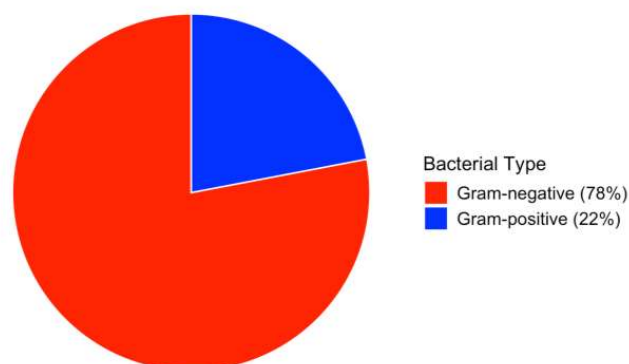
HAIs are primarily concentrated in departments treating critically ill patients (Intensive Care, Internal Medicine, Infectious Diseases).

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Characteristics of Pathogens

Distribution of Pathogens (n=206)

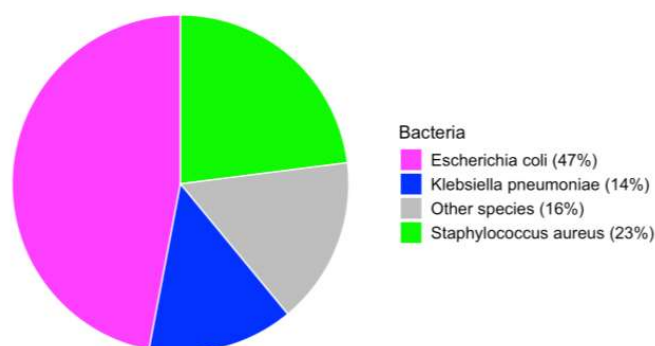
Gram Stain Classification of Bacteria



Gram-negative bacteria were predominant in bloodstream infection cases at Thong Nhat General Hospital.

Distribution of Leading Pathogens (n=206)

Bacterial Pathogen Distribution (Sorted)



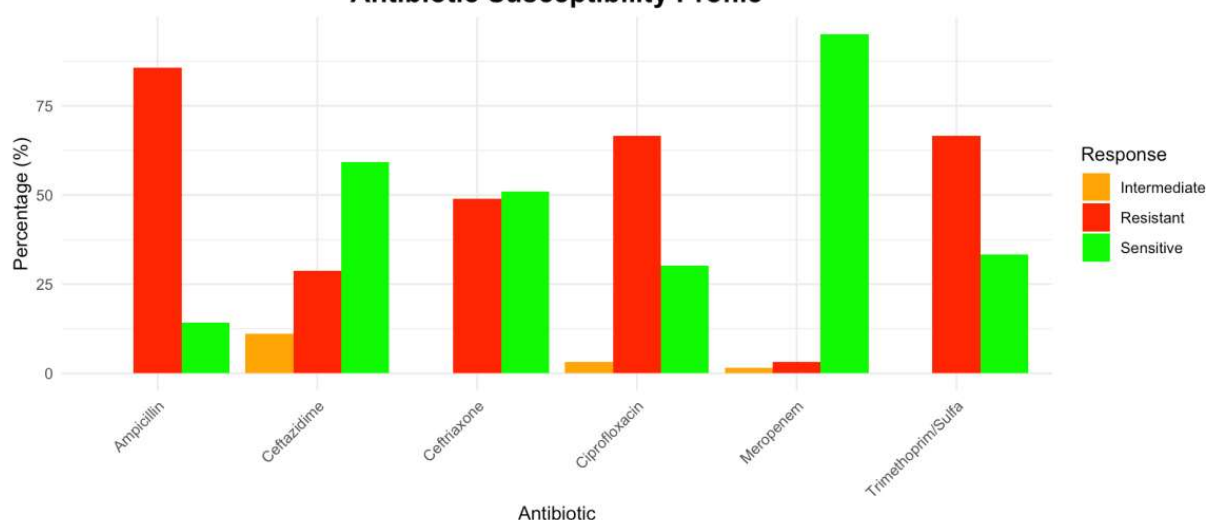
E. coli, *S. aureus*, and *K. pneumoniae* were the three most common pathogens.

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Characteristics of Pathogens

Antibiotic Resistance Rate of *E. coli* (n=63)

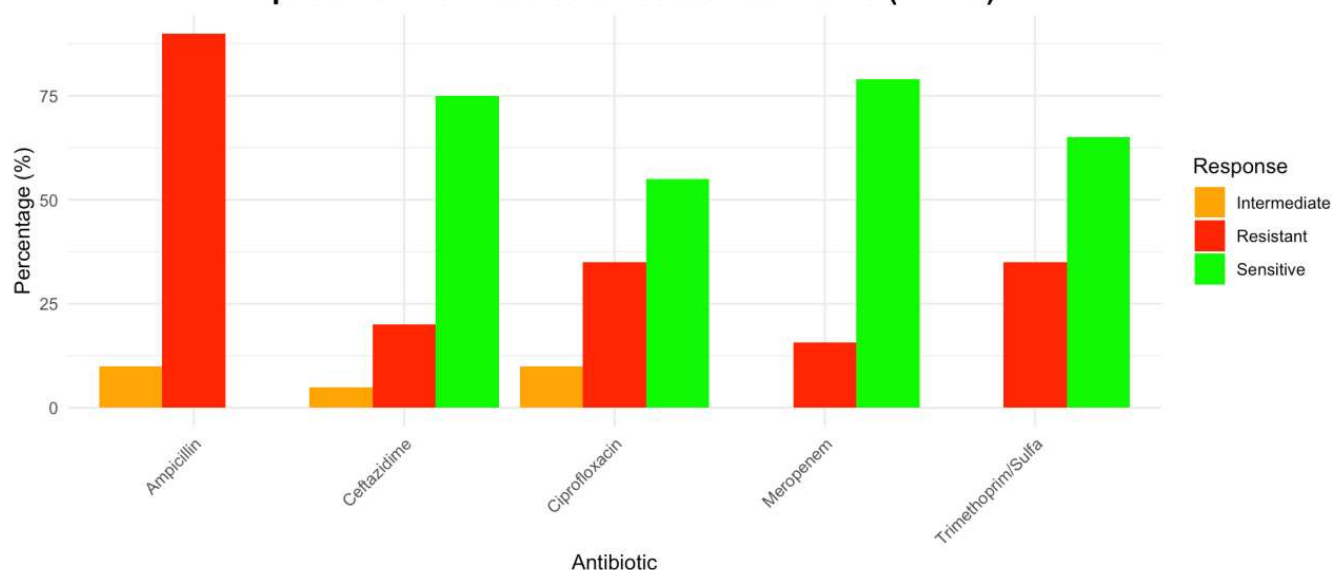
Antibiotic Susceptibility Profile



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Characteristics of Pathogens

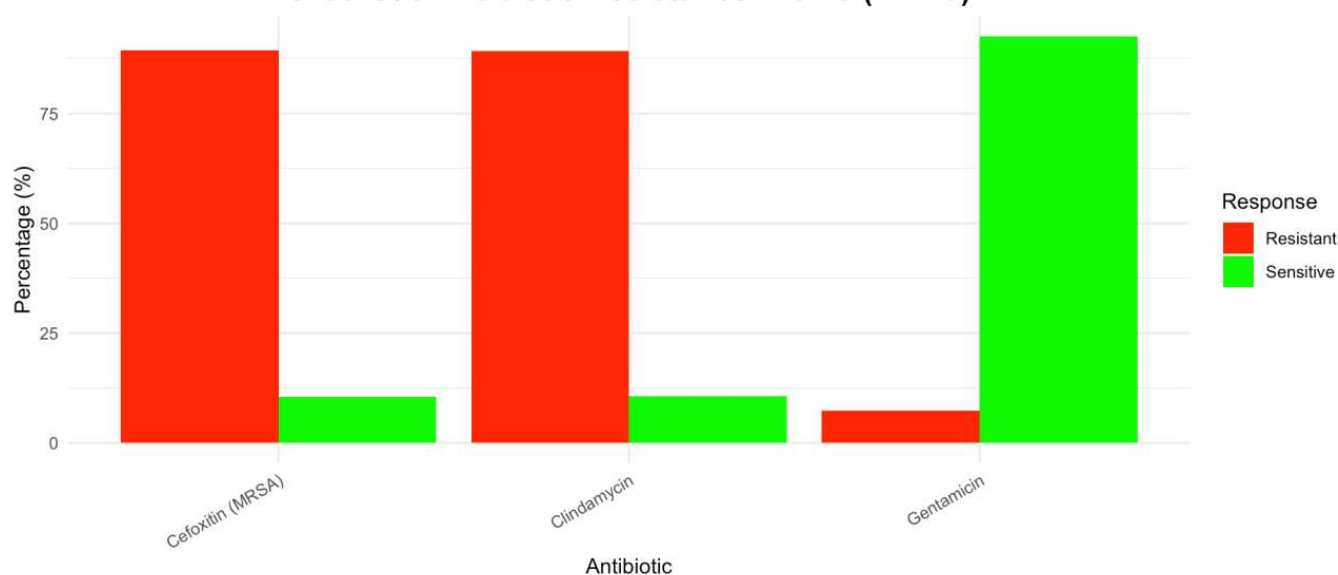
K. pneumoniae Antibiotic Resistance Profile (n = 20)



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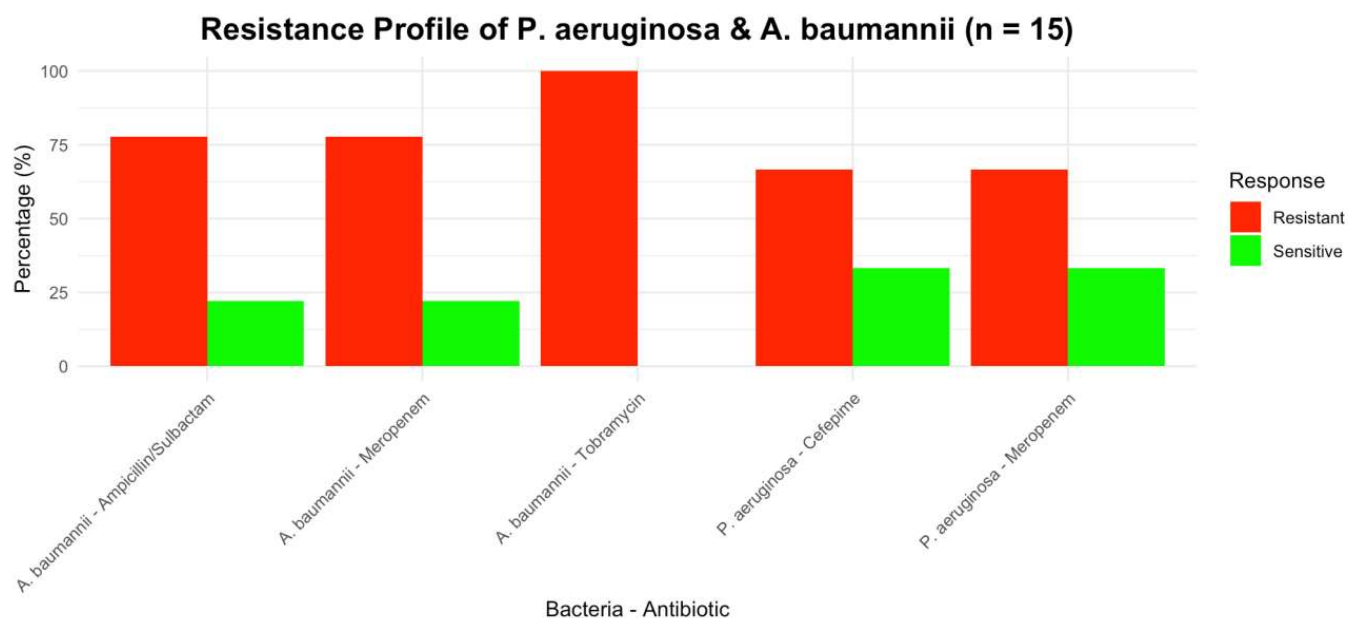
Characteristics of Pathogens

S. aureus Antibiotic Resistance Profile (n = 28)



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Characteristics of Pathogens



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RESULTS:

Section 2: Effectiveness Analysis (3 Pillars)

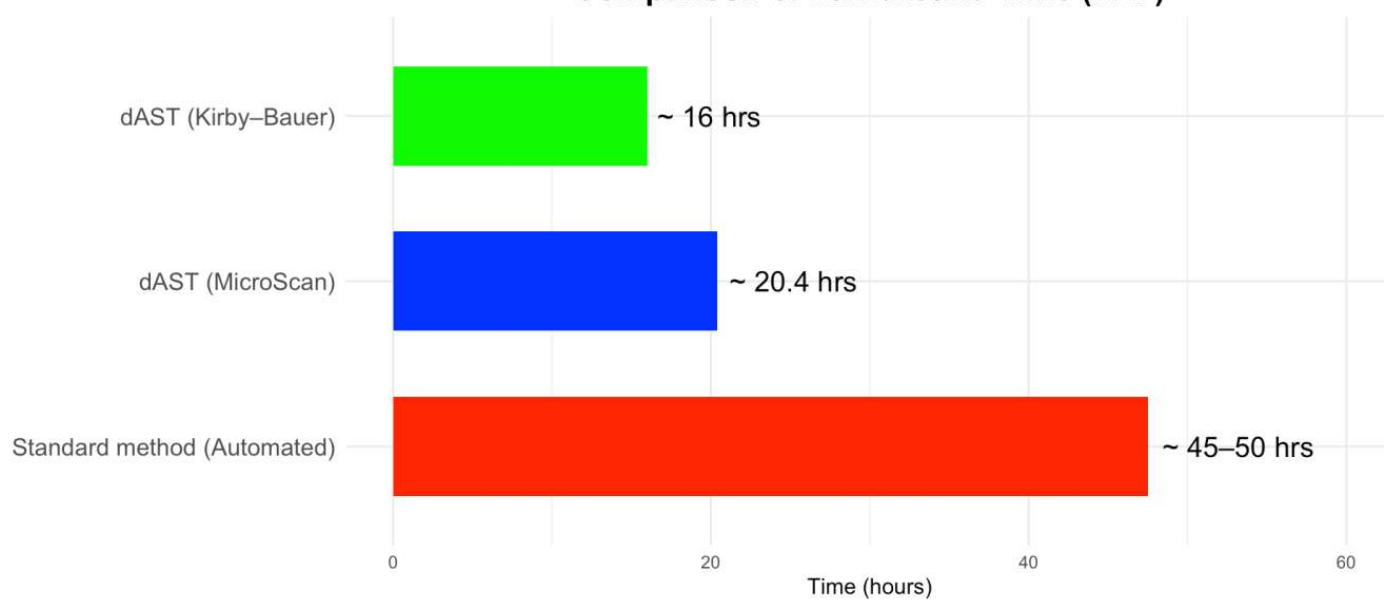
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FINDING 1: SPEED(TAT)

dAST is significantly faster than the standard method

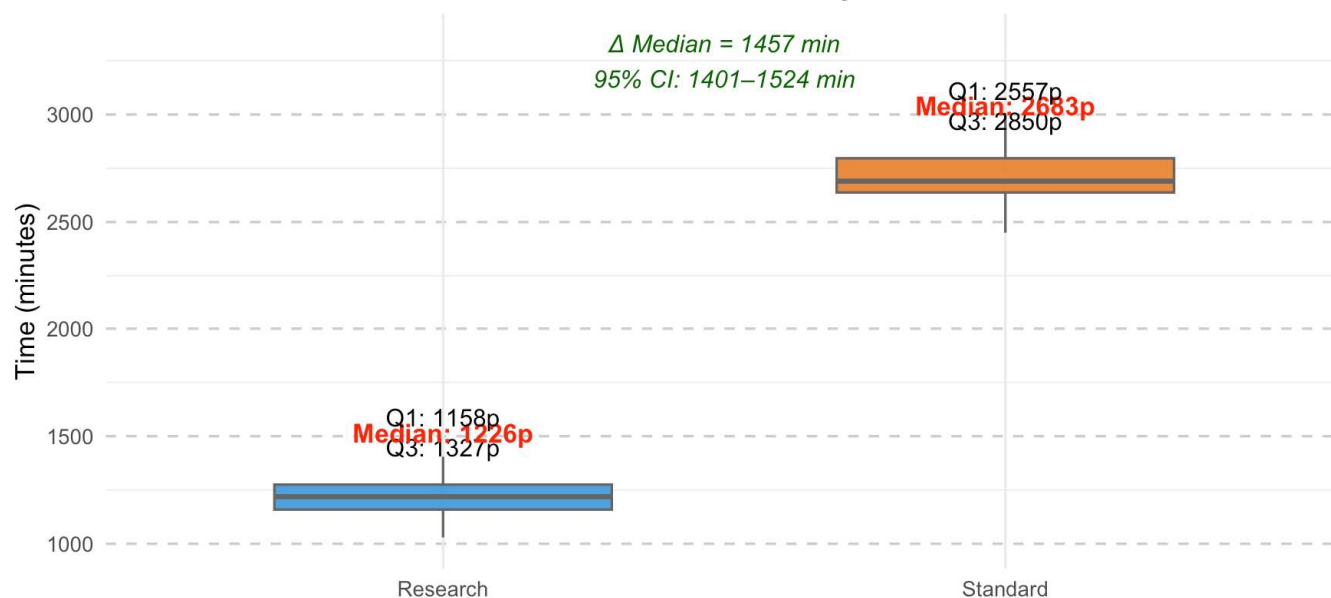
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Comparison of Turnaround Time (TAT)



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Turnaround Time Comparison



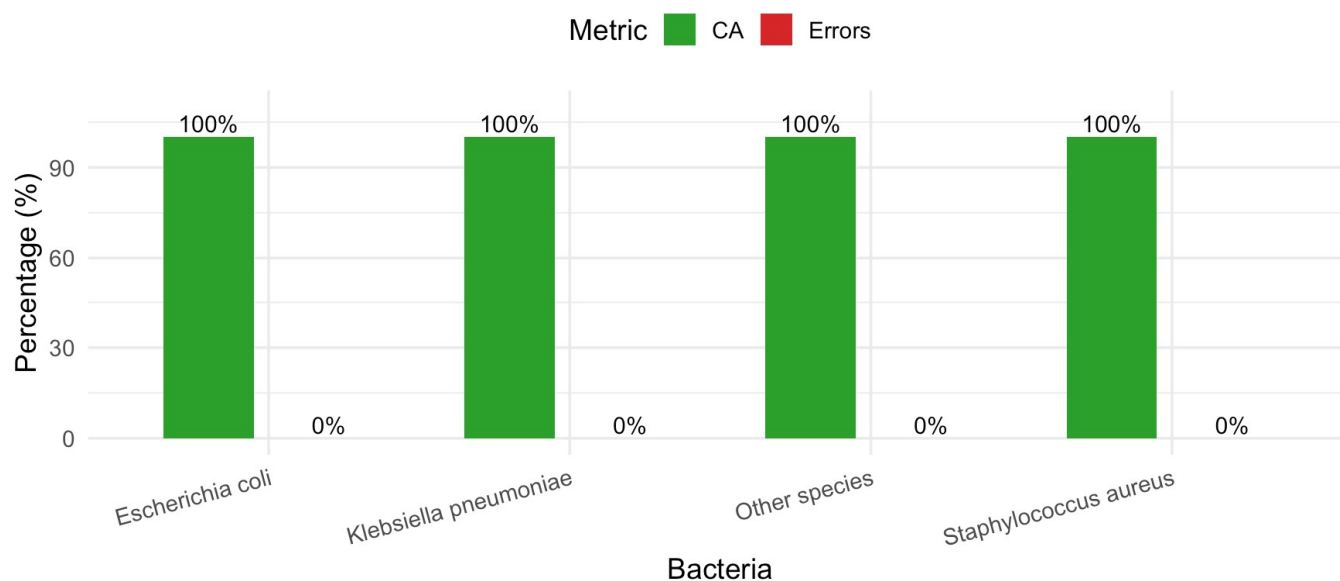
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Finding 2: Accuracy (Identification/ID)

dAST (MicroScan) provided 100% accurate identification results

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Identification Accuracy Results (n = 145)



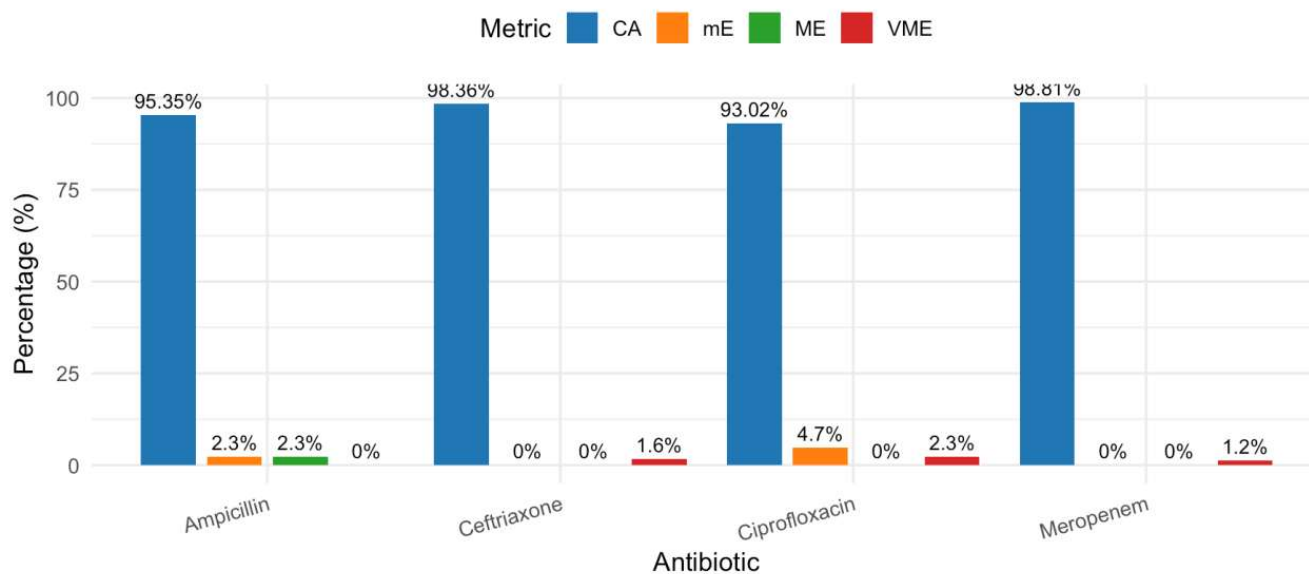
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Finding 3: **Accuracy** (Antibiotic Susceptibility Testing/AST)

Both dAST methods complied with the safety standards set by CLSI

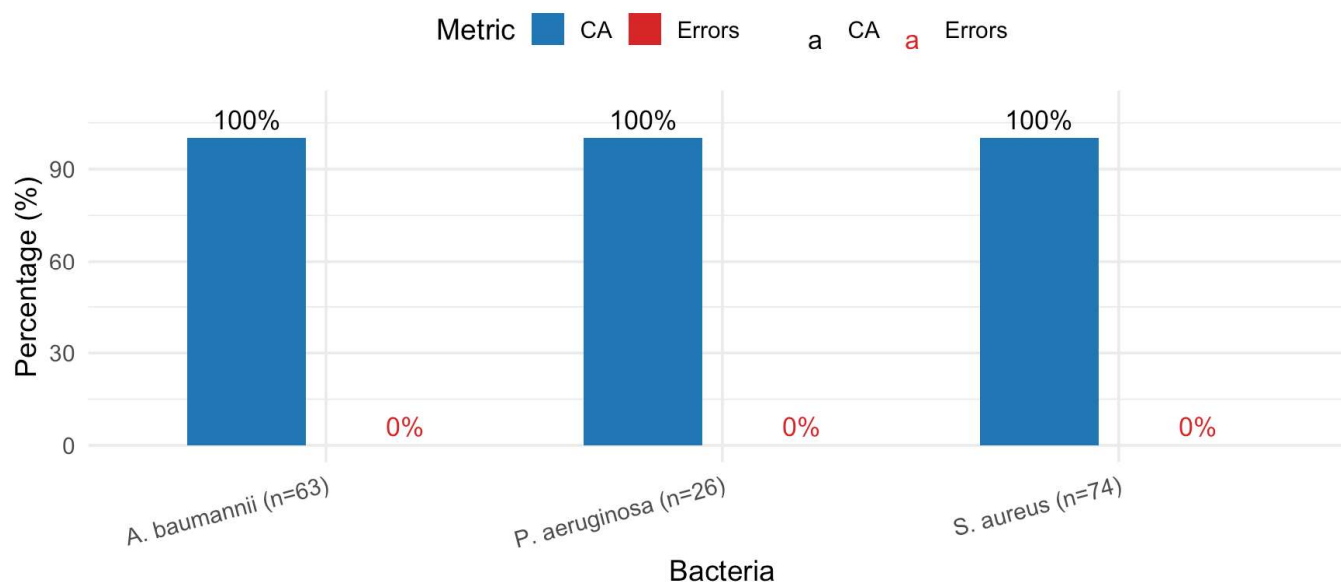
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AST Results: dAST (Kirby-Bauer) – Enterobacterales (n = 510)

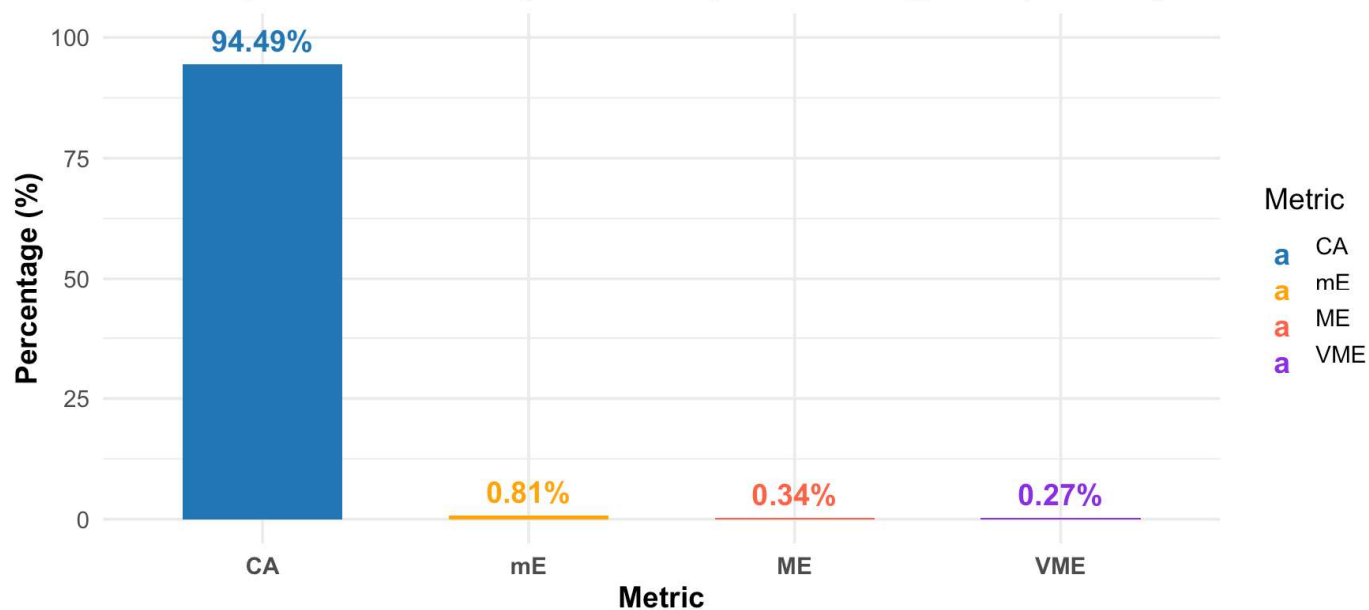


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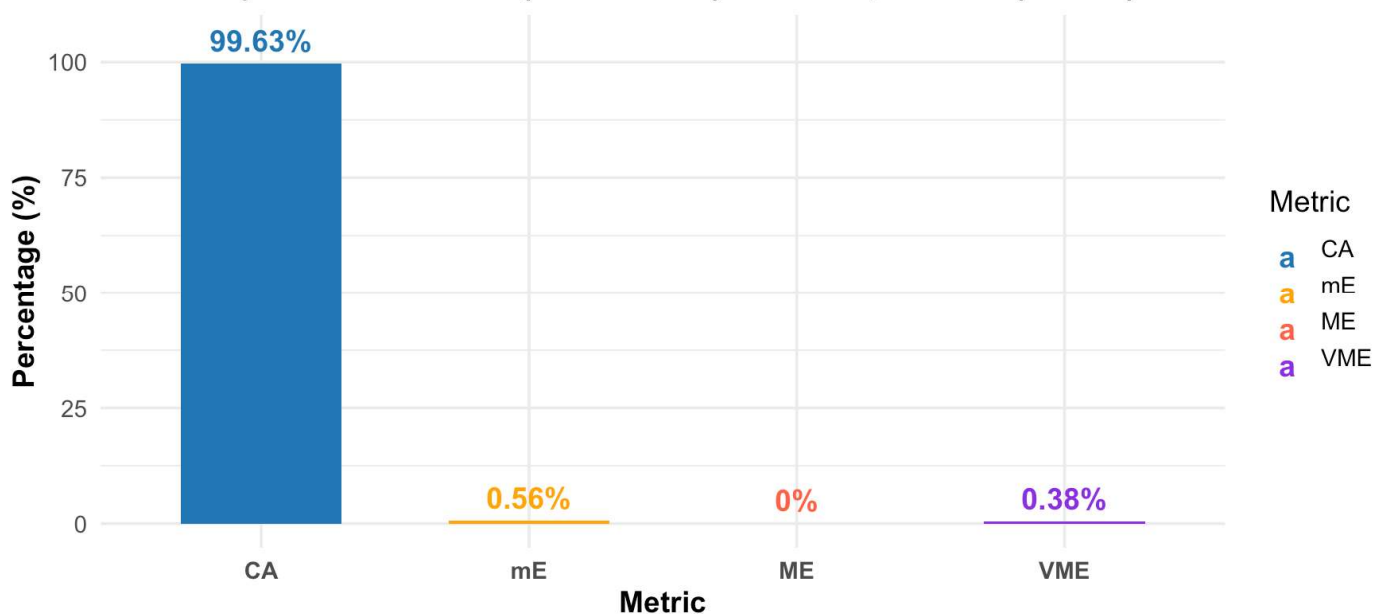
Accuracy Results: Kirby-Bauer – Other GN Bacteria (n = 163)



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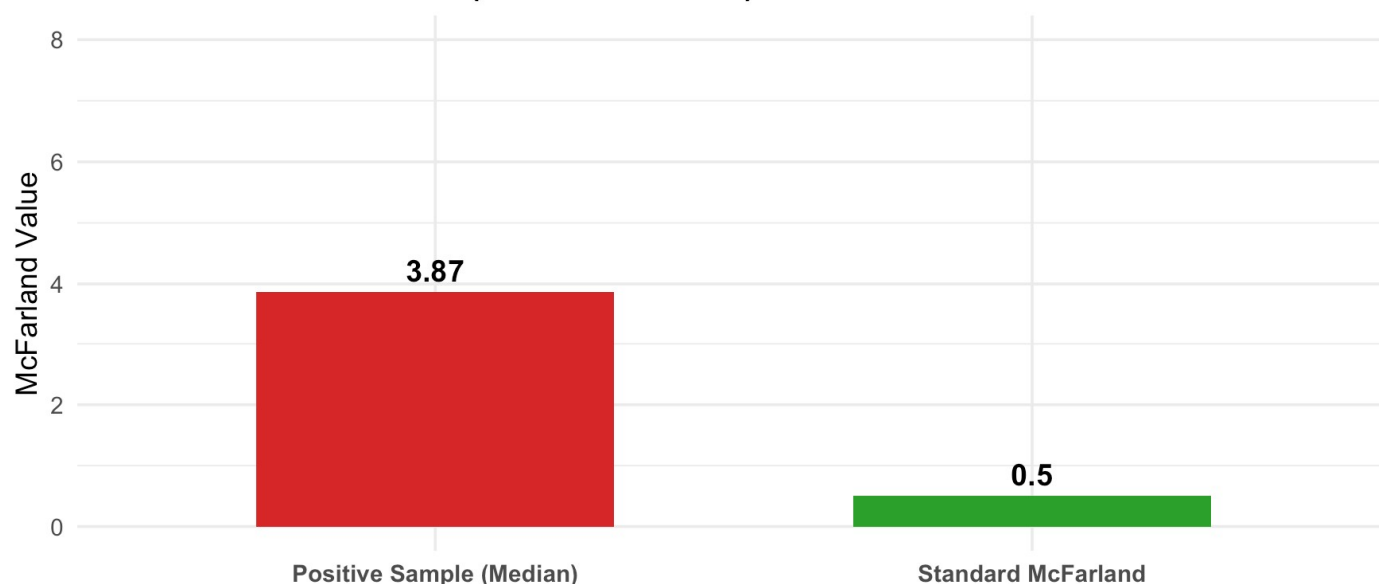
Accuracy Metrics: dAST (MicroScan) – Gram-negative (n = 114)

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Accuracy Metrics: dAST (MicroScan) – Gram-positive (n = 32)

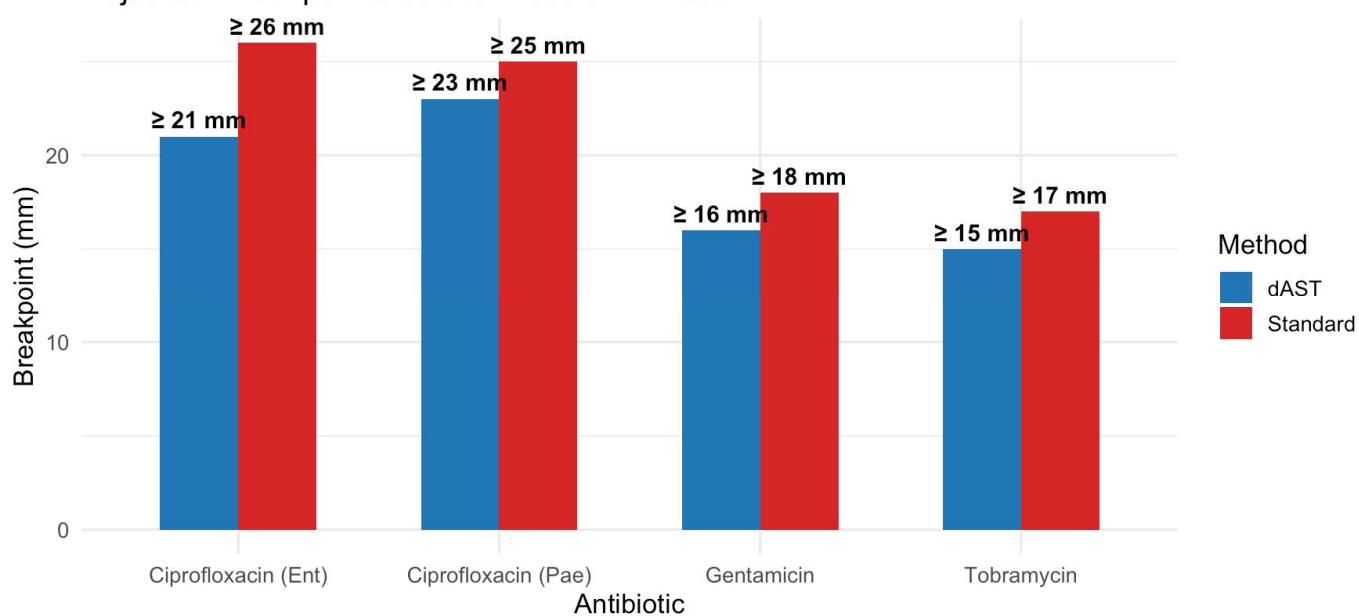
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Bacterial Concentration (McFarland Units)



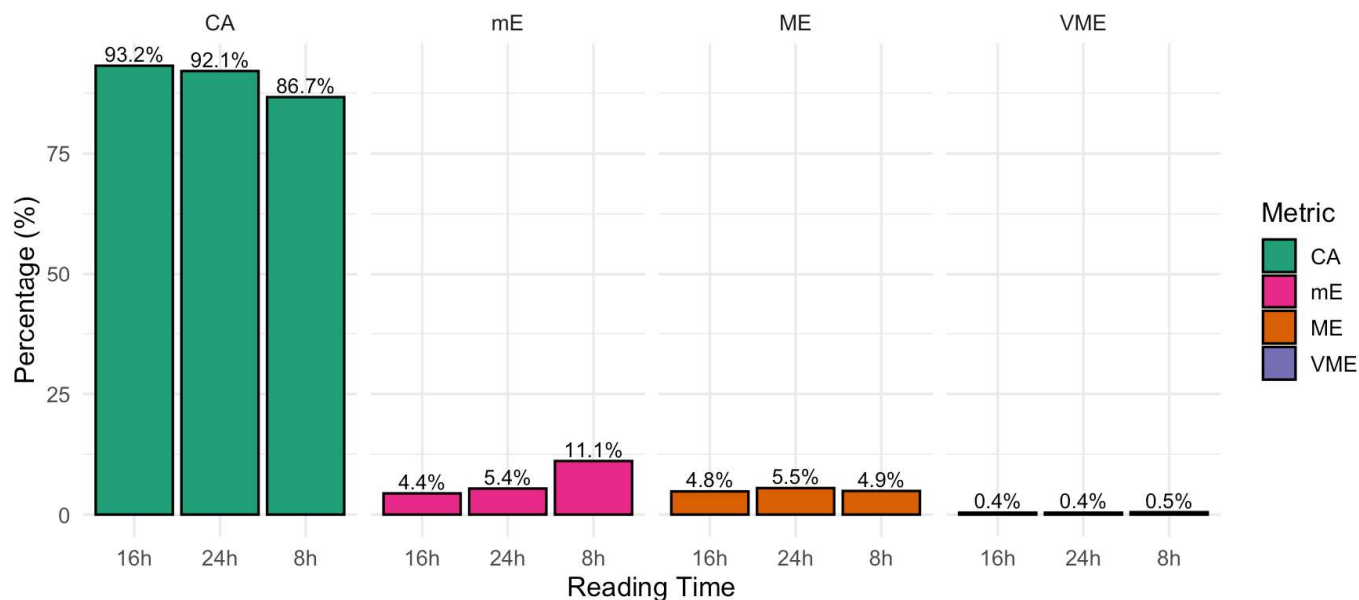
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Adjusted Breakpoints due to Inoculum Effect



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Impact of Reading Time on dAST Accuracy

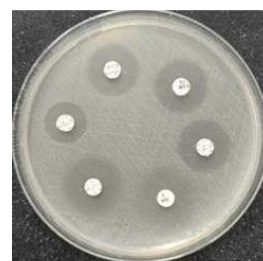


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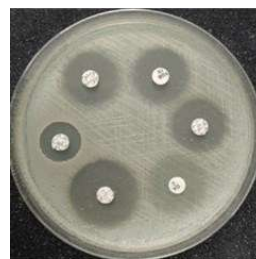
Impact of Reading Time on AST Accuracy

The images illustrate the development of the inhibition zone over time

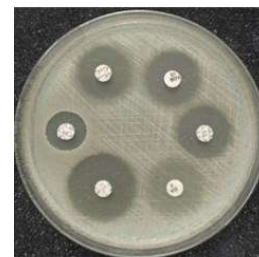
- ✓ **After 8 hours:** The inhibition zone is still blurred; bacterial growth is uneven, making accurate interpretation difficult and prone to error.
- ✓ **After 16–24 hours:** The inhibition zone becomes clearly defined; bacterial growth is dense, resulting in stable and accurate readings.



Đĩa AST trực tiếp sau 8h ủ



Đĩa AST trực tiếp sau 16h ủ



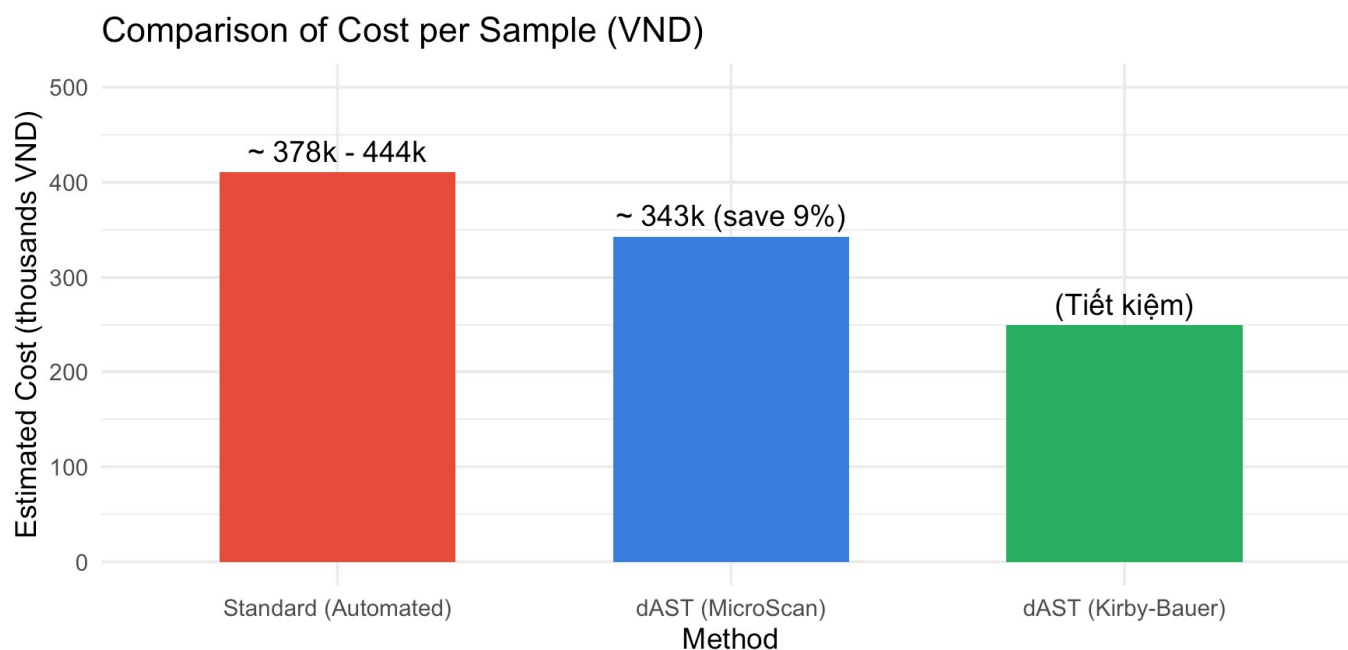
Đĩa AST trực tiếp sau 24h ủ

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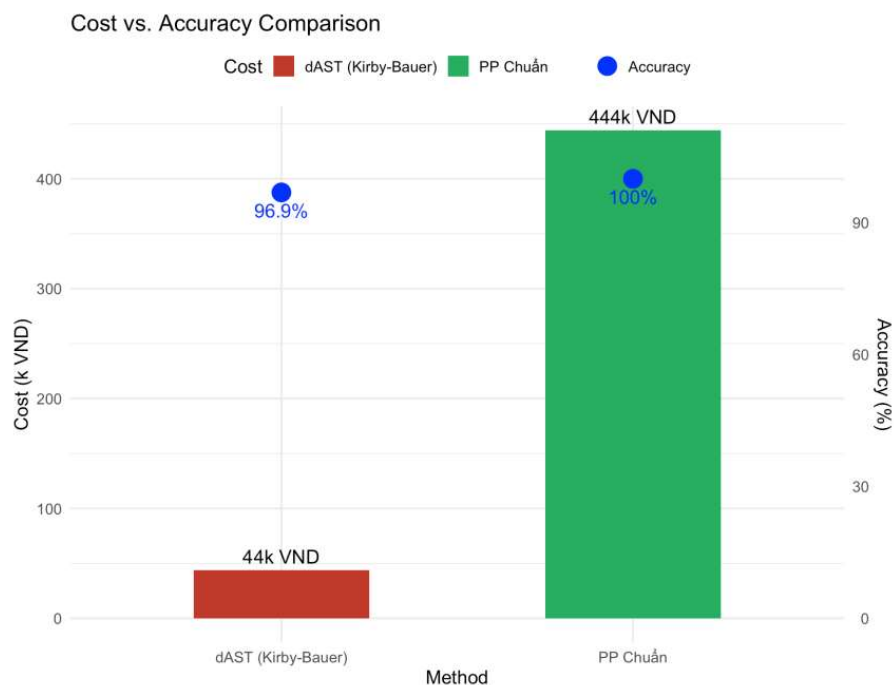
FINDING 4: COST-EFFECTIVENESS

dAST offers significant cost savings compared to the standard protocol

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4. Discussion & Conclusion

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3 pillars of Effectiveness



FASTER

Shortens the time to receive AST results from **24 to 32 hours**, allowing for earlier infection treatment by more than a day.



ACCURATE

Category Agreement (CA) is > 94-99%, Very Major Errors (VME) are all **below 3%**, meeting the safety standards of CLSI/FDA.



REASONABLE COST

Significant cost savings, especially the Kirby-Bauer method (90% reduction in consumable costs).

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Clinical Significance



Support for Clinical Decision Making: Provides **AST results 24-32 hours earlier**, helping physicians quickly transition from "empirical" antibiotic therapy to "targeted" therapy.



Antimicrobial Stewardship (AMS): A powerful tool to promote **antibiotic de-escalation**, reduce the use of broad-spectrum antibiotics, and alleviate antimicrobial resistance pressure.



Improved Prognosis: Early targeted treatment has been proven to help **reduce mortality**, decrease **length of stay (LoS)**, and reduce total **treatment costs**.

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Discussion



Aligning with Trends: Our results (CA > 94%) are **consistent** with **international** systematic reviews, confirming that dAST is a **reliable** technique.



A systematic review by **Opota et al. (2016)** showed that dAST (Kirby-Bauer) had a **mean CA of 93.8%** and a **VME of 1.7%**, which is very **close** to our results.



The study by **Timbrook et al. (2017)** indicates that implementing rapid diagnostic testing (such as **dAST**) combined with AMS helps significantly **reduce mortality** and **treatment costs**.

Opota O, et al, Eur J Clin Microbiol Infect Dis, 2016, PMID: 27245594
Timbrook TT, et al, Clin Infect Dis, 2017, PMID: 28329124

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Discussion (cont'd)



Automated dAST (MicroScan): Our results (CA **94.5% - 99.6%**) are **consistent** with **international studies**. **Infante et al. (2020)** report an overall CA of **92.86%** when using direct Microscan, and **Jacobs et al. (2022)** also reported high accuracy.



Sample Processing (SST): The use of Serum Separator Tubes (SST) for centrifugation is an effective method. **Morales et al. (2024)** (study on pediatric patients) used SST with the Phoenix M50 instrument and reported CA > 99%.

Infante A, et al, Eur J Clin Microbiol Infect Dis, 2020, PMID: 32860167
Jacobs MR, et al, Antimicrob Agents Chemother, 2022, PMID: 35100072
Morales P, et al, Microorganisms, 2024, PMID: 39182747

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Discussion (cont'd)

Selecting the Appropriate Method for Thong Nhat Dong Nai General Hospital

	dAST (Kirby-Bauer)	dAST (MicroScan)
Advantages	- Extremely low cost (90% savings) - High accuracy - Flexible	- Automation, simultaneous identification and AST - Excellent accuracy (VME<0.4%) - Provides MIC results
Disadvantages	- Manual - Requires experienced technicians - Results read after 16-18h	- Higher cost - Requires sample processing (centrifugation)

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Discussion (cont'd)

Optimal Result Reading Time (Kirby-Bauer)

8-hour mark	- CA accuracy (86.7%) --> does not meet requirements (<90%) 11.1% minor errors (mE) - Results should not be reported at this time point
16-hour mark	- CA accuracy (93.2%) and error indices (VME 0.4%, ME 4.8%, mE 4.4%) Significant improved, meets requirements
18-hour mark	CA result (92.1%) and errors are no better than the 16-hour mark

Conclusion: The optimal result reading time for dAST(Kirby-Bauer) is **16-18 hours** after incubation.

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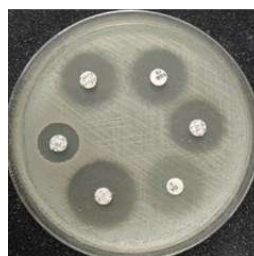
Result Reading Time

The image shows the development of the zone of inhibition over time.

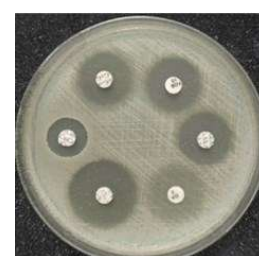
- ✓ **After 8 hours:** The zone of inhibition is still **faint/fuzzy**, bacterial growth is uneven, making accurate reading difficult and prone to errors.
- ✓ **After 16-24 hours:** The zone of inhibition is **clear/distinct**, bacterial growth is dense, providing stable and accurate reading results.



Direct AST plate after 8 hours of incubation



Direct AST plate after 16 hours of incubation



Direct AST plate after 24 hours of incubation

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Technique Consideration: Bacterial concentration

3.87

McFarland (Median)
(1.97 – 7.16)

0.5

McFarland (Standard)
Standardized Suspension
Concentration

The bacterial concentration in the positive blood culture bottle (median 1.16×10^9 CFU/ml) is significantly higher than the standard concentration

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Discussion (cont'd)

Inoculum Effect



High bacterial concentration (called the **inoculum effect**) can make the zone of inhibition smaller, leading to the risk of reporting "susceptible" as "**resistant**" (ME) or "susceptible" as "**intermediate**" (mE).



CLSI/EUCAST has adjusted (lowered) the breakpoint values for dAST (Kirby-Bauer) to compensate for this effect.



The dAST (MicroScan) procedure uses centrifugation and dilution to 0.5 McFarland, which helps minimize the inoculum effect, potentially explaining the very low VME/ME error rates.

Smith KP, et al, Antimicrob Agents Chemother, 2018, PMID: 29735552
Cartagena AJ, et al, bioRxiv, 2025, (Nghiên cứu về Carbapenem inoculum effect)

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Discussion (cont'd)

Limitations & Challenges



Polymicrobial Infection: Both dAST methods are unreliable if the blood culture bottle contains **more than 1 type of bacteria**.

Adherence required: Only perform dAST when Gram stain clearly shows a single bacterial morphology.



Specific Resistance Mechanisms: It is difficult to detect certain resistance mechanisms (such as **ESBL, Carbapenemase, MLSB**) without supplemental screening tests.



Personnel Requirements: The Kirby-Bauer method requires **experienced technicians** to read the results, and the MicroScan method requires careful sample processing (centrifugation).

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5. Conclusion & Suggestions

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General Conclusions



Both dAST methods (manual Kirby-Bauer and automated MiroScan) are confirmed to be **feasible, accurate, and effective** for implementation at Thong Nhat Dong Nai General Hospital.



This is an important solution that helps **improve the quality of care** for patients with sepsis, while simultaneously supporting the hospital's Antimicrobial Stewardship (AMS) program.

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Suggestions



Routine Implementation: Apply dAST as a standard procedure for all positive (single-organism) blood culture bottles in the hospital.



Develop SOP: Issue a Standard Operating Procedure (SOP) detailing the steps for both techniques (Kirby-Bauer and MicroScan) to ensure consistency.



Clinical Collaboration: Closely coordinate with clinical physicians and the Antimicrobial Stewardship (AMS) team to interpret and effectively use the early results.



Extended Research: Evaluate the actual clinical impact (mortality rate, length of stay) after implementation dAST.

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References



Kumar A, et al, (2006), Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock, *Crit Care Med*, 34(6):1589-96, (PMID: 16625125)



Opota O, et al, (2016), Rapid antimicrobial susceptibility testing from positive blood cultures: a systematic review of the literature, *Eur J Clin Microbiol Infect Dis*, 35(9):1391-403, (PMID: 27245594)



Timbrook TT, et al, (2017), A systematic review of the implementation of rapid diagnostic testing and antimicrobial stewardship programs,,, *Clin Infect Dis*, 64(9):1171-1180, (PMID: 28329124)



Khan S, et al, (2024), Evaluation of three protocols for direct susceptibility testing for Gram-negative rods from flagged positive blood culture bottles, *Microbiol Spectr*, 12(4):e03081-23, (PMID: 38446069)



Morales P, et al, (2024), Evaluation of Direct Antimicrobial Susceptibility Testing of,,, Positive Pediatric Blood Culture Bottles Using BD Phoenix M50, *Microorganisms*, 12(8):1704, (PMID: 39182747)

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Thank you!

Q & A

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T-CELL RESPONSES TO EV-A71 STRUCTURAL PROTEINS IN HAND FOOT AND MOUTH DISEASE PATIENTS

PhD student: Lam Anh Nguyet

Supervisors:

- Assoc. Prof Ha Manh Tuan (UMP)
- Prof Le Van Tan (OUCRU)

CONTENTS

	Introduction
	Virus structure and Peptide design
	ELISPOT assay
	T-cell responses Results
	Summary

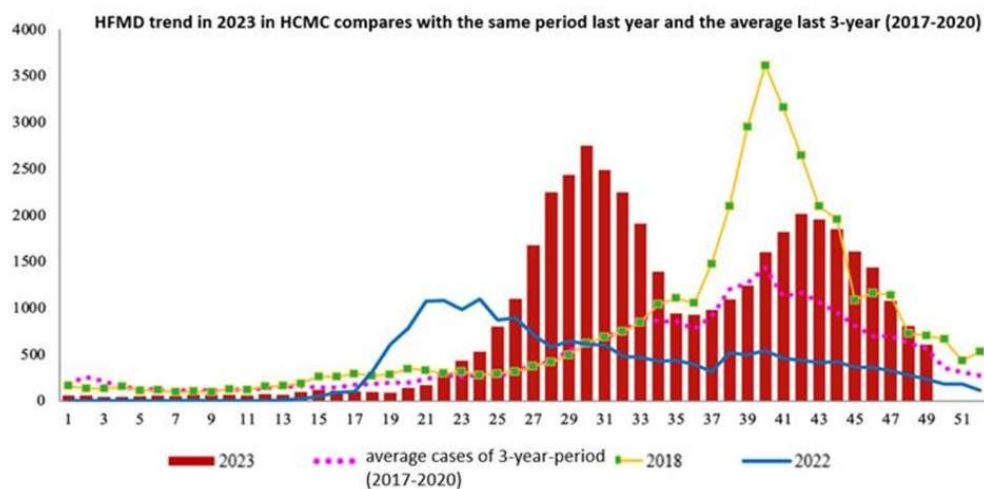
I. INTRODUCTION



>1million cases/year across the Asia-Pacific region

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Severe enterovirus A71 associated HFMD outbreak, Vietnam, 2023
>100,000 reported cases and 23 deaths



❖ Outbreak in 2023:

- Highest peak at week 30: > 2.500 cases
- Second peak at week 42: > 2.000 cases

Source: H/CDC

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The economic burden and necessity of vaccination

2016-2017	Cases	Cost (USD)
Inpatients	94.313	40.290.514
Outpatients (estimated)	532.397	50.471.235
Total	626.710	90.761.749

Nhan, et al. Economic Burden attributed to children presenting to hospital with Hand, Foot, and Mouth Disease. Infectious Disease Society of American. 2019; 1-7. DOI: 10.1093/ofid/ofz284

→ **Overload of health system and economic burden**

- 50% of children in the community possessed neutralizing antibodies during 2011 HFMD epidemic (Kuo FL and et al, doi:10.1371/journal.pntd.0008124)
 - 97-100% of children had seropositive after 7 days infected enteroviruses (Nguyet LA and et al, DOI: 10.3201/eid2602.190721)
- **Vaccine for HFMD is really urgently needed.**
- Evaluating neutralizing antibodies may not be the only mechanisms to explain severe or mild cases (Chunfu Yang and et al, doi:10.1186/1743-422X-8-306)
- **It's important to assess humoral and cellular immune responses in those with natural infection to inform vaccine design.**

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Knowledge gaps

- There has been no study assessing T-cell responses in HFMD patients, while T-cell responses may play an important role in controlling disease severity.

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Aims

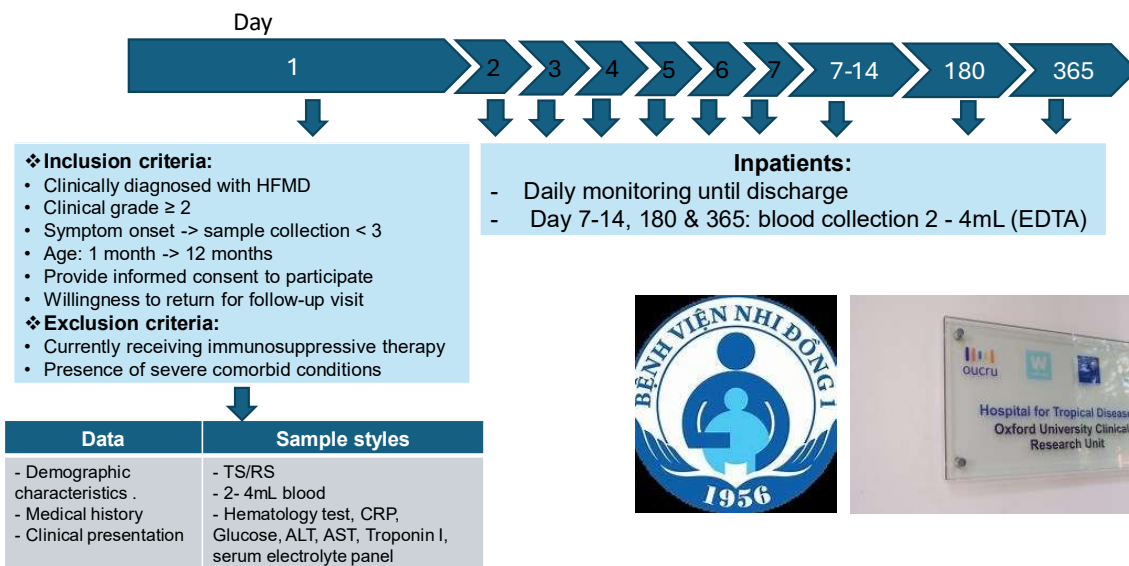
- To study T-cell responses to EV-A71 structural proteins in hand foot and mouth disease patients with PCR confirmed EV-A71 infection.

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Sampling procedure

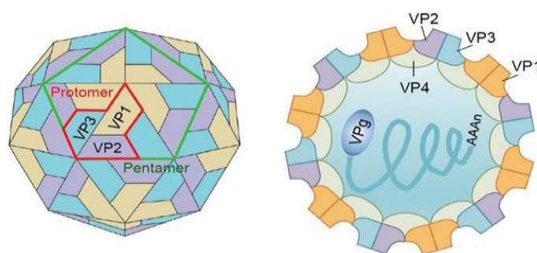
Criteria for disease collection, exclusion and data collection



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II. Virus structure and peptide design



Enterovirus structure:

- Picornavirus, belonging to type A non-polio enterovirus family
- A positive-sense single RNA strand
- 7.400 nucleotides
- 4 capsid proteins (VP1-4)
 - VP1-3: Expose outside of the capsid -> **immunologically reactive epitopes**
 - VP4: Located inside the virus capsid -> connected tightly with viral genome

Designing EV-A71 peptides for ELISPOT

- A crucial step to measure T cell responses
- To choose peptides that will effectively stimulate T cells to produce cytokines (IFN gamma)
- Each fragment: 15 aa
- Overlapping: 10 aa
- The last length fragment may ≥ 10 aa

In our group:



Alba Grifoni, Ph.D.



Tran Tan Thanh, Post Doc.

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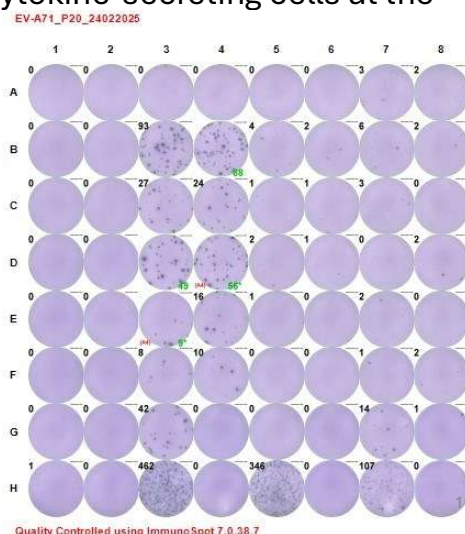
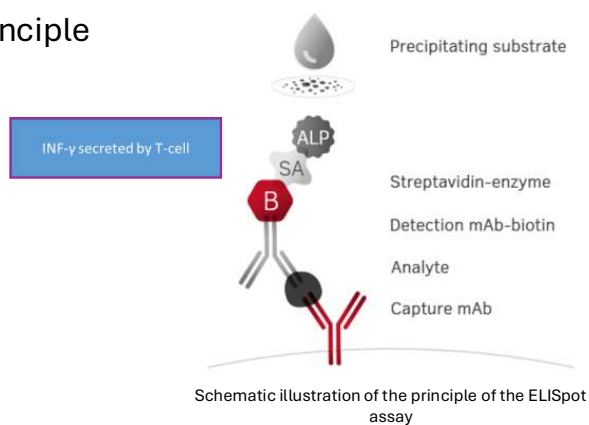
9

III. ELISOPT assay

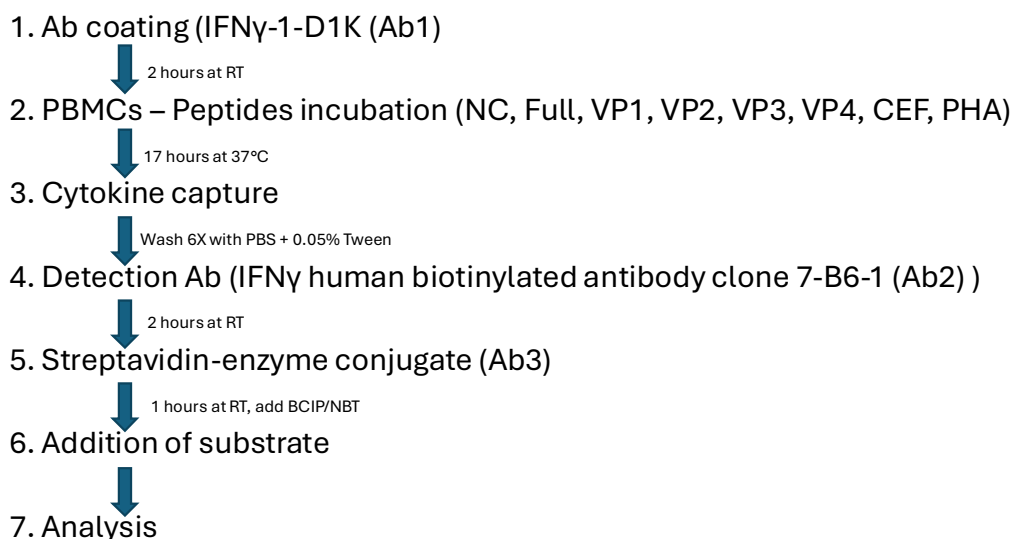
- What is ELISpot?

ELISpot (The Enzyme-linked immunosorbent spot) assay is a highly sensitive immunoassay that measures the frequency of cytokine-secreting cells at the single-cell level.

- Principle



ELISPOT (Workflow)

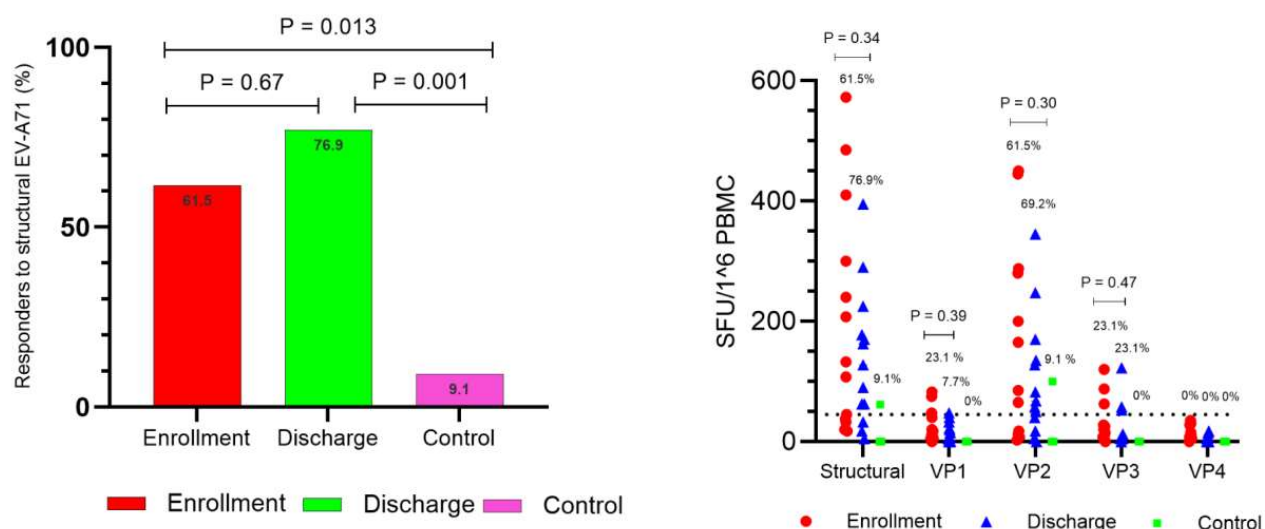


IV. T-cell MD response results_Patient group

Characteristics	Patients with HFMD caused by EV-A71 confirmed by PCR	Control group
Age in months, median (range)	27 (6–56)	13 (7–31)
Male/Female	9/4	7/4
Days from disease onset to enrollment, median (range)	2 (1–8)	2 (1–9)
Days of hospitalization, median (range)*	10 (4–14)	6 (3–13)
Highest clinical stage during hospitalization, n (%)**		
2A	0	0
2B1	1	1
2B2	12	10
3	13	11
Discharge status, n (%)		
Recovered	13	11
Death	0	0

*Reflecting the window time between enrollment and discharge samples

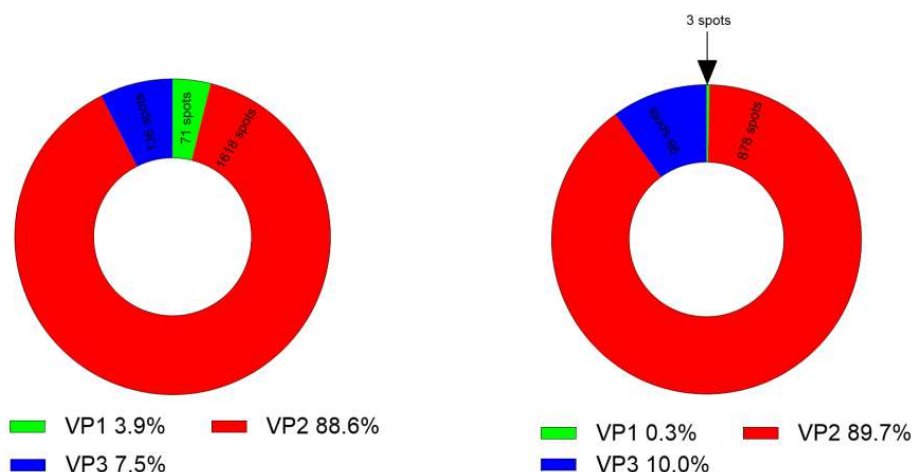
T-cell response to the peptide pools of EV-A71 viral proteins



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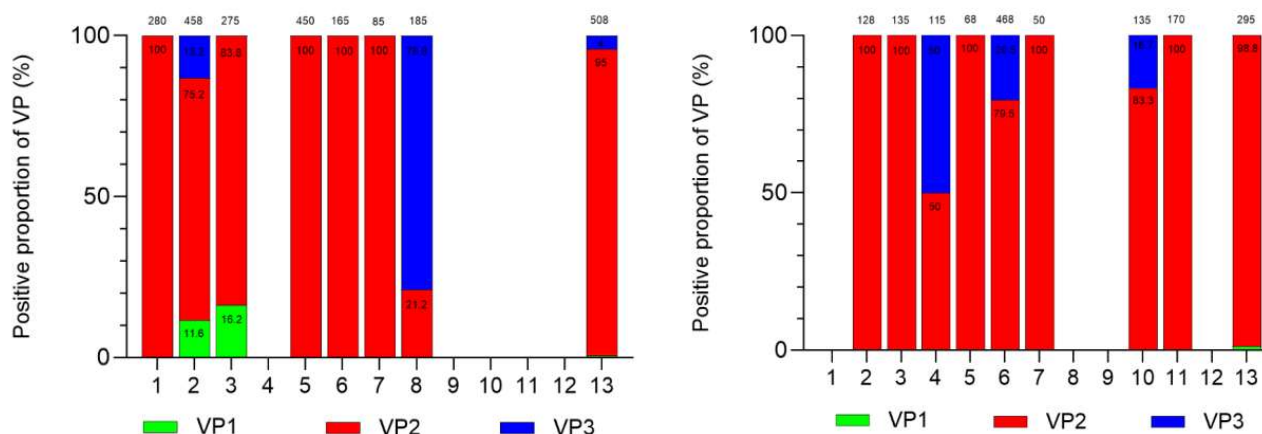
Contributions of individual viral structural proteins to overall levels of structural EV-A71 T-cell response reflected by SFU per million PBMC in HFMD patients



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Donor level magnitude of T-cell responses measured at enrollment and discharge



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Summary

- Our findings complement the previous study from China in healthy adults (<https://doi.org/10.4049/jimmunol.1301439>)

keyword: VP1 gamma T32tpor wssay.pdf
or shared file

The Journal of Immunology

VP2 Dominated CD4⁺ T Cell Responses against Enterovirus 71 and Cross-Reactivity against Coxsackievirus A16 and Polioviruses in a Healthy Population

Shuguang Tan,^{*,†} Xiaojuan Tan,[‡] Xiaoman Sun,^{*,†} Guangwen Lu,^{*} Chun-Chi Chen,^{*} Jinghua Yan,^{*,†} Jun Liu,^{*,‡} Wenbo Xu,[‡] and George F. Gao^{*,†,‡,§}

Enterovirus 71 (EV71)-associated hand-foot-mouth disease has become a major threat to public health in the Asia-Pacific region. Although T cell immunity is closely correlated with clinical outcomes of EV71 infection, little is known about T cell immunity baseline against EV71 and T cell immunogenicity of EV71 Ags in the population, which has restricted our understanding of immunoprotection mechanisms. In this study, we investigated the cellular immune responses against the four structural Ags of EV71 and determined the immunohierarchy of these Ags in healthy adults. A low frequency of EV71-responsive T cells was detected circulating in peripheral blood, and broad T cell immune responses could be identified in most of the subjects after *in vitro* expansion. We demonstrated that the VP2 Ag with broad distribution of immunogenic peptides dominates T cell responses against EV71 compared with VP1, VP3, and VP4. Furthermore, the responses were illuminated to be mainly single IFN- γ -secreting CD4⁺ T cell dependent, indicating the previous natural acute viral infection of the adult population. Conservancy analysis of the immunogenic peptides revealed that moderately variant peptides were in the majority in coxsackievirus A16 (CV-A16) whereas most of the peptides were highly variant in polioviruses. Less efficient cross-reactivity against CV-A16 might broadly exist among individuals, whereas influences derived from poliovirus vaccination would be limited. Our findings suggest that the significance of VP2 Ag should be addressed in the future EV71-responsive immunological investigations. And the findings concerning the less efficient cross-reactivity against CV-A16 and limited influences from poliovirus vaccination in EV71-contacted population would contribute to a better understanding of immunoprotection mechanisms against enteroviruses. *The Journal of Immunology*, 2013, 191: 1637–1647.

Downloaded from <http://www.jimmunol.org/>

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Summary

- In HFMD patients with PCR confirmed EV-A71 infection, T cell responses to full structural proteins were documented in 62% (8/13) and 77% (10/13) of PBMC collected at enrollment and at discharge, respectively.
- The VP2 is the main target of T-cell response.
- The first study to assess T-cell response in HFMD, therefore the data has important implication for vaccine development. Accordingly, VP2 might represent an important target for vaccine design.
- Limitation: The quantity of the collected PBMCs was insufficient to enable us to assess the response beyond the structural proteins.

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QUALITY CONTROL CENTER FOR MEDICAL LABORATORY – DEPARTMENT OF MEDICAL LABORATORY



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Nhóm nghiên cứu các Bệnh nhiễm trùng mới nổi

La Jolla Institute for Immunology, San Diego

Alba Grifoni
Alessandro Sette

15 năm

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70 năm





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MEDICAL TECHNOLOGY

MATHEMATICAL MODEL FOR PREDICTING ANTIBIOTIC EFFICACY AGAINST CARBAPENEM-RESISTANT ACINETOBACTER BAUMANNII: FROM DUAL TO TRIPLE COMBINATION THERAPY

Lam Kien Thanh, M.D.

VAN LANG UNIVERSITY



VAN LANG
UNIVERSITY

MEDICAL TECHNOLOGY

Introduction

Objectives

Method

Results and Discussion

Conclusion

INTRODUCTION

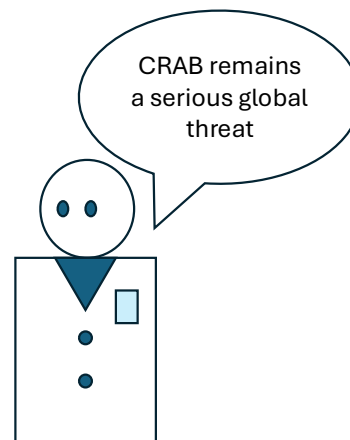
Global Antibiotic Resistance Situation

Carbapenem-Resistant Bacteria - A Serious Threat

- Carbapenem-resistant *Acinetobacter baumannii* (CRAB) is classified by WHO as a critical priority requiring urgent action
- Global resistance rate: 40-70% of countries
- Mortality rate: 30-75% in patients with infections

Situation in Southeast Asia and Vietnam

- CRAB rate in Southeast Asia: >65%
- Attributable mortality from CRAB: 42-52%
- In Vietnam:
 - Carbapenem resistance: 55-90%
 - Mortality rate from CRAB ventilator-associated pneumonia: 52%
 - Hospital mortality rate: 56% (2019-2020)



Tacconelli E et al. WHO Global Priority List 2017; Chung DR et al. Am J Respir Crit Care Med 2011;184:1409-1417
Vu TVD et al. VINARES 2016-2017. Antimicrob Resist Infect Control 2021;10:78
Diep DTH et al. J Glob Antimicrob Resist 2023;33:267-275

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INTRODUCTION

IDSA 2024

Gene => Antibiotic
Selection

1. Where to get genetic testing?
2. If genes cannot be detected, which drug to choose?
3. Recommended antibiotics difficult to find in Vietnam (Cefiderocol, Sulbactam-durlobactam)

15
năm

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HỌC 2025

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năm

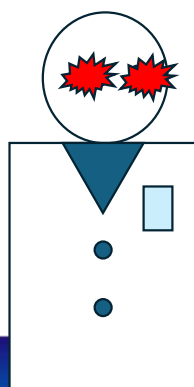
INTRODUCTION



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MEDICAL TECHNOLOGY

1. One microdilution tray takes 45 minutes to prepare
2. Testing 5 pairs takes 4 hours
3. The entire hospital currently has 30 patients requiring testing...



IDSA 2023

Phối hợp kháng sinh

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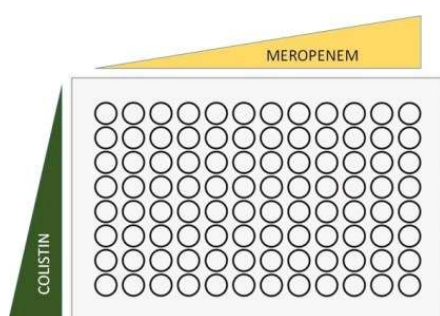


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MEDICAL TECHNOLOGY

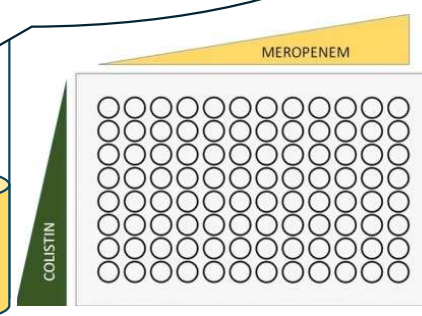
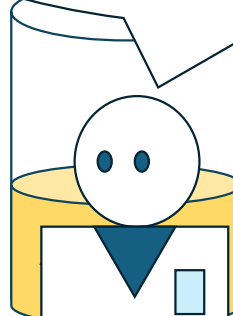
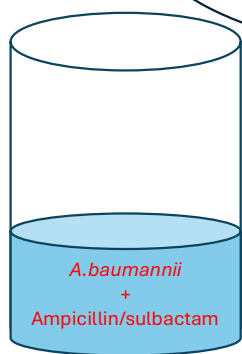
The most daunting stage is
creating the microdilution tray

**Extremely time-
consuming**



Test concentration

- + Colistin 0,0312 – 2 mcg/mL
- + Meropenem 0,125 – 128 mcg/mL
- + Ampicillin/sulbactam 8/4 mcg/mL
- + *A. baumannii*: 5×10^5 CFU/mL



Test concentration

- + Colistin 0,0312 – 2 mcg/mL
- + Meropenem 0,125 – 128 mcg/mL
- + *A. baumannii*: 5×10^5 CFU/mL

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70 năm

How to Assess Synergy?

$$FIC_{2 \text{ drugs}} = \frac{MIC_{A \text{ in combination}}}{MIC_{A \text{ alone}}} + \frac{MIC_{B \text{ in combination}}}{MIC_{B \text{ alone}}}$$

FIC ≤ 0.5: Synergy

0.5 < FIC ≤ 1: Additive

1 < FIC ≤ 4: Indifference

FIC > 4: Antagonism

$$FIC_{3 \text{ drugs}} = \frac{MIC_{A \text{ in combination}}}{MIC_{A \text{ alone}}} + \frac{MIC_{B \text{ in combination}}}{MIC_{B \text{ alone}}} + \frac{MIC_{C \text{ in combination}}}{MIC_{C \text{ alone}}}$$

FIC ≤ 0.8: Synergy

0.8 < FIC ≤ 4: Additive or Indifference

FIC > 4: Antagonism

Berenbaum M.C. A method for testing for synergy with any number of agents. *J. Infect. Dis.* 1978;137:122–130.
doi: 10.1093/infdis/137.2.122.

Then you still have to calculate all sorts of things. **Is this method also not feasible?**



How to Assess Synergy

$$FIC_{2 \text{ drugs}} = \frac{MIC_{A \text{ in combination}}}{MIC_{A \text{ alone}}} + \frac{MIC_{B \text{ in combination}}}{MIC_{B \text{ alone}}}$$

$$FIC_{3 \text{ drugs}} = \frac{MIC_{A \text{ in combination}}}{MIC_{A \text{ alone}}} + \frac{MIC_{B \text{ in combination}}}{MIC_{B \text{ alone}}} + \frac{MIC_{C \text{ in combination}}}{MIC_{C \text{ alone}}}$$

WAIT A MINUTE!!

Synergistic interactions between antibiotics against *A. baumannii* follow predictable mathematical models that can be inferred from determining individual MICs for each antibiotic?



Meropenem - Colistin

Meropenem - Colistin - Ampicillin/ sulbactam

OBJECTIVES

- **OBJECTIVE 1:** Compare the in vitro synergy rates of colistin, meropenem, and ampicillin/sulbactam in 2-drug and 3-drug formulations against CRAB strains
- **OBJECTIVE 2:** Develop mathematical models to predict FIC values (synergy) of meropenem–colistin and meropenem–colistin–ampicillin/sulbactam combinations from individual MIC results of each antibiotic.
- **OBJECTIVE 3:** Build a toolkit to support FIC determination from MIC

METHODS

Study Design

- Cross-sectional study
- In vitro laboratory study

Location and Time

- Location: University of Medicine and Pharmacy Hospital, Ho Chi Minh City, Vietnam
- Time: June - December 2022

Ethics Approval

- Ethics Committee: University of Medicine and Pharmacy, Ho Chi Minh City
- Decision number: 1005/HDDĐ-ĐHYD, dated December 9, 2022
- Compliant with Declaration of Helsinki (1964) and subsequent amendments

SAMPLE SIZE

Sample Size Calculation - Objective 1 (Synergy Assessment)

- Formula: $n \geq Z^2_{1-\alpha/2} \times p(1-p) / d^2$
- Type 1 error (α): 0.05
- Colistin-meropenem synergy rate (p): 0.98
- Margin of error (d): 0.05
- Minimum sample size: 31 XDR *A. baumannii* strains

Sample Size Calculation - Objective 2 (Predictive Model)

- According to Harrell's recommendation for regression analysis:
- Minimum 10 observations/predictor variable
- Number of predictor variables: 3 (MIC of colistin, meropenem, ampicillin/sulbactam)
- Minimum sample size: 30 strains

Actual Sample Size

+ 61 carbapenem-resistant *A. baumannii* strains
+ From 53 non-duplicate patients
+ Exceeds requirements for both objectives

Jiang Z et al. Infect Drug Resist 2018;11:1083-1095 (colistin-meropenem synergy rate)
Harrell FE. Regression Modeling Strategies (rule of 10 observations/variable)

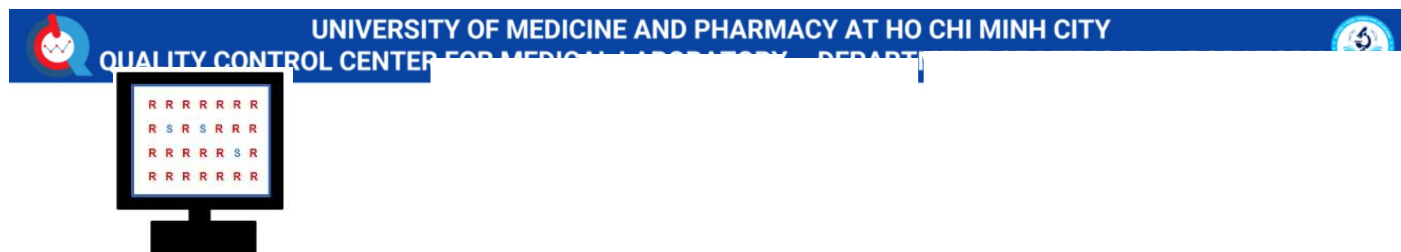
SELECTION CRITERIA

Inclusion Criteria

- *A. baumannii* strains isolated from clinical samples
- Carbapenem-resistant according to CLSI:
 - Imipenem: zone diameter ≤ 18 mm
 - Meropenem: zone diameter ≤ 14 mm
- Non-duplicate strains:
 - First strain from each patient
 - OR different antibiotic profile in at least 2 major antibiotic groups

Exclusion Criteria

- Duplicate strains from the same patient (unless antibiotic profile differs)
- Strains with unidentified species
- Contaminated strains



1. Identify of XDR *Acinetobacter baumannii*

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RESULTS AND DISCUSSION – OBJECTIVE 1

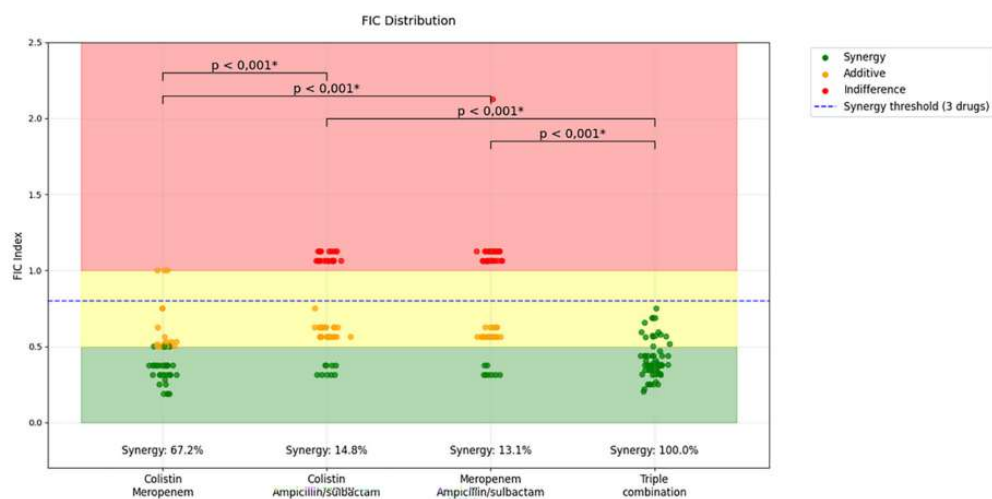


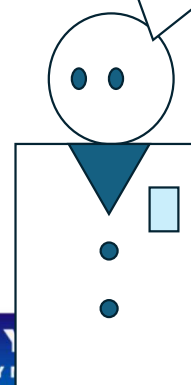
Figure 1. Distribution of FIC values for different antibiotic combinations against carbapenem-resistant *Acinetobacter baumannii*

Colored regions represent synergistic effect (green), additive effect (yellow), and neutral effect (pink). Statistical analysis was performed using the Friedman test, followed by Dunn's post-hoc test with Bonferroni correction for multiple comparisons. Asterisks (*) indicate statistical significance with *** $P < 0.001$.

RESULTS AND DISCUSSION – OBJECTIVE 2

	$a \frac{1}{MIC_A} + b \frac{1}{MIC_B}$
FIC	$a MIC_A^2 + b MIC_B^2$
Ln(FIC)	$a MIC_A + b MIC_B$
Log10(FIC)	$a \sqrt[3]{MIC_A} + b \sqrt[3]{MIC_B}$
Sqrt(FIC)	$a \sqrt{MIC_A} + b \sqrt{MIC_B}$
	$a \frac{1}{\sqrt{MIC_A}} + b \frac{1}{\sqrt{MIC_B}}$
	$a \log(MIC_A) + b \log(MIC_B)$
	$a \ln(MIC_A) + b \ln(MIC_B)$

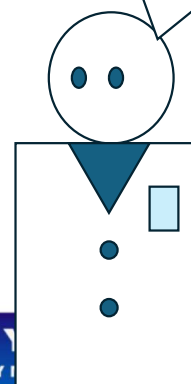
How to determine
the formula for **2**
drugs



RESULTS AND DISCUSSION – OBJECTIVE 2

	$a \frac{1}{MIC_A} + b \frac{1}{MIC_B} + c \frac{1}{MIC_C}$
FIC	$a MIC_A^2 + b MIC_B^2 + c MIC_C^2$
Ln(FIC)	$a MIC_A + b MIC_B + c MIC_C$
Log10(FIC)	$a \sqrt[3]{MIC_A} + b \sqrt[3]{MIC_B} + c \sqrt[3]{MIC_C}$
Sqrt(FIC)	$a \sqrt{MIC_A} + b \sqrt{MIC_B} + c \sqrt{MIC_C}$
	$a \frac{1}{\sqrt{MIC_A}} + b \frac{1}{\sqrt{MIC_B}} + c \frac{1}{\sqrt{MIC_C}}$
	$a \log(MIC_A) + b \log(MIC_B) + c \log(MIC_C)$
	$a \ln(MIC_A) + b \ln(MIC_B) + c \ln(MIC_C)$

How to determine
the formula for **3**
drugs



RESULTS AND DISCUSSION – OBJECTIVE 2

Best combination for 2 drugs:

- $\text{Ln}(\text{FIC}) = \text{InvSqrt}(\text{MIC})$
- $\text{Ln}(\text{FIC}) = \text{Inverse}(\text{MIC})$
- $\text{Ln}(\text{FIC}) = \text{Ln}(\text{MIC})$

Deploy linear regression 32 times, Ridge regression 32 times, LASSO 32 times, Random Forest 32 times to obtain this 2-drug combination matrix. The number displayed is the highest R^2



2-Drug Combination: R^2 Heatmap

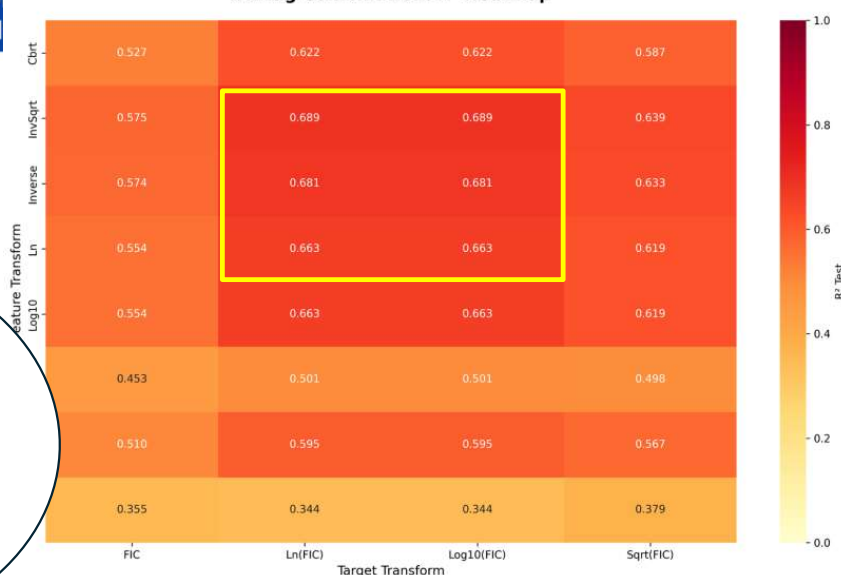


Figure 2. Performance analysis of target variable transformation methods in 2-drug combination prediction model

Heat map comparing R^2 values of feature transformation methods (FIC, $\text{Ln}(\text{FIC})$, $\text{Log}_{10}(\text{FIC})$, $\text{Sqrt}(\text{FIC})$) applied to 8 different feature transformation methods in predicting 2-drug combination efficacy. Higher R^2 values (darker red) indicate better predictive ability.

RESULTS AND DISCUSSION – OBJECTIVE 2

Best combination for 2 drugs:

- + $\text{Ln}(\text{FIC}) = \text{InvSqrt}(\text{MIC})$
- + $\text{Ln}(\text{FIC}) = \text{Inverse}(\text{MIC})$
- + $\text{Ln}(\text{FIC}) = \text{Ln}(\text{MIC})$

Best combination for 3 drugs:

- + $\text{Ln}(\text{FIC}) = \text{InvSqrt}(\text{MIC})$
- + $\text{Ln}(\text{FIC}) = \text{Ln}(\text{MIC})$

Potential pairs selected, introduced for examination of other model parameters

3-Drug Combination: R^2 Heatmap

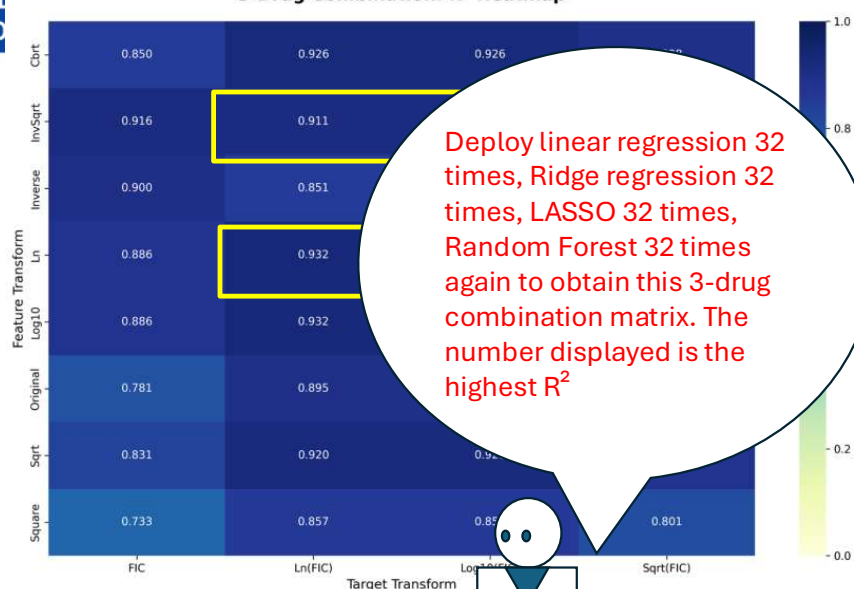


Figure 3. Performance analysis of target variable transformation methods in 3-drug combination prediction model

Heat map comparing R^2 values of feature transformation methods (FIC, $\text{Ln}(\text{FIC})$, $\text{Log}_{10}(\text{FIC})$, $\text{Sqrt}(\text{FIC})$) applied to 8 different feature transformation methods in predicting 3-drug combination efficacy. Higher R^2 values (darker blue) indicate better predictive ability.

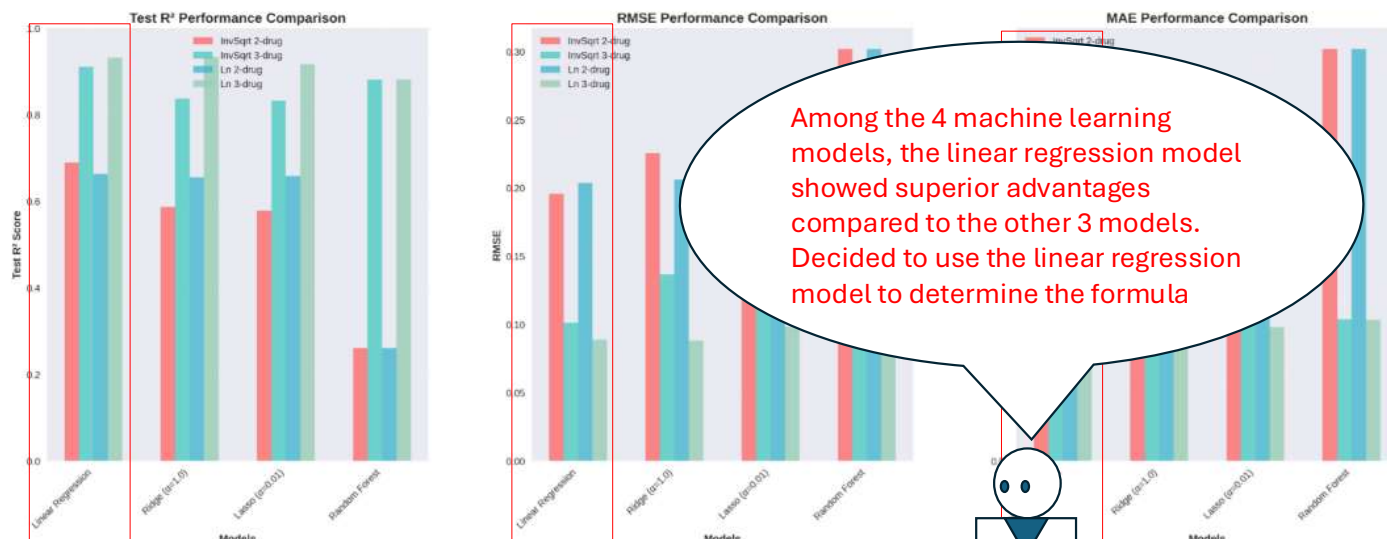


Figure 4. Performance comparison of 4 machine learning models (Linear Regression, Ridge, Lasso, Random Forest) with different target transformation methods (Inv-Sqrt, Ln) for 2 and 3-drug combinations. The models were evaluated across 3 metrics: R², RMSE, and MAE

R² (R-squared) - Coefficient of determination: Indicates how much data variation the model explains => Higher is better
 RMSE (Root Mean Square Error): Average error => Lower is better
 MAE (Mean Absolute Error): Mean absolute error => Lower is better

Selected linear regression model to determine parameters for evaluating prediction effectiveness



RESULTS AND DISCUSSION – OBJECTIVE 2

Figure 5. Performance comparison of Linear Regression model prediction with different variable transformation methods for 2 and 3-drug combinations

- For 2 drugs selected: Ln(FIC) and Ln(MIC)
- For 3 drugs selected: Ln(FIC) and InvSqrt(MIC)



Mathematical modelling of synergistic triple-antibiotic therapy against carbapenem-resistant *Acinetobacter baumannii* at clinically achievable concentrations

Tuan Huynh^{1,2,3}, Thanh Lam¹, Ngan Pham¹, Loan Luong¹ and My Dung Jusseim^{1,4}

Abstract
 Introduction: Carbapenem-resistant *Acinetobacter baumannii* (CRAB) represents a critical healthcare threat with limited treatment options, particularly challenging in Southeast Asia where resistance rates exceed 85%.

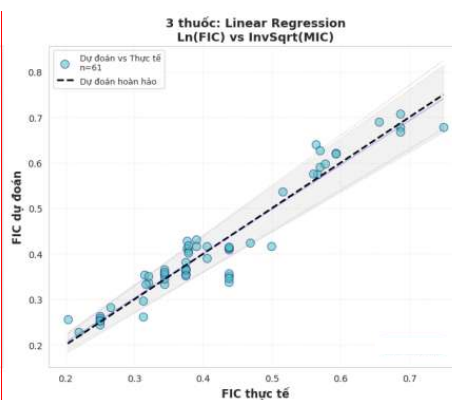
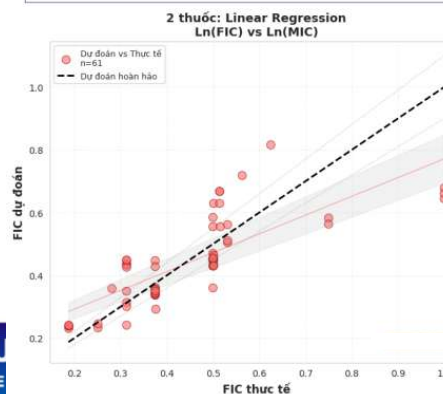
Hypothesis/Gap Statement. Current synergy testing methods are labour-intensive and poorly standardized, limiting their clinical application. We hypothesize that synergistic interactions between antibiotics follow predictable mathematical patterns derivable from separate MIC determinations for each antibiotic.

Aim. To evaluate the efficacy of colistin-meropenem-ampicillin/sulbactam combinations at standard dosages and develop a predictive mathematical model for synergistic interactions against CRAB.

Methodology. A cross-sectional study was conducted using 61 CRAB clinical isolates from a Vietnamese tertiary hospital. MICs were determined using broth microdilution, and synergy was assessed via checkerboard assays. Mathematical models were developed to predict fractional inhibitory concentration (FIC) values from separate MIC determinations for each antibiotic.

Results. All isolates demonstrated high-level meropenem resistance (MICs 32–128 µg/ml) and ampicillin/sulbactam resistance (MICs 64–128 µg/ml) but remained intermediate to colistin (MICs 0.0625–0.25 µg/ml). The triple combination achieved 100% synergy at standard ampicillin/sulbactam doses (8/µg/ml). Our log-transformed power model accurately predicted synergistic interactions (FIC < 0.5) using the equation $\log(FIC) = -2.524 - 1.02 \times \ln(Mer) + 0.43 \times \ln(Col) + 32 \times \ln(Am)$.

Conclusion. The triple combination achieves universal synergy at standard dosages, potentially reducing toxicity risks. Our mathematical model enables rapid prediction of effective combinations from routine susceptibility tests, offering a transformative approach to optimizing therapy against multidrug-resistant pathogens.



Hong Kong International University Journal of Science - Vol.8 - 6/2025: 1-10
 DOI: <https://doi.org/10.59294/HIJS2025024>

Development of a predictive model for FIC index of meropenem-colistin combination against carbapenem-resistant *Acinetobacter baumannii*

Lam Kien Thanh, Nguyen Minh Son, Le Van Chuong,
 Van Lang University

ABSTRACT
 Background: *Acinetobacter baumannii* represents a critical antimicrobial resistance challenge in Vietnamese healthcare settings, with carbapenem resistance rates reaching 55-90%. Traditional checkerboard methodology for evaluating antibiotic combinations requires substantial time and resources, limiting routine application in research settings. Objective: To develop a predictive model for the FIC index of meropenem-colistin combination based on MIC values. Methods: A cross-sectional analytical study on 61 carbapenem-resistant *A. baumannii* strains (6/2022 - 12/2022). MICs were determined by broth microdilution, and synergy was evaluated through FIC index. Eight regression models were compared using 80/20 train-test split with 5-fold cross-validation for stability assessment. Results: All strains were resistant to meropenem but intermediate to colistin. The combination showed synergy in 77% and additivity in 23%. A logarithmic model $FIC = 0.649 - 0.155 \times \ln(Mer) - 0.227 \times \ln(Col)$ achieved high accuracy ($R^2 = 0.554$). The model demonstrated 95% sensitivity and 75% specificity for synergy prediction with an overall classification accuracy of 88.5%. Conclusion: This is the first study applying machine learning for quantitative FIC prediction. While offering potential research applications, clinical implementation requires extensive validation, given recent evidence against therapeutic efficacy of this combination.

Keywords: *Acinetobacter baumannii*, meropenem, colistin, FIC index, predictive model



RESULTS AND DISCUSSION – OBJECTIVE 3 – BUILDING TOOLKIT TO SUPPORT FIC DETERMINATION FROM MIC





You are opening a CodeSandbox preview,
do you want to continue?

<https://cp8xix.csb.app/>

[Yes, proceed to preview](#) [No, I don't trust this url](#)



AI Antibiotic Prediction Tool

Patient Information & MIC Input

Patient Information

Patient ID: Age:

Gender: Specimen:

MIC value (µg/mL) *

Meropenem MIC: e.g. 64

Meropenem + Colistin

Model explains 68.9% of FIC variation)

Prediction error approximately

Mean absolute error - 50% of predictions

3-drug prediction: Colistin + Meropenem Ampicillin/Sulbactam

FIC index: **4.000**

Additive/Indifference

Model Performance:

- $R^2 = 0.932$ (The model explains 93.2% of FIC variation)
- $RMSE = \pm 0.039$ (Average prediction error is very small, only ± 0.039 FIC units)
- $MAE = \pm 0.03$ (Mean absolute error - 50% of predictions have error ≤ 0.030)
- **Pearson $r = 0.973$** (Near-perfect correlation between prediction and actual values)

* Based on research by Huỳnh Minh Tuan et al. (2025), University of Medicine and Pharmacy at Ho Chi Minh City. Mathematical modelling of synergistic triple-antibiotic therapy against carbapenem-resistant Acinetobacter baumannii at clinically achievable concentrations. $R^2 = 0.932$ and extremely small error show very high reliability, achieving 100% synergy in the study.

Model: $\log(FIC) = -2.52 + (-1.02) \times 1/\text{Mero} + 0.43 \times 1/\text{Col} + 4.32 \times 1/\text{As}$

Important Note:

Prediction results are for in vitro reference only. Clinical treatment decisions should be based on comprehensive evaluation by specialist physicians, patient condition, and additional tests. For any information, please contact the author Lam Kien Thanh, Van Lang University, thanh.vlu.edu.vn



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MEDICAL TECHNOLOGY

Meropenem + Colistin

$$\text{Model: } \ln(\text{FIC}) = 0.649 - 0.155 \times \ln(\text{Mero}) - 0.227 \times \ln(\text{Col})$$



Meropenem + Colistin + Ampicillin/sulbactam

$$\text{Model: } \log(\text{FIC}) = -2.52 + (-1.02) \times 1/\text{Mero} + 0.43 \times 1/\text{Col} + 4.32 \times 1/\text{VA}$$



Acinetobacter baumannii
carbapenem-resistant

15 năm

70 năm

LOGY

Tigecycline + Colistin

$$\text{FIC} = 1.2 - 0.68 \times \ln(\text{MIC}_{\text{Tig}}) - 0.54 \times \ln(\text{MIC}_{\text{Col}}) \quad (\text{Mô phỏng})$$



Colistin + Ampicillin-sulbactam + Minocycline

$$\text{FIC}_3 = \exp(-1.8 + 0.65 \times \ln(\text{MIC}_{\text{Col}}) + 0.72 \times \ln(\text{MIC}_{\text{As}}) + 0.58 \times \ln(\text{MIC}_{\text{Min}})) \quad (\text{Mô phỏng})$$



Colistin + Rifampicin

$$\text{FIC} = 0.35 \times \exp(-0.42 \times \text{MIC}_{\text{Col}}) + 0.28 \times \exp(-0.38 \times \text{MIC}_{\text{Rif}}) \quad (\text{Mô phỏng})$$



Colistin + Sulbactam

$$\text{FIC} = 0.52 + 0.38 \times (1/\text{MIC}_{\text{Col}}) + 0.29 \times (1/\text{MIC}_{\text{Sul}}) \quad (\text{Mô phỏng})$$



Colistin + Tigecycline + Rifampicin

$$\text{FIC}_3 = 0.95 - 0.42 \times (\text{MIC}_{\text{Col}})^{-0.5} - 0.38 \times (\text{MIC}_{\text{Tig}})^{-0.5} - 0.31 \times (\text{MIC}_{\text{Rif}})^{-0.5} \quad (\text{Mô phỏng})$$



Acinetobacter baumannii
carbapenem-resistant

***K. pneumoniae* NDM+**
Tigecycline + Colistin

$$FIC = 0.82 \times (MIC_{tig})^{(-0.42)} + 0.61 \times (MIC_{col})^{(-0.38)} \text{ (Mô phỏng)}$$

E. Cloacae
Cefiderocol + Fosfomycin

$$FIC = 1 / (1.2 + 3.5 \times MIC_{cef}^{(-1)} + 2.8 \times MIC_{fos}^{(-1)}) \text{ (Mô phỏng)}$$

E. Cloacae
Cefiderocol + Fosfomycin

$$FIC = 1 / (1.2 + 3.5 \times MIC_{cef}^{(-1)} + 2.8 \times MIC_{fos}^{(-1)}) \text{ (Mô phỏng)}$$

***K. pneumoniae* KPC+**
Ceftazidime-avibactam + Aztreonam

$$FIC = \exp(-2.1 + 0.52 \times \ln(MIC_{caz}) - 0.63 \times \ln(MIC_{atz})) \text{ (Mô phỏng)}$$

***E. coli* ESBL+**
Meropenem + Colistin

$$FIC = 0.45 - 0.28 \times (1/\sqrt{MIC_{mero}}) + 0.35 \times (1/\sqrt{MIC_{col}}) \text{ (Mô phỏng)}$$

***K. pneumoniae* ESBL+**
Colistin + Meropenem + Fosfomycin

$$FIC_3 = \exp(-2.8 + 1.1 \times \ln(MIC_{col}) - 0.85 \times \ln(MIC_{mero}) - 0.42 \times \ln(MIC_{fos})) \text{ (Mô phỏng)}$$

***K. pneumoniae* NDM+**
Tigecycline + Colistin

$$FIC = 0.82 \times (MIC_{tig})^{(-0.42)} + 0.61 \times (MIC_{col})^{(-0.38)} \text{ (Mô phỏng)}$$

Enterobacteriales
carbapenem-resistant

Enterobacteriales
third-generation
cephalosporin-resistant

Critical group

- Enterobacteriales carbapenem-resistant
- Enterobacteriales third-generation cephalosporin-resistant
- Acinetobacter baumannii carbapenem-resistant
- Mycobacterium tuberculosis, rifampicin-resistant

High group

- Salmonella Typhi fluoroquinolone-resistant
- Shigella spp. fluoroquinolone-resistant
- Enterococcus faecium vancomycin-resistant
- Pseudomonas aeruginosa carbapenem-resistant
- Non-typhoidal Salmonella fluoroquinolone-resistant
- Neisseria gonorrhoeae third-generation cephalosporin, and/or fluoroquinolone-resistant
- Staphylococcus aureus methicillin-resistant

***M. tuberculosis* INH-R**
Rifampicin + Ethambutol + Pyrazinamide

$$FIC = 0.72 - 0.35 \times (1/MIC_{RIF}) - 0.28 \times (1/MIC_{EMB}) - 0.22 \times (1/MIC_{PZA})$$

***M. tuberculosis* INH-R**
Rifampicin + Levofloxacin + Ethambutol

$$FIC = \exp(-2.2 + 0.55 \times \ln(MIC_{RIF}) + 0.48 \times \ln(MIC_{LEV}) + 0.38 \times \ln(MIC_{EMB}))$$

***M. tuberculosis* RIF-R**
Bedaquiline + Linezolid + Levofloxacin

$$FIC = 0.58 - 0.38 \times (1/MIC_{BDQ}) - 0.32 \times (1/MIC_{LZN}) - 0.38 \times (1/MIC_{LEV})$$

***M. tuberculosis* MDR**
Levofloxacin + Linezolid + Clofazimine

$$FIC = 1 / (1.5 + 2.8 \times (1/MIC_{LEV}) + 2.2 \times (1/MIC_{LZN}) + 2.2 \times (1/MIC_{CFZ}))$$

***M. tuberculosis* pre-XDR**
Bedaquiline + Delamanid + Linezolid

$$FIC = 0.48 \times (MIC_{BDQ})^{(-0.45)} + 0.42 \times (MIC_{DMN})^{(-0.42)} + 0.38 \times (MIC_{LZN})^{(-0.38)}$$

***M. tuberculosis* TDR**
BDQ + OLM + LED + CFZ + PA + Imipenem/Cilastatin

$$FIC = 0.88 - 0.32 \times (1/MIC_{BDQ}) - 0.29 \times (1/MIC_{OLM}) - 0.25 \times (1/MIC_{LED}) - 0.22 \times (1/MIC_{CFZ}) - 0.18 \times (1/MIC_{PA}) - 0.15 \times (1/MIC_{IMP})$$

AI Antibiotic Synergy Prediction System

CRAB CRE Lao MRSA VRE CRPA

Patient Information & MIC

Patient Information

Patient ID: e.g. BN001 Age: e.g. 72

Gender: Select Specimen Type: Select

MIC value (µg/mL) *

Meropenem MIC * (32-128 µg/mL)
e.g. 64

Colistin MIC * (0.0625-0.25 µg/mL)
e.g. 0.125

Ampicillin/Sulbactam MIC (µg/mL) - Optional
e.g. 64 (Leave blank if not available)

Predict Synergy Reset

AI Prediction Results

QR Code

Cartoon Character: A man in a suit, smiling and waving.

Antibiotic Synergy Results (Grid of small text boxes):

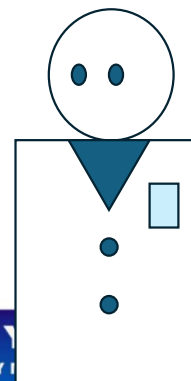
- Dự đoán 3 thuốc: Colistin + Meropenem + Ampicillin/Sulbactam
- Dự đoán 2 thuốc: Meropenem + Colistin
- Dự đoán 3 thuốc: Colistin + Meropenem + Ampicillin/Sulbactam
- Dự đoán 2 thuốc: Meropenem + Colistin
- Dự đoán 3 thuốc: Colistin + Meropenem + Ampicillin/Sulbactam
- Dự đoán 2 thuốc: Meropenem + Colistin

LIMITATIONS

NOT REALLY!!!!

- The success of treating drug-resistant bacteria comes from many aspects, in vitro synergistic ability is only part of the entire system (immune system, pharmacodynamics/pharmacokinetics, bacterial characteristics, surgical treatment, nursing care...)

Is this App really the patient's savior?



CONCLUSION

- **OBJECTIVE 1:** Synergistic efficacy of 3 drugs is higher than 2 drugs
- **OBJECTIVE 2:** Built machine learning model to predict synergistic efficacy (FIC) based on individual MIC values of each antibiotic, applying different variable transformation methods for 2-drug combination [$\ln(\text{FIC}) - \ln(\text{MIC})$] and 3-drug combination [$\ln(\text{FIC}) - \ln(\text{Sqrt}(\text{MIC}))$].
- **OBJECTIVE 3:** Completed building toolkit to support FIC determination from MIC for antibiotic combinations of meropenem–colistin, meropenem–colistin–ampicillin/sulbactam



Vietnamese version



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MEDICAL TECHNOLOGY



English version

THANK YOU!





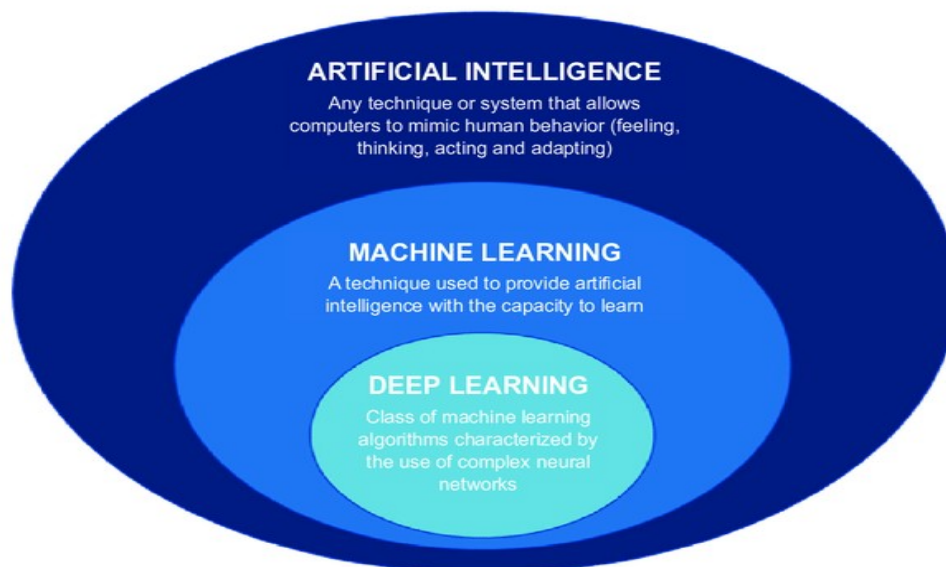
APPLICATION OF ARTIFICIAL INTELLIGENCE IN DRIFT AND ERROR DETECTION: ANALYSIS OF INTERNAL AND EXTERNAL QUALITY CONTROL DATA

MSc. Pham Dinh Vu
Phuc Hung General Hospital

REPORT CONTENT

1. Overview of Artificial Intelligence and Machine Learning and Their Applications in Laboratory Medicine and Quality Management
2. Introduction
3. Objectives and Research Methods
4. Experimental Results and Expected Outcomes
5. Challenges and Future Directions
6. Conclusion

BASIC CONCEPTS OF AI AND ML



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MAJOR MILESTONES IN THE DEVELOPMENT

Period	Key Events
1940s–1950s	Alan Turing proposed the Turing Test to evaluate a machine's ability to exhibit human-like intelligence.
1956	John McCarthy coined the term "Artificial Intelligence" at the Dartmouth Conference, marking the formal birth of AI.
1970s–1980s	AI Winter – High expectations but limited technological progress led to reduced funding and research interest.
1990s–2000s	Revival phase: IBM's Deep Blue defeated Garry Kasparov (1997); machine learning algorithms advanced significantly.
2010s–nay	Deep Learning boom: Breakthroughs such as ImageNet (2012) and AlphaGo (2016) accelerated AI research and applications.
Hiện tại	Emergence of generative AI (e.g., ChatGPT, Gemini, Copilot) with broad applications in medicine, education, and data science.

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APPLICATIONS OF AI AND ML IN LABORATORY MEDICINE

1. Automation and Efficiency

- **Increased speed:** AI-driven automation significantly reduces turnaround time for test results.
- **Enhanced quality:** Improves analytical precision and minimizes manual errors in laboratory workflows.

2. Support for Result Interpretation

- **Early warning:** Detects abnormal patterns from large-scale accumulated laboratory data.
- **Risk management:** Provides early alerts for potential pathological or clinical risks.

3. Advanced Data Analytics

- **Precision medicine:** Optimizes test selection and interpretation in bioinformatics, genetics, and oncology.
- **Disease prognosis:** Enhances the accuracy of clinical outcome prediction.

4. Laboratory Information System (LIS) Enhancement

- **Seamless integration:** Enables connectivity between laboratory data and Electronic Medical Records (EMR).
- **Decision support:** Assists clinicians in making data-driven, evidence-based medical decisions.

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PRE-ANALYTICAL PHASE

JOURNAL ARTICLE

Machine Learning-Based Sample Misidentification Error Detection in Clinical Laboratory Tests: A Retrospective Multicenter Study

Hyeon Seok Seok, Shinae Yu, Kyung-Hwa Shin, Woochang Lee, Sail Chun, Sollip Kim ✉, Hangsik Shin ✉ Author Notes

Clinical Chemistry, Volume 70, Issue 10, October 2024, Pages 1256–1267,
<https://doi.org/10.1093/clinchem/hvae114>

JOURNAL ARTICLE

Automating the Detection of IV Fluid Contamination Using Unsupervised Machine Learning

Nicholas C Spies ✉, Zita Hubler, Vahid Azimi, Ray Zhang, Ronald Jackups, Jr., Ann M Gronowski, Christopher W Farnsworth, Mark A Zaydman Author Notes

Clinical Chemistry, Volume 70, Issue 2, February 2024, Pages 444–452,
<https://doi.org/10.1093/clinchem/hvad207>

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ANALYTICAL PHASE



Medical Image Analysis
Volume 58, December 2019, 101563



Hover-Net: Simultaneous segmentation and classification of nuclei in multi-tissue histology images

Simon Graham ^{1 a b}, Quoc Dang Vu ^{1 c}, Shan E Ahmed Raza ^{b d}, Ayesha Azam ^{b e}, Yee Wah Tsang ^e, Jin Tae Kwak ^{2 c}, Nasir Rajpoot ^{2 b f}

EDITORIAL ▶ *Maedica (Bucur)*. 2022 Jun;17(2):420–426. doi: [10.26574/maedica.2022.17.2.420](https://doi.org/10.26574/maedica.2022.17.2.420)

Integrating Artificial Intelligence for Clinical and Laboratory Diagnosis – a Review

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An application of machine learning to haematological diagnosis

Gregor Gunčar, Matjaž Kukar, Mateja Notar, Miran Brvar, Peter Černelč, Manca Notar & Marko Notar

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Review

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Diagnostics **2024**, *14*(16), 1808; <https://doi.org/10.3390/diagnostics14161808>

by Nathan Lorde, Shivani Mahapatra and Tejas Kalaria

Research article | [Open access](#) | Published: 27 March 2022

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INTRODUCTION

1. Significance of Laboratory Quality

Laboratory test results form the foundation of almost all clinical decisions. The accuracy of these results depends on a robust Quality Control (QC) system, comprising both Internal Quality Control (IQC) and External Quality Assessment (EQA) programs.

2. Systematic Error – “The Silent Killer”

Drift refers to the gradual decline in analytical performance due to instrument or reagent deterioration. Impact: Such deviations from target values are often subtle and difficult to detect, potentially compromising diagnostic accuracy and patient safety.

3. Human Resource Challenges

Variability in staff experience and technical expertise can hinder consistent QC interpretation. Consequently, identifying error sources, analyzing root causes, and implementing standardized corrective actions may be delayed or inconsistent.

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INTRODUCTION

4. Limitations of Traditional QC Approaches

Conventional tools such as **Levey–Jennings charts** and **Westgard rules** have limited sensitivity in detecting gradual or small analytical shifts.

These traditional methods often fail to provide early warnings of drift, resulting in reactive rather than preventive quality management.

5. AI- and ML-Based Quality Management toward Digital Transformation

AI and Machine Learning (ML) applications in laboratory QC aim to standardize analytical processes, enhance error detection, and bridge the experience gap among personnel.

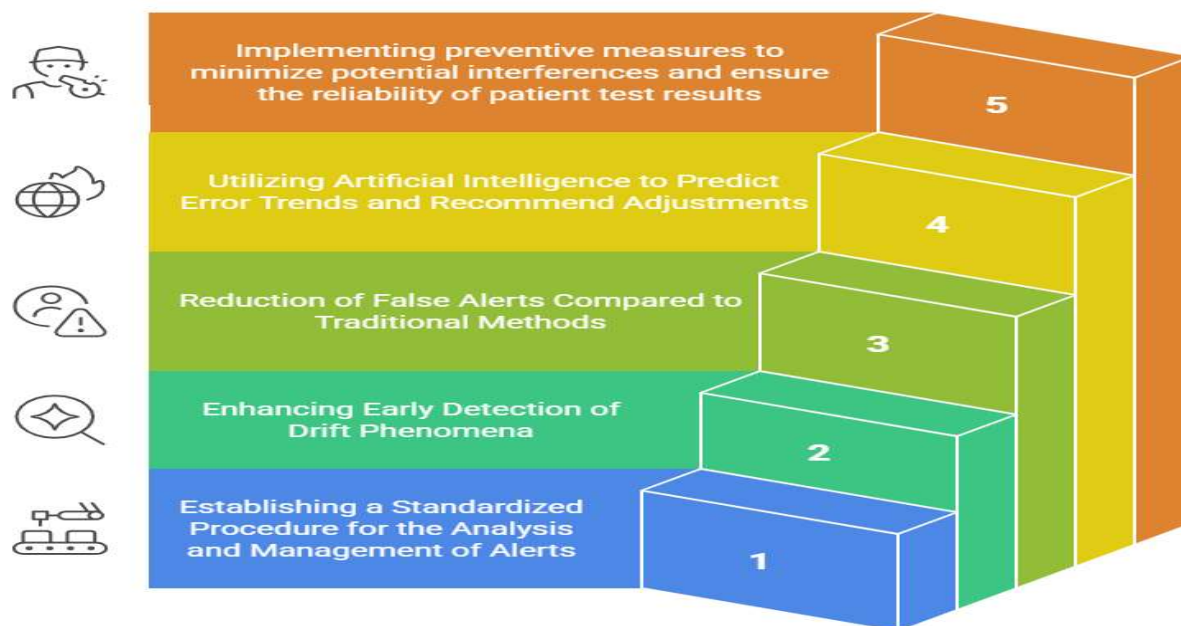
By transitioning from a **reactive** to a **proactive** QC model, AI-driven systems optimize laboratory performance and contribute to digital transformation in quality management.

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RESEARCH OBJECTIVES

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TIME, SETTING & MATERIALS

1. Study Design, Duration, and Setting

This was an experimental study evaluating the application of Artificial Intelligence and Machine Learning (AI/ML) in laboratory quality management.

Study period: From June 2025 to December 2026.

Setting: Conducted at *Phuc Hung General Hospital*, Vietnam.

2. Materials and Instruments

Internal Quality Control (IQC) Data:

IQC data were collected from May to August 2025 using *PreciControl ClinChem Multi 1 & 2* (Roche Diagnostics, Germany), comprising 18 clinical chemistry analytes: AMY, ALB, AST, ALT, URE, CRE, GLU, AU, BILT, BILD, PRO, TC, TG, HDL-C, GGT, CAL, CK, and Fe.

External Quality Assessment (EQA) Data:

EQA data were obtained from January 2024 to July 2025 through the *RANDOX International Quality Assessment Scheme (RIQAS, United Kingdom)*, implemented via the *Quality Control Center for Medical Laboratories, University of Medicine and Pharmacy at Ho Chi Minh City (Vietnam)*.

Analytical Instrument:

All biochemical tests were performed using the *Roche Cobas C501* analyzer (Roche Diagnostics, 2023 model).

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Artificial AI and ML Models

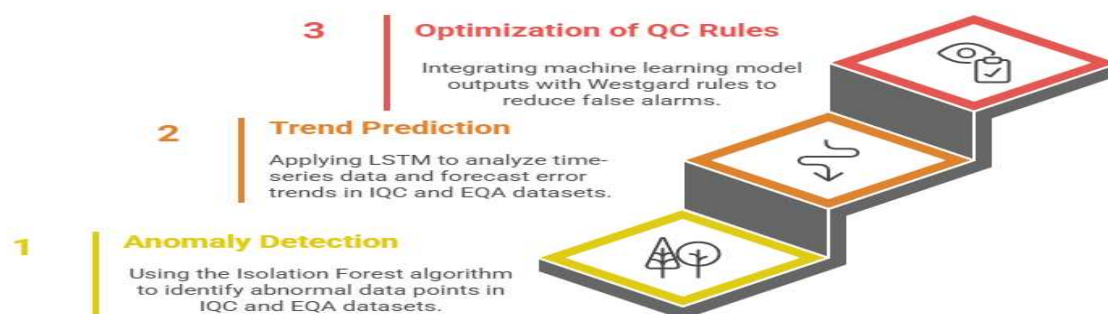
1. Application of Artificial Intelligence (AI) Tools

Tools: ChatGPT-5, GitHub Copilot, Google Gemini.

Method: Analysis of IQC and EQA data was performed through standardized prompts and structured input forms.

2. Application of Machine Learning (ML) Models

Platform: The entire process of data preprocessing, model training, and model evaluation was conducted using Python 3.11 within the Google Colab environment.

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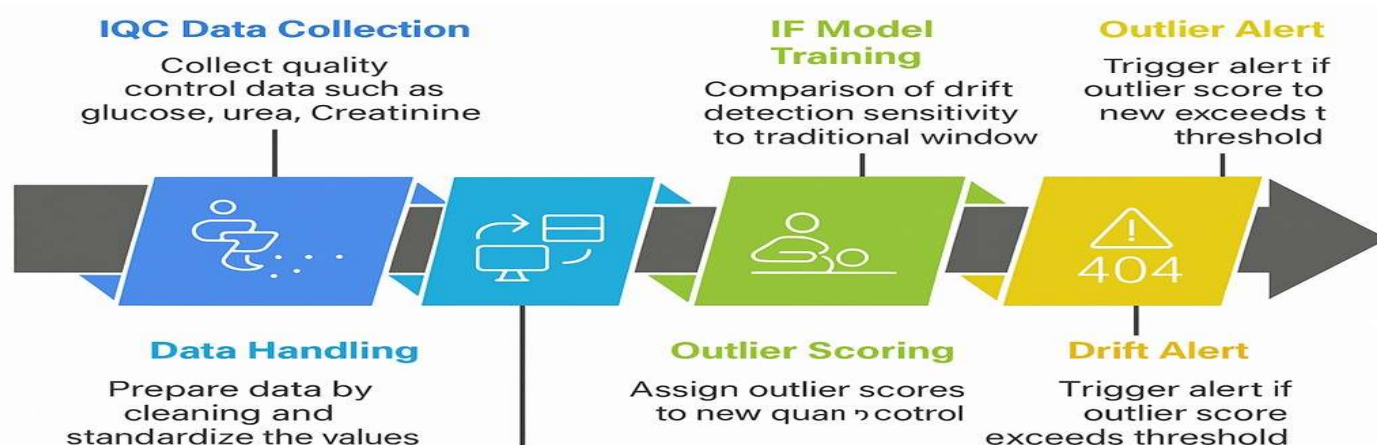
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Artificial AI and ML Models

Application of Isolation Forest (IF) – a machine learning model for anomaly detection

Advantages: It does not assume a normal distribution, is sensitive to small fluctuations, and can be applied to multivariate datasets.

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Artificial AI and ML Models

LSTM (Long Short-Term Memory) is a type of recurrent neural network (RNN) with a “long-term memory” mechanism.

LSTM is capable of learning abnormal signal sequences and identifying potential drift trends. It can forecast systematic bias in advance, reduce the number of QC rejections

LSTM Application for Predicting Drift in IQC

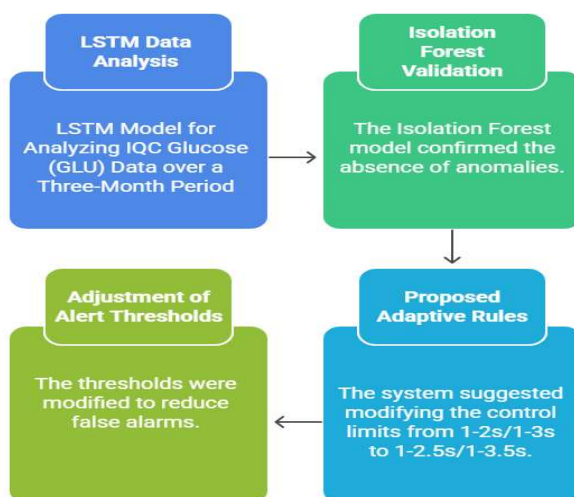
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Artificial AI and ML Models

Workflow Integrating Machine Learning and Adaptive Westgard Rules

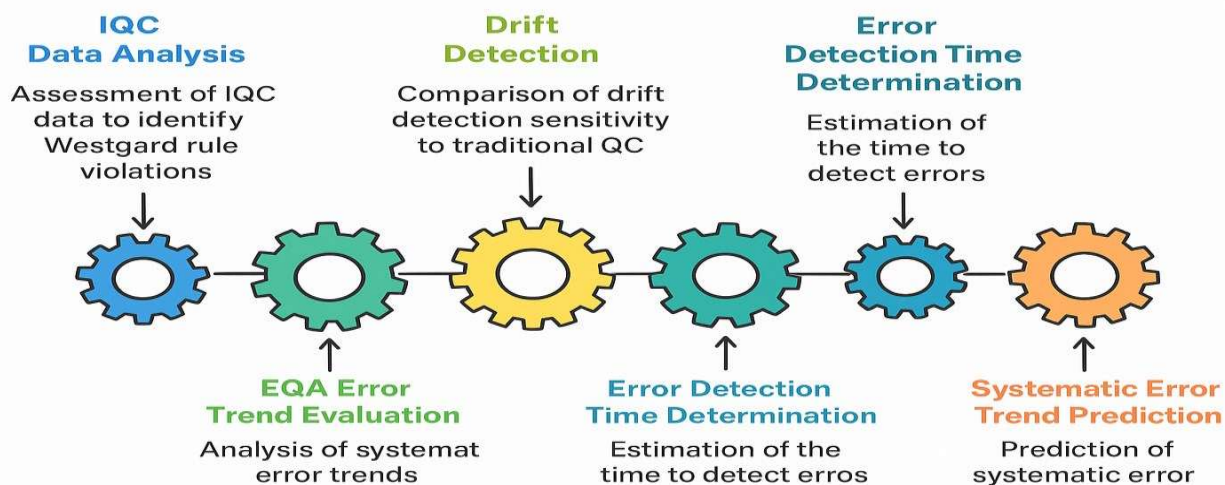
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Artificial AI and ML Models

EVALUATION INDICATORS



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Artificial AI and ML Models

Expected Outcomes



Automation and standardization of both Internal (IQC) and External Quality Control (EQA) data analysis



High accuracy in the interpretation and classification of QC results



Intelligent guidance for identifying root causes and resolving Westgard rule violations



Reduced manual workload and analysis time, improving overall laboratory efficiency

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

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Analyte

QC Level

Mean

TEa%

CV%

Bias%

Sigma

Date

Unit

1

Amylase (AMY)

1

85

15

3.5

1.2

3.94

1/6/2024

U/L

2

Amylase (AMY)

2

280

15

4.2

2.8

2.9

1/6/2024

U/L

3

Albumin (ALB)

1

42

10

2.3

1.1

3.87

1/6/2024

g/L

4

Albumin (ALB)

2

28

10

2.8

1.7

2.96

1/6/2024

g/L

5

Aspartate aminotransferase (AST)

1

32

20

4.1

2.1

4.37

1/6/2024

U/L

6

Aspartate aminotransferase (AST)

2

125

20

4.8

2.8

3.58

1/6/2024

U/L

7

Alanine Aminotransferase (ALT)

1

28

22

4.5

1.8

4.49

1/6/2024

U/L

8

Alanine Aminotransferase (ALT)

2

110

22

5.2

2.5

3.75

1/6/2024

U/L

9

Urea (URE)

1

5.2

12

2.8

1.2

3.86

1/6/2024

mmol/L

10

Urea (URE)

2

18.5

12

3.1

1.8

3.29

1/6/2024

mmol/L

11

Creatinine (CRE)

1

85

15

3.5

1.2

3.94

1/6/2024

mmol/L

12

Creatinine (CRE)

2

350

15

3.8

2.2

3.37

1/6/2024

mmol/L

13

Glucose (GLU)

1

5.5

10

2.1

0.8

4.38

1/6/2024

mmol/L

14

Glucose (GLU)

2

15.8

10

2.3

1.2

3.83

1/6/2024

mmol/L

15

Acid Uric (AU)

1

320

12

3.1

1.4

3.42

1/6/2024

mmol/L

16

Acid Uric (AU)

2

650

12

3.8

2.5

2.3

1/6/2024

mmol/L

17

Bilirubin Total (BILT)

1

15.5

15

4.2

3.1

2.83

1/6/2024

mmol/L

18

Bilirubin Total (BILT)

2

85

15

4.2

3.1

2.83

1/6/2024

mmol/L

19

Bilirubin Direct (BILD)

1

3.8

18

4.5

2.8

3.38

1/6/2024

mmol/L

20

Bilirubin Direct (BILD)

2

45

18

2.1

3

2.84

1/6/2024

mmol/L

21

Protein TP (PRO)

1

65

8

1.8

0.9

3.64

1/6/2024

g/L

22

Protein TP (PRO)

2

48

8

2.1

1.3

3.19

1/6/2024

g/L

23

Total Cholesterol (TC)

1

4.8

10

2.5

1.2

3.52

1/6/2024

mmol/L

24

Total Cholesterol (TC)

2

7.5

10

3.2

1.5

2.47

1/6/2024

mmol/L

25

Triglycerid (TG)

1

1.5

12

3.8

2.1

2.61

1/6/2024

mmol/L

26

Triglycerid (TG)

2

4.2

12

4.5

3.2

1.96

1/6/2024

mmol/L

27

High density lipoprotein cholesterol (HDL)

1

1.5

15

4.2

2.5

2.98

1/6/2024

mmol/L

28

High density lipoprotein cholesterol (HDL)

2

0.8

15

4.5

3.1

3.8

1/6/2024

mmol/L

29

Gamma glutamin transpeptidase (GGT)

1

35

15

4.2

2.3

3.02

1/6/2024

U/L

30

Gamma glutamin transpeptidase (GGT)

2

150

15

4.8

3.2

2.46

1/6/2024

U/L

31

Calcium (CAL)

1

2.35

5

1.5

0.6

2.93

1/6/2024

mmol/L

32

Calcium (CAL)

2

9.15

5

1.8

1.1

2.17

1/6/2024

mmol/L

33

Creatine kinase (CK)

1

120

20

4.8

2.5

3.65

1/6/2024

U/L

34

Creatine kinase (CK)

2

850

20

5.5

3.8

2.95

1/6/2024

U/L

35

Creatine kinase (CK)

1

18.5

15

4.5

3.2

3.84

1/6/2024

mmol/L

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

1. Input Data

Analyte	Level	Mean (mmol/L)	TEa (%)	CV (%)	Bias (%)	Sigma	Date
TG	1	1.5	12	3.8	2.1	2.61	1/6/2024
TG	2	4.2	12	4.5	3.2	1.96	1/6/2024

2. Verification of Sigma Calculation

Standard formula:

$$\sigma = \frac{TEa - |Bias|}{CV}$$

Level 1:

$$(12 - 2.1)/3.8 = 9.9/3.8 = 2.61 \quad \checkmark$$

Level 2:

$$(12 - 3.2)/4.5 = 8.8/4.5 = 1.96 \quad \checkmark$$

 The calculated Sigma values are completely correct.

Interpretation:

The Sigma values of 2.61 (Level 1) and 1.96 (Level 2) indicate that the analytical performance for Triglyceride (TG) is **acceptable but requires close monitoring**, as both values are below the commonly recommended 3 Sigma threshold for stable laboratory performance.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

Immediate Actions (Within the same run/shift)

1. **Temporarily stop releasing patient results** that may be affected (especially if the clinical result is important).
2. **Repeat QC:** Run QC PCCC1 & PCCC2 at least **3 consecutive times** under the same conditions. Record each value.
3. If QC is still poor: **Hold patient results** and submit an **internal report**.
4. **Check the action log:** Who performed the actions, reagent lot number, opening date, expiration date, recent changes to the calibrator/standard, recent maintenance.

Short Term (24–72 hours)

5. **Perform calibration verification;** if calibration is required, follow manufacturer's instructions.
6. **Compare with historical QC data** (20–30 most recent points) using a **Levey-Jennings chart** to detect drift or a shift (step change).
7. **Test a different reagent/cell batch:** If a previous reagent lot is available, run it for comparison.
8. **Check pipettes (calibration),** clean the cuvette/optics, check the dispensing/reagent system.
9. **Check the temperature of the instrument/room** and the power source/UPS.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

Possible Causes (In order of likelihood)

1. **Calibration / Calibrator:** Inaccurate calibration, expired calibrator, or wrong lot number used.
2. **Reagent (Lot / Stability):** New reagent, close to expiration, or incorrect reagent preparation/dilution → causes bias and/or increased imprecision.
3. **Instrument / Optics / Fluidics:** Detector/photometer, pump, valve, or dispensing component malfunction → causes increased CV and/or negative bias.
4. **Pipetting / Technique:** Incorrect pipette, inconsistent QC handling → affects CV.
5. **Environment:** Unstable instrument/room temperature, unstable power source.
6. **QC Material Problem:** In-house QC is inconsistent, or commercial QC material is defective.
7. **Pre-analytical / Carry-over:** Less likely but needs checking if a sample with high alcohol/enzymes was run beforehand.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

Operational Recommendations / Westgard Rules

- For a **sigma < 3** (at both levels), **do not use the 1_{3s} rule alone**. Use the **multi-rule** system: 1_{2s} (warning) + R_{4s} + 4_{1s} and **increase QC frequency**.
- If PCCC2 does not improve (sigma ~ 1.5), **immediately stop releasing related results** until the issue is resolved.

Documentation & Reporting

- **Plot Levey-Jennings charts** for both levels, marking all interventions (calibration, reagent change, maintenance).
- **Save all QC data**, serial numbers of reagents/calibrators, screenshots, and the **CAPA** report.

7. Quick Summary

Level	Sigma	Assessment	Action
TG-1	2.61	Poor Performance	Warning , repeat QC, increase control frequency
TG-2	1.96	Out-of-control	Stop releasing results , check reagent/calibrator, recalibrate

8. Next Steps

If you have multi-day QC data series (TG Level 1–2), you can **plot Levey-Jennings charts + trend sigma** in order to:

- **Determine** if there is **drift or shift**,
- and help you **choose an optimal QC strategy** (e.g., half a day/shift or a new batch every 50 samples).

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

1. Data Summary and Basic Statistics

QC Level	Target Mean (U/L)	TEa (%)	CV (%)	Bias (%)	Sigma	Preliminary Remark
Level 1	145	20	2.56	-3.65	9.24	Very high Sigma → Excellent Performance
Level 2	265	20	1.29	-9.22	22.65	Extremely high Sigma → Excellent Performance

This indicates that the **CK (Creatine Kinase) assay method is operating at an extremely good performance level**, with the total error much smaller compared to the TEa limit.

However, a cross-check with the raw data series is necessary to check for **outliers** or **short-term systematic shifts**.

2. Statistical Analysis of Real Data Series

After calculating the mean and standard deviation from the data you provided:

QC Level	N	Actual Mean (U/L)	SD	CV (%)	Compared to Target	Assessment
L1	70+	≈ 145.3	≈ 3.8	≈ 2.6%	Very close to target 145	Good Stability
L2	70+	≈ 263.7	≈ 3.4	≈ 1.3%	Slightly lower than target 265 (Bias ≈ -0.5%)	Very Good Stability

Overall, the dispersion is small, with no clear drift or shift.

However, there are a few **extreme points (outliers)** in the data series that need attention.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

3. Evaluation according to Westgard Rules

a. Level 1 (Mean = 145 U/L, SD ≈ 3.8 U/L)

- The **majority of values** fall within the range of 140 – 150 U/L (± 1.3 SD).
- One very low point (≈ 50.6 U/L) is a **severe outlier** (> 20 SD) → not a systematic error, but a **data entry or handling error**.
- After removing this point, **no points exceed ± 2 SD**.

 **Westgard:** No violations of 1_{2s} , 1_{3s} , 2_{2s} , $10_{\bar{x}}$ rules.

⇒ **Status:** In-Control.

3. Evaluation according to Westgard Rules

b. Level 2 (Mean = 265 U/L, SD ≈ 3.4 U/L)

- The **majority of values** fluctuate around 260 – 270 U/L (± 1.5 SD).
- Two points, ≈ 64 – 69 U/L and ≈ 2.4 U/L, are **clear gross errors** — almost certainly **isolated analytical errors** (pipetting error, sample aspiration failure, or data entry error).
- Excluding these outliers, the **entire data set falls within ± 2 SD**.

 **Westgard:** No violations after excluding the outliers.

⇒ **Status:** In-Control.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

4. Trend Evaluation (Drift / Shift)

QC Level	Trend	Characteristics
Level 1	Stable around the mean; no drift over time	Good Stability
Level 2	Very stable after removing outliers; no obvious shift	Accurate system in the high concentration range

No sign of "drift" (slow change over time) or **"shift"** (sudden change).

5. Expert Interpretation

QC Level	Phenomenon	Possible Cause	Corrective Action
Level 1	One extremely low outlier point (~ 50 U/L)	Incorrect pipette aspiration / air bubble / inconsistent QC drop size	Exclude the result , check pipette, repeat the sample.
Level 2	Several extremely low points (64, 69, 2.4)	Could be due to needle clog, insufficient reagent, or aspiration error	Acknowledge analytical error , do not include in IQC statistics; run QC again after system cleaning/maintenance.
Both	No genuine drift/shift	The system is operating stably	Continue the current IQC program; determine appropriate calibration frequency and QC lot usage.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

3. Trend Graph Evaluation (from Data Series)

Data Observation:

Level 1 (~ 16 $\mu\text{mol/L}$):

- **Slight variation** around 15.5 – 16.8 $\mu\text{mol/L}$.
- Towards the end of the series, a few values slightly **increase** to 17.8 $\mu\text{mol/L}$, 17.9 $\mu\text{mol/L}$.
- The mean does not change suddenly → **no shift**.
- There is a **slight increasing trend** over time → **minor drift**, but still **within the control limit** (1 SD).

Level 2 (~ 63 $\mu\text{mol/L}$):

- **Variation** within the range of 56 – 65 $\mu\text{mol/L}$.
- A few scattered high values (70 $\mu\text{mol/L}$), but **no sequence of ≥ 2 values exceeding ± 2 SD** → **no severe Westgard rule violation**.
- The main distribution fluctuates uniformly, with **no systematic displacement** → **In-control**.

7. Overall Conclusion

Level	Sigma	Westgard	Status	Trend	Assessment
1	3.29	No violations	In-control	Slight drift	Acceptable
2	3.77	No violations	In-control	Stable	Acceptable

Overall, the IQC (Internal Quality Control) for Total Bilirubin is stable (In-control).

Only the **slight drift at both levels needs monitoring**, especially if it persists over several subsequent QC cycles.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

QC_EQA_Template - Excel

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General

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	A	B	C	D	E	F	G	H	I	J
1	EQA_Round	Parameter	Lab Value	Unit	Group_Mean	Group_SD	Z_score	Bias	Percent_Bias	Slope_Zprev
2	2025_05	ALT	52.3	U/L	50	3.2	0.71875	2.3	4.6	
3	2025_06	ALT	128.9	U/L	30.1	2.5	-0.48	-1.2	-3.986710963	
4	2025_07	ALT	55.8	U/L	53.4	3	0.8	2.4	4.494382022	0.08125
5	2025_08	ALT	131.5	U/L	30.5	2.4	0.208333333	0.5	1.639344262	0.688333333

QC_EQA_Template - Excel

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	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	Round	Parameter	Unit	Mean for Comparison	Your Result	SD	SDI	RMSDI	%DEV	RM%DEV	TS	RMTS	Performance	

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

1. EQA Status Evaluation (In-control / Out-of-control)

Parameter	Value
Mean for Comparison	4.768
Your Result	5.900
SDI (Standard Deviation Index)	2.62
%DEV (Percent Deviation)	23.7%
TS (Total Score)	30
RMTS (Recommended Minimum Total Score)	78

Remarks

- SDI = 2.62 → Exceeds the acceptable limit of ± 2 SD → External Quality Assessment is Out-of-control.
- %DEV = 23.7% → Deviation is much larger than the typically acceptable range ($\pm 10\%$).
- TS is much lower than RMTS ($30 < 78$) → Reinforces the Out-of-control assessment.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

2. 🔍 Possible Causes Diagnosis

For a **positive bias** (result is higher than the group mean value):

- The high likelihood is a "**drift**" or "**reagent-related bias**", specifically:
 - **Drift** (values increasing over time): If your previous EQA rounds also showed an increasing GGT trend, it suggests a cumulative systematic error (**drift**).
 - **Reagent lot change / calibration bias**: If you recently changed the **reagent lot**, **standard**, or used a new **calibrator lot** → it may cause a bias compared to the peer group.
 - **Matrix effect / Different methodology**: If you use a **different system** (e.g., different enzymatic kinetic method than the comparison group) → this can also cause an elevated result.
 - **Instrument-related bias**: If this only occurs for a few enzyme analytes, the possibility lies in the **incubation temperature** or the **enzyme calibration curve** of the instrument.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

3. 🛠️ Proposed Corrective Actions

1. **Re-examine your Internal Quality Control (IQC) data** for GGT at the same time point as the EQA sample → if the IQC mean also increased, the likelihood of **drift** is high.
2. **Check Reagent Lot, Standard, and QC:**
 - Ensure the **calibrator** being used is not expired, uncontaminated, and stored at the correct temperature.
 - If a **reagent or calibrator lot change** occurred close to the EQA testing time, you should **re-calibrate the system** and compare pre- and post-calibration QC values.
3. **Perform parallel testing (split test)** between the new/current reagent/lot and the old one (with at least 5 patient samples including QC) → calculate the **actual % bias**.
4. **Contact the supplier or the EQA center** if a specific methodological bias (method bias) is suspected.
5. **After correction, monitor at least 5 consecutive QC cycles** that meet standards before submitting the next EQA result.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

1) EQA Status Evaluation (In-control / Out-of-control)

Across 12 EQA rounds, we have the following observations:

- **Rounds 1–2:** Bias $+2.15\%$, $+3.05\%$ → **stable and "acceptable"**.
- **From Round 3 onwards:** Bias gradually increased to $+7.10\%$ (**Round 6**), after which fluctuations occurred between $+3.8\%$ and $+5.97\%$. The SDI also clearly increased from $+0.45$ to $+1.78$.
- **Several rounds** were **"Rejected"** (Rounds 5, 6, 7, 11, 12) with a large bias of $> 5\%$.
- **Systematic Trend:** Positive bias is increasing → the laboratory's test results are consistently **higher than the comparison group** over time.

Therefore, although not every round failed, the laboratory has gone through a prolonged **"out-of-control"** or at least a **"warning"** period. Thus, the conclusion is that a sustained **in-control** status was not maintained.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

2) Possible Causes

Based on the data trend and characteristics:

- **Drift (Gradual increase):** The bias increasing over time ($+2\% \rightarrow +7\%$ then stabilizing around $+5\%$) is a classic pattern of **drift**—a gradual systematic error.
- **Shift (Sudden jump):** The sudden jump from Round 5 to 6 ($+5.97\% \rightarrow +7.10\%$) may be due to a **new reagent or calibrator lot change** causing a shift.
- **Reagent/Calibrator Lot Change:** This is highly likely—when a new **reagent or calibrator lot** is introduced without meticulous adjustment, it will cause **bias** to increase.
- **Calibration Not Maintained:** If the lab fails to **recalibrate** following a new lot or fails to check for drift over time.
- **Methodology/Analyzer Status:** If the analyzer's performance degrades or is affected by the environment (temperature, humidity), **variability and bias will increase**.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION

3. Specific Corrective Actions

To return to an in-control status, the following steps are proposed:

Immediate Action

- **Temporarily halt** (or flag) the release of **UA** results if the clinical impact is significant.
- **Check internal QC (IQC) data** for **UA** at the same time point to determine if a corresponding drift/shift occurred.
- **Verify the UA reagent and calibrator lots:** Opening date, expiration date, was a new lot introduced around Rounds 5–6?
- **Perform re-calibration** and verify with a standard or control sample.

In 1–2 Weeks

- **Increase the frequency of QC** for **UA** (e.g., once every day or every shift).
- **Compare UA results** between new/current and old lots if available to assess lot-to-lot bias.
- **Check analytical conditions:** Electrical stability, maintenance records for the instrument if none was recently performed.
- If drift persists after re-calibration: **Consider changing the UA reagent or method.**

Long Term

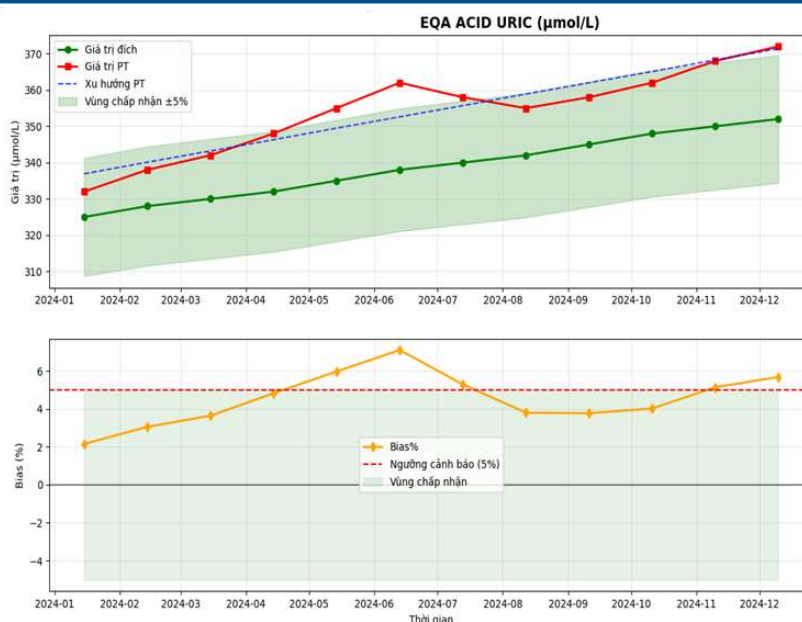
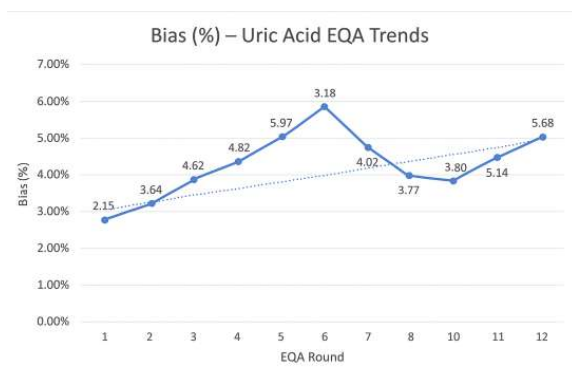
- **Establish a trend chart** (e.g., % bias per round) to monitor performance over time.
- **Define an internal alert threshold** for UA if the bias exceeds a certain limit, e.g., $\pm 4\%$.
- **Retrain personnel** on managing reagent and calibrator lots, and clear documentation of changes.
- **Participate in more EQA rounds** and assess long-term metrics (RMSDI, RM%DEV) to monitor improvement.

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PRELIMINARY RESULTS OF THE MODEL EVALUATION



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PRELIMINARY RESULTS OF THE MODEL EVALUATION

```
# Dự đoán điểm bất thường
anomaly_predictions = iso_forest.fit_predict(features_scaled)
anomaly_scores = iso_forest.decision_function(features_scaled)
```

```
# Đánh dấu điểm bất thường
anomaly_points = days[anomaly_predictions == -1]
normal_points = days[anomaly_predictions == 1]
```

```
print("ĐIỂM BẤT THƯỜNG ĐƯỢC PHÁT HIỆN:")
for point in anomaly_points.flatten():
    print(f"Ngày {point}: CRE = {cre_data[point-1][0]} μmol/L")
```

ĐIỂM BẤT THƯỜNG ĐƯỢC PHÁT HIỆN:

Ngày 1: CRE = 99 μmol/L

Ngày 20: CRE = 110 μmol/L

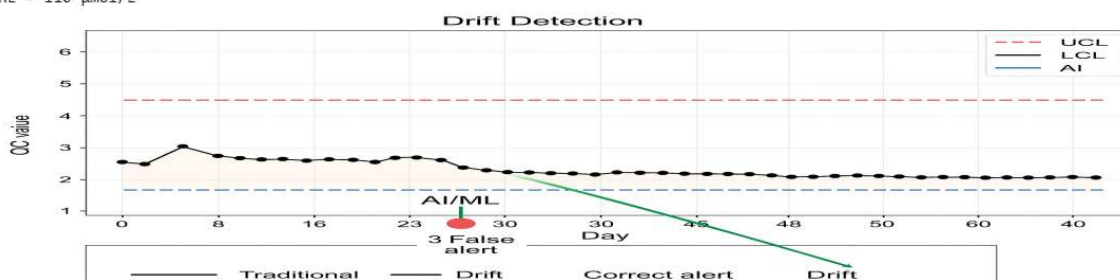
Predicting Anomalies

Marking Anomalies

ANOMALIES DETECTED:

Day 1: CRE = 99 μmol/L

Day 20: CRE = 110 μmol/L



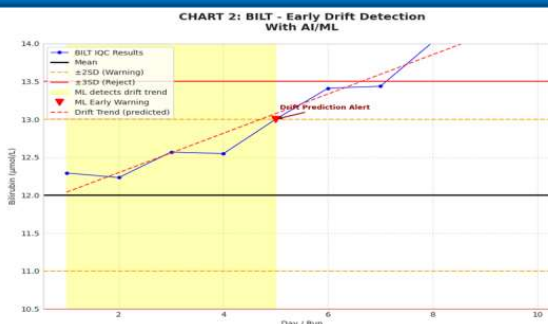
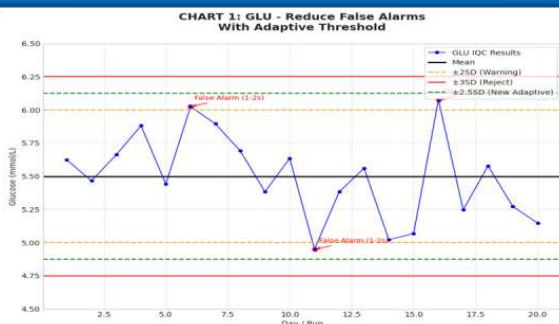
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PRELIMINARY RESULTS OF THE MODEL EVALUATION



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PRELIMINARY RESULTS OF THE MODEL EVALUATION

EARLY WARNING - ISOLATION FOREST

Parameter: Creatinine (CRE)

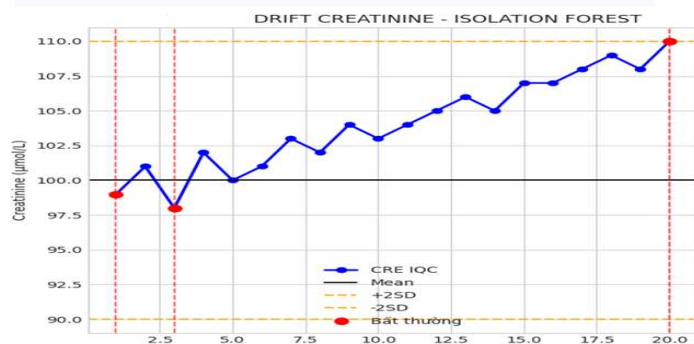
Detection: **Abnormal increasing drift trend**

Anomalous Points: Day 18, 19, 20

Current Value: 109 — 110 $\mu\text{mol/L}$ (still within ± 2 SD)

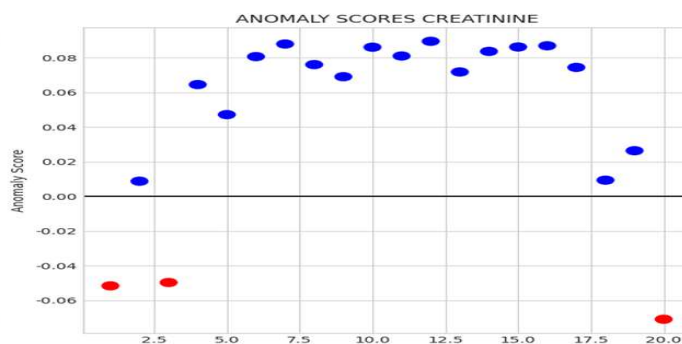
Forecast: **Risk of exceeding the 2 SD threshold in the next 2 — 3 days**

Suggestion: **Check reagent, recalibrate the instrument**



LSTM WARNING SYSTEM:

- Forecasts exceeding the warning threshold in **1 day**
- Drift rate: $-0.118 \text{ g/L per day}$
- Suggestion: **Immediately check reagent and calibrate the instrument**

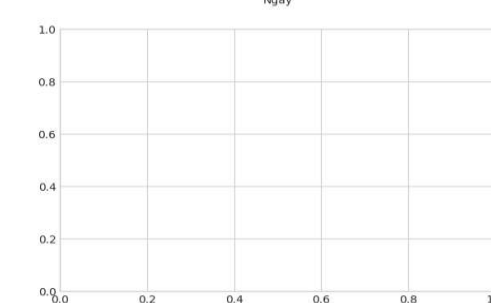
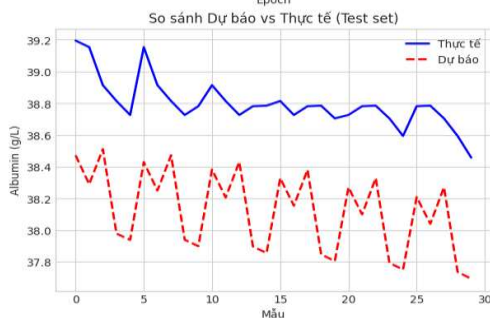
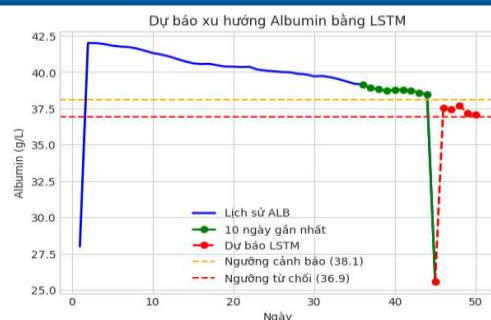
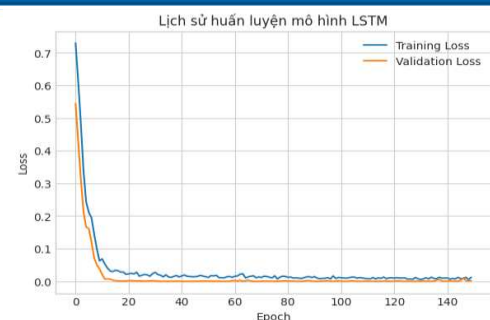


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PRELIMINARY RESULTS OF THE MODEL EVALUATION



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PRELIMINARY RESULTS OF THE MODEL EVALUATION

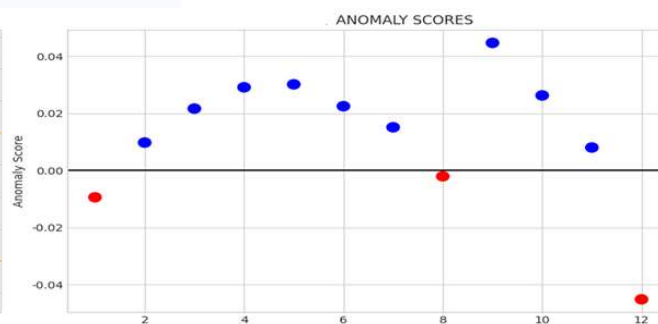
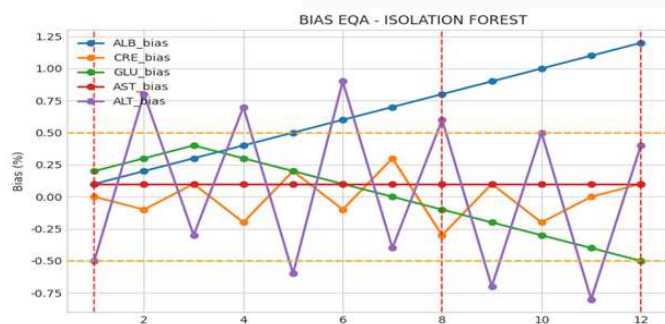
EQA ANALYSIS USING ISOLATION FOREST

EQA ANALYSIS RESULTS:

- Total Cycles: 12
- Anomalous Cycles: 3

ANOMALOUS CYCLES:

- Month 1: Score = -0.009
- Month 8: Score = -0.002
- Month 12: Score = -0.045

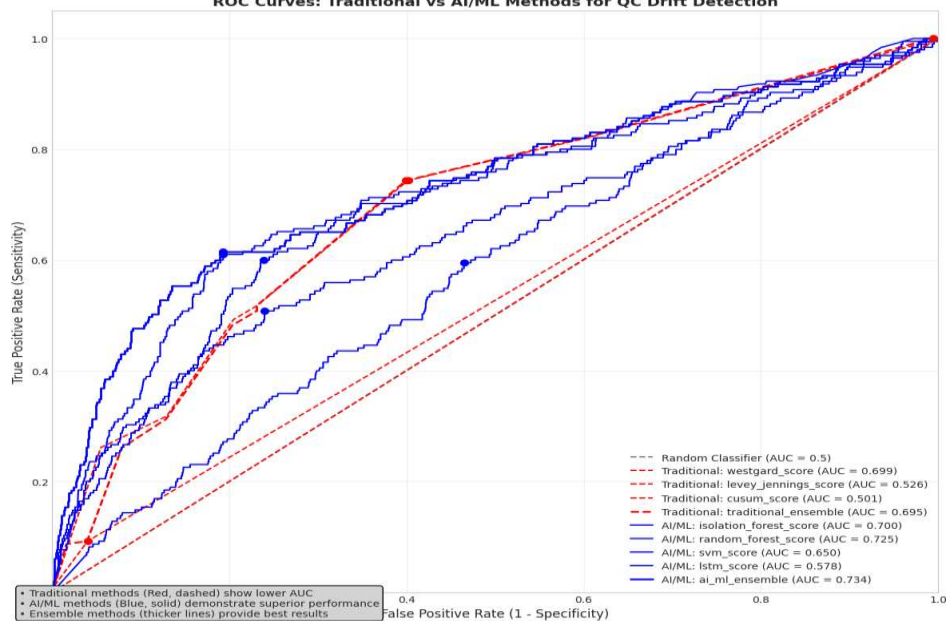
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PRELIMINARY RESULTS OF THE MODEL EVALUATION

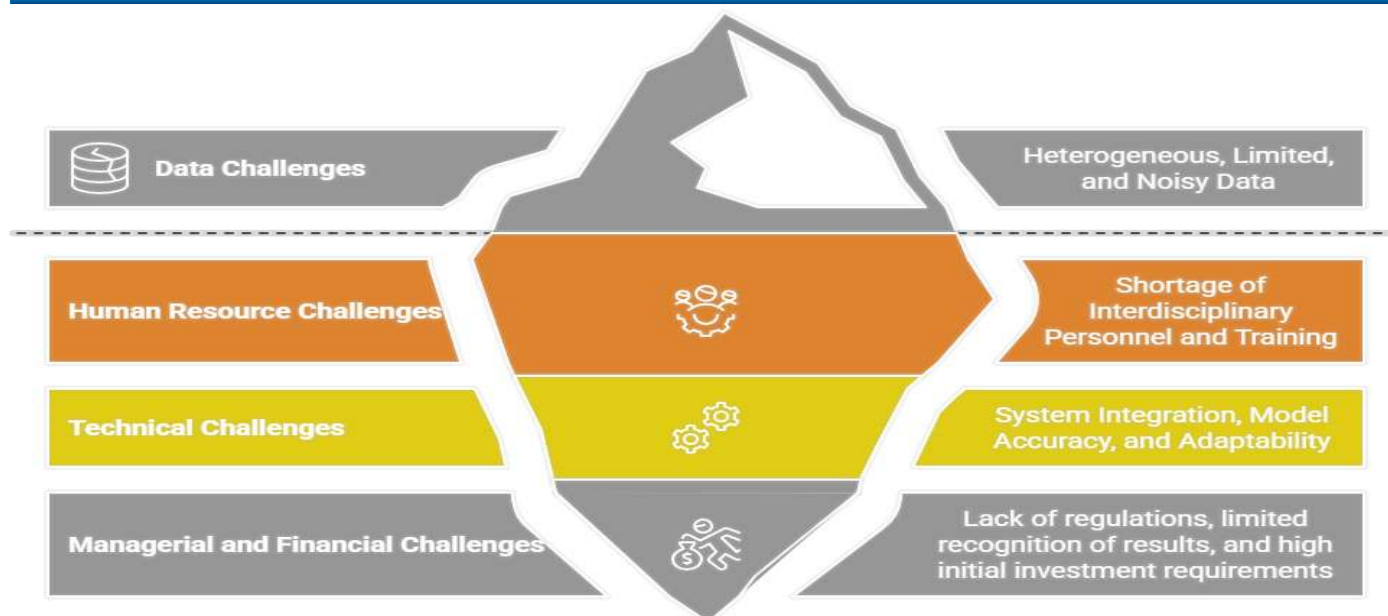
ROC Curves: Traditional vs AI/ML Methods for QC Drift Detection

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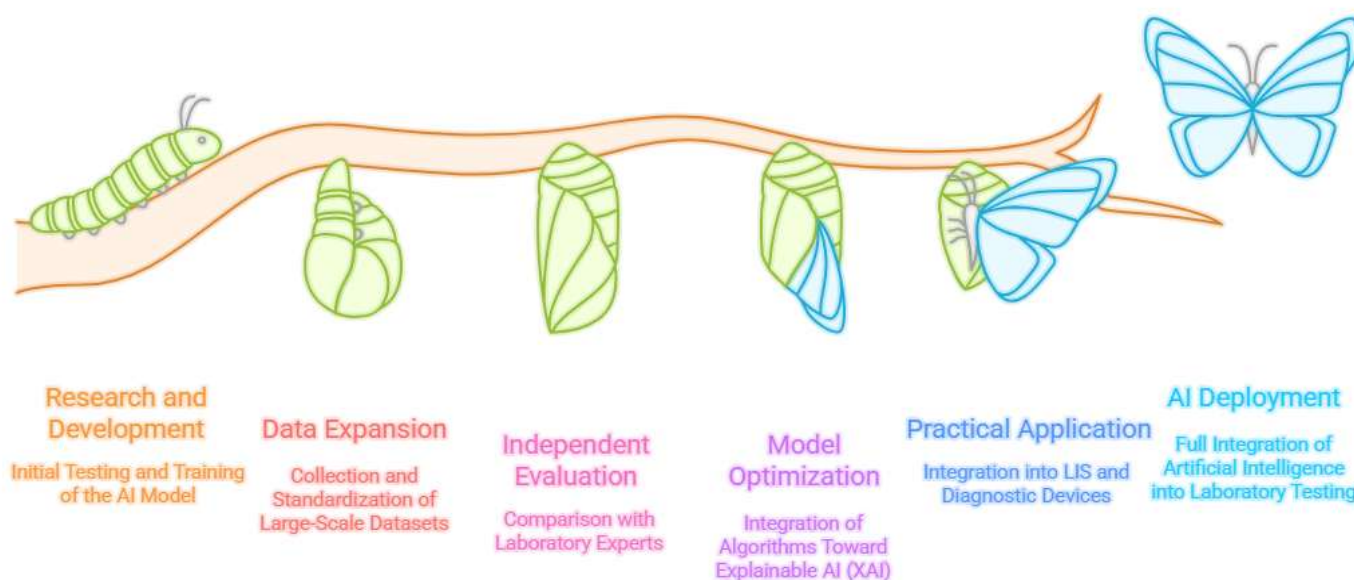
CHALLENGES AND FUTURE DIRECTIONS

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STRATEGIC DIRECTIONS FOR THE NEXT STAGE

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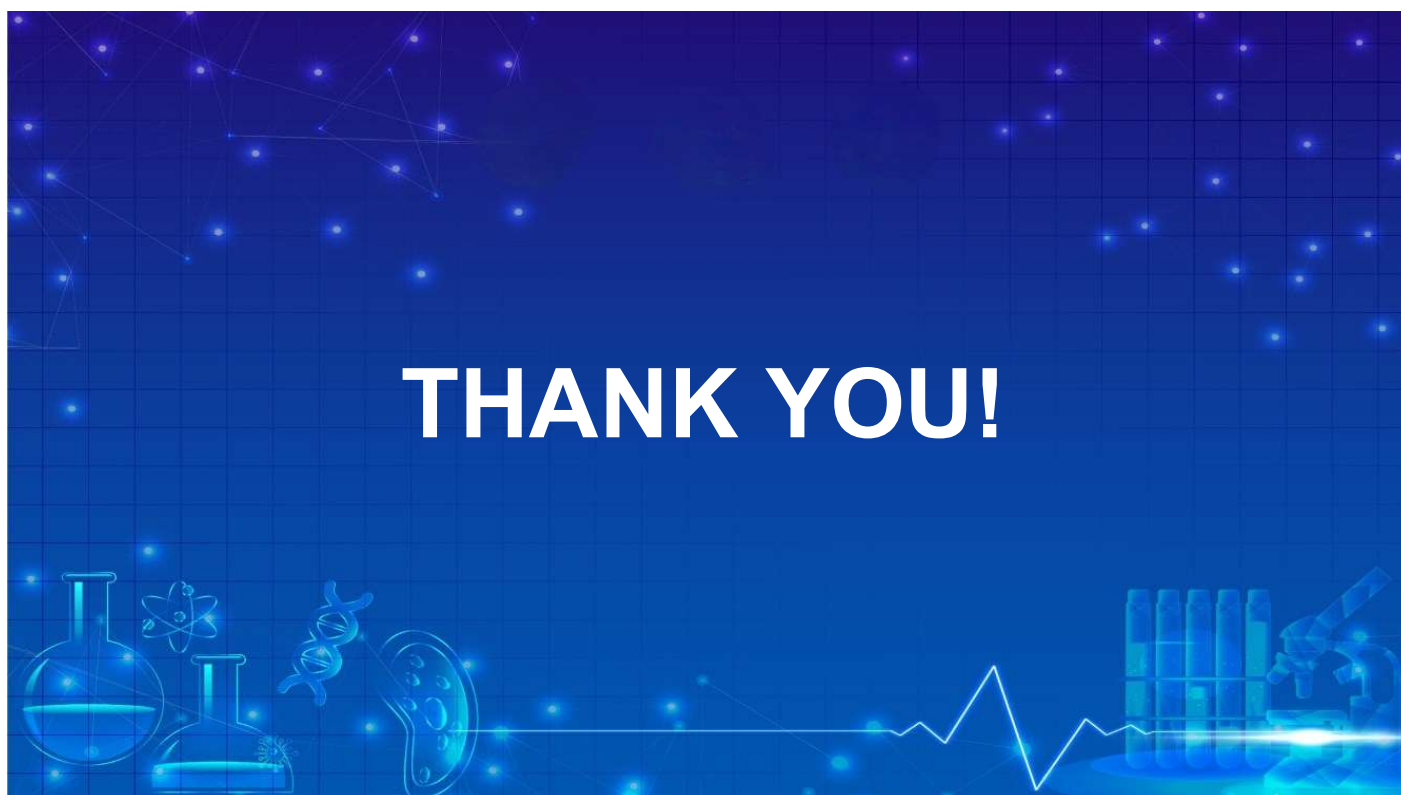
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CONCLUSION

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THANK YOU!





Định danh và phân loại chủng trong cùng một ngày

Hệ thống định danh nhanh vi sinh vật MALDI Biotyper® sirius one

Định danh nhanh chóng bằng công nghệ khối phổ MALDI-TOF

- Thời gian định danh: bé hơn 1 phút
- Thư viện: 4,700 loài, bao gồm vi khuẩn, nấm men, nấm sợi
- Định danh trực tiếp từ chai cấy máu dương tính
- Ứng dụng phát hiện vi khuẩn kháng kháng sinh

Hệ thống phân loại chủng vi sinh vật cho kiểm soát nhiễm khuẩn và dịch tễ IR Biotyper®

Công nghệ quang phổ hồng ngoại biến đổi Fourier

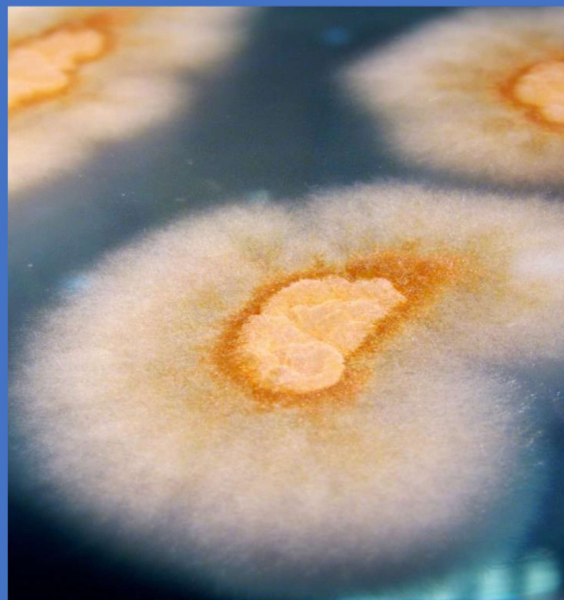
- Phân loại các chủng nhanh chóng trong vòng < 3 giờ
- Ứng dụng phổ biến cho nấm men và nấm sợi
- Dùng trong kiểm soát nhiễm khuẩn và điều tra dịch tễ
- Kết nối với Hệ thống định danh vi sinh vật MALDI Biotyper® và mạng LIS

Công ty TNHH Trang Thiết Bị Y Tế Trần Danh

Số 14, đường 36, phường Tân Quy, quận 7, Tp. HCM
SĐT: 028 22 536 106, Email: nguyennga@tdmedical.vn

Định danh nấm sợi bằng Hệ thống khối phổ MALDI Biotyper

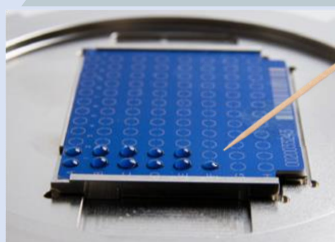
- Định danh nấm sợi là thách thức không hề nhỏ đối với các phòng xét nghiệm vi sinh. Tuy nhiên, dưới quá trình cải tiến liên tục của Bruker, hệ thống khối phổ MALDI Biotyper cho phép kỹ thuật viên định danh dễ dàng các mẫu nấm sợi đầy thử thách này.
- Phương pháp “Phết trực tiếp sợi nấm” có thể được sử dụng dễ dàng trong hầu hết các trường hợp, khi sợi nấm phía rìa có thể nhìn thấy rõ ràng và có thể được lấy dễ dàng.



Quy trình “Phết trực tiếp sợi nấm”



1 Nhỏ axit formic lên đĩa phết mẫu MBT Biotarget 96.



2 Dùng que tăm ướt để lấy sợi nấm ở phía rìa của nấm sợi.

3 Sợi nấm được bôi lên giọt axit formic có sẵn trên đĩa phết mẫu dùng một lần MBT Biotarget 96, sau đó giải phóng các protein, đờ khô và thêm một giọt chất nền HCCA.

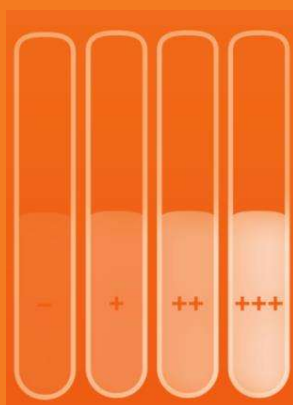


4 Sấy khô đĩa chứa mẫu trong điều kiện được kiểm soát ở nhiệt độ cao, sử dụng MBT FAST™ Shuttle, đảm bảo quá trình kết tinh chuẩn hóa của chất nền đồng thời đẩy nhanh quá trình sấy khô.

RANDOX

SERUM INDICES CONTROL

QUẢN LÝ TIỀN PHÂN TÍCH ẢNH HƯỞNG CỦA HIL



ACUSERA

ACUSERA SERUM INDICES CONTROL

Dùng cho IVD nhằm theo dõi đáp ứng của thiết bị và khả năng phát hiện các mẫu bị tan huyết (Haemolysis), vàng da (Icterus) hoặc đục mỡ (Lipemia) có thể ảnh hưởng tới kết quả xét nghiệm. Nội kiểm Acusera Serum Indices là nội kiểm định tính và báo cáo theo các mức -, +, ++, +++ cho Haemolysis, Icterus, Lipemia.

Sản phẩm ở dạng đông khô, nên xét nghiệm như một mẫu bệnh nhân.



Chất phân tích

Haemolysis (H) | Icterus (I) | Lipemia (L)

Mô tả

Serum Indices Control

Size

4 x 5ml

Mã

SI10448

Lợi điểm chính



Dạng đông khô giúp tăng độ ổn định



Sử dụng huyết thanh người, đảm bảo tính tương đồng (commutable)



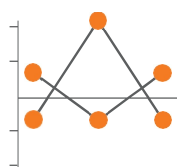
Ổn định sau hoàn nguyên 14 ngày;
Hạn dùng 2 năm kể từ ngày sản xuất



Nội kiểm bên thứ ba, đánh giá khách quan

Dải giá trị

	Haemolysis (H)		Icterus (I)		Lipemia (L)	
	Thang cảm quan	mg/dl	Thang cảm quan	mg/dl	Thang cảm quan	mg/dl
Level 1	-	<30	-	<2	-	<50
Level 2	+	30 - 100	+	2 - 4	+	50 - 100
Level 3	++	100 - 200	++	4 - 10	++	100 - 150
Level 4	+++	200 - 500	+++	10 - 20	+++	150 - 200



ACUSERA 24•7 Phần mềm QC trực tuyến với thống kê nhóm đồng đẳng theo thời gian thực

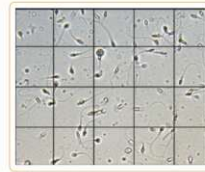
Được thiết kế để sử dụng cùng bộ sản phẩm nội kiểm Acusera, phần mềm Acusera 24•7 sẽ giúp bạn theo dõi và diễn giải dữ liệu QC. Bạn có thể truy cập một loạt tính năng mạnh mẽ như biểu đồ tương tác, tính tự động Độ không đảm bảo đo (Measurement Uncertainty) & Sigma Metrics, cùng dữ liệu nhóm đồng đẳng (peer group) theo thời gian thực được tổng hợp từ cơ sở dữ liệu phong phú các phòng xét nghiệm tham gia. Acusera 24•7 trở thành giải pháp quản lý QC toàn diện nhất hiện có.



RIQAS Chương trình ngoại kiểm lớn nhất Thế Giới với hơn 50,000 PXN tham gia

Với hơn 360 thông số xét nghiệm thường quy và chuyên sâu, bao gồm trong 33 chương trình EQA toàn diện và linh hoạt, RIQAS được thiết kế để bao phủ mọi lĩnh vực xét nghiệm lâm sàng. Mỗi chương trình đều có phạm vi bao phủ dải nồng độ rộng, tần suất thường xuyên, cùng báo cáo giàu thông tin nhưng thân thiện với người dùng.

SQA-iO⁺VU⁺



Cleared by



BẢNG GIÁ

GIÁ MÁY SQA-iO	80.000.000VNĐ
GIÁ MÁY SQA-VU	80.000.000VNĐ
GIÁ BỘ NGOẠI KIỂM	7.500.000VNĐ

MES SQA-iO & SQA-VU là thiết bị phân tích tinh trùng tự động **NHANH VÀ CHÍNH XÁC NHẤT THẾ GIỚI** do Medical Electronic Systems (MES Global - Tập đoàn hàng đầu thế giới với hơn 30 năm kinh nghiệm nghiên cứu về các giải pháp phân tích tinh dịch đồ tự động) – Dành cho bác sĩ, trung tâm hỗ trợ sinh sản, bệnh viện phòng thí nghiệm với chi phí đầu tư phải chăng.

Tốc độ phân tích siêu nhanh Chỉ trong vòng 75 giây kể từ khi mẫu ly giải, NHANH VÀ CHÍNH XÁC NHẤT THẾ GIỚI HIỆN TẠI , tăng số lượng mẫu được thực hiện trong 1 ngày	Độ chính xác được chứng minh ở hơn 50 quốc gia
Lưu dữ liệu điện toán đám mây Lưu trữ tất cả các kết quả test của bệnh nhân (Chỉ số, kết quả, video ở toàn bộ các lần test)	Chi phí đầu tư hợp lý Phù hợp với tài chính của các bác sĩ, trung tâm hỗ trợ sinh sản, bệnh viện, phòng thí nghiệm vừa và nhỏ

PHÂN TÍCH 21 CHỈ SỐ CHỈ SAU 75s theo tiêu chuẩn WHO 5 hoặc WHO 6

- | | | |
|------------------------------|--|---|
| 1. Thể tích tinh dịch | 8. Di động không tiến tới | 15. Vận tốc |
| 2. Bạch cầu | 9. Bất động IM | 16. Điểm chất lượng tinh trùng |
| 3. Độ PH | 10. Hình thái bình thường | 17. Tổng số tinh trùng mỗi lần xuất tinh |
| 4. Mật độ | 11. Mật độ tinh trùng di động | 18. Tổng số tinh trùng di động |
| 5. Tỷ lệ tinh trùng di động | 12. Mật độ tinh trùng di động tiến tới nhanh | 19. Tổng số tinh trùng di động tiến tới |
| 6. Di động tiến tới nhanh PR | 13. Mật độ tinh trùng di động tiến tới chậm | 20. Tổng số tinh trùng hoạt động |
| 7. Di động tiến tới chậm | 14. Mật độ tinh trùng di động hoạt động | 21. Tổng số tinh trùng có hình thái bình thường |

ĐƯỢC TIN CẬY SỬ DỤNG TẠI



TÌM HIỆU THÊM SẢN PHẨM TẠI ĐÂY



PixoTest[®] Vision

MÁY PHÂN TÍCH 4 CHỈ SỐ MỠ MÁU

PixoTest Vision Giúp chẩn đoán nhanh về các vấn đề rối loạn mỡ máu, xơ vữa động mạch vành, các biến chứng tai biến đột quỵ do mỡ máu gây ra. Phù hợp cho các bác sĩ tìm mạch giới thiệu cho các bệnh nhân của mình

 Chi phí hợp lý	 Vận hành đơn giản	 Tự động nội kiểm	 Lưu trữ kết quả
 Nhỏ gọn, tính di động cao	 Cung cấp kết quả nhanh	 Độ chính xác cao	 Tư vấn sức khỏe với AI



PHÂN TÍCH 4 CHỈ SỐ Lipid hoàn chỉnh

- 1 Cholesterol Toàn phần (TC)
- 2 Cholesterol lipoprotein tỷ trọng cao (HDL)
- 3 Cholesterol lipoprotein tỷ trọng thấp (cLDL)*
- 4 Triglyceride (TG)

Các chứng chỉ và giải thưởng của PixoTest Vision



Ứng dụng Pixo Health sẵn sàng tại:



Máy test mỡ máu tại PixoTest gồm những gì



✓ 3 pin Toshiba

✓ 1 thẻ chứa code máy

Bộ test kit mỡ máu PixoTest gồm những gì



✓ 5 kim cho súng bắn

✓ 5 que hút mẫu test



Eveline·care

HỆ THỐNG HỖ TRỢ CANH TRỨNG TOÀN CẦU

EVELINE CARE là giải pháp hỗ trợ sinh sản đầu tiên trên thế giới áp dụng thuật toán AI và công nghệ PixoTest của iXensor giúp tìm ra sự thay đổi nồng độ hormone LH ở mỗi chu kỳ.

PixoTest Biến chiếc điện thoại thông minh trở thành thiết bị chẩn đoán trong ống nghiệm (IVD) thông qua công nghệ cảm biến độc quyền.



KHÔNG PHẢI ĐOÁN VẠCH QUE, nhận kết quả chỉ tiết theo 3 mức Thấp - Cao - Đạt Đỉnh tức thì



Luôn kết nối với đội ngũ bác sĩ có chuyên môn cao liên tục



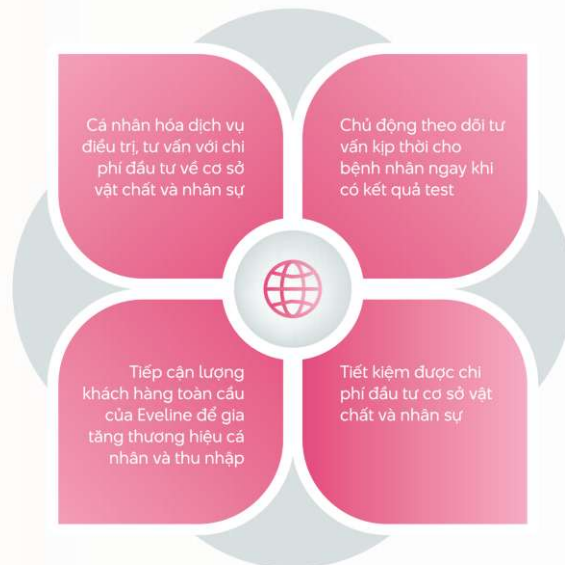
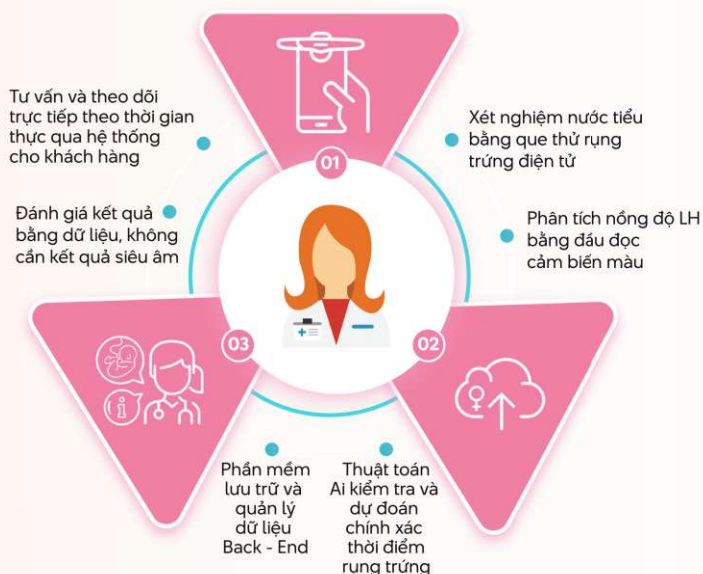
Theo dõi, lịch sử lưu trữ kết quả ngay trên điện thoại



Cơ hội tiếp cận công nghệ y tế mới với mức chi phí hợp lý



HỆ THỐNG CANH TRỨNG EVELINE CARE - TRỢ LÝ CÔNG NGHỆ NÂNG CAO HIỆU QUẢ DỊCH VỤ CHĂM SÓC SỨC KHỎE SINH SẢN DÀNH CHO BÁC SĨ THÔNG QUA BACK-END SYSTEM EVELINE CARE.



Hệ thống kiểm soát và quản lý chỉ số sức khỏe máu E-Blood

Từ giọt máu, hiểu sâu cơ thể, sống trọn vẹn hơn!



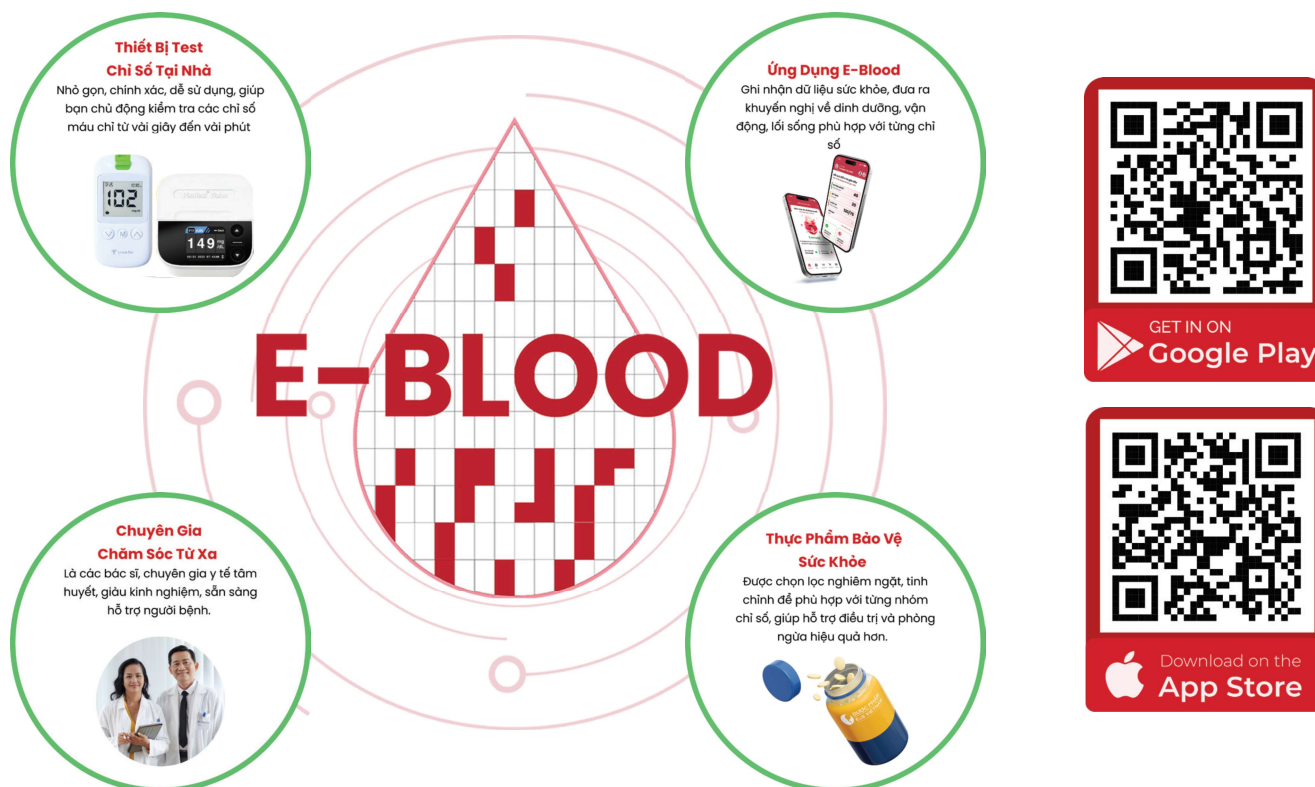
E-BLOOD TẠO RA Hệ Sinh Thái Kết Nối Để người dùng không chỉ ‘biết chỉ số’ mà còn hiểu được mình cần làm gì tiếp theo tương ứng với các ngưỡng kết quả hiện tại để nhằm giảm thiểu các biến chứng có thể xảy ra đột ngột với bản thân.

Đồng thời, đây cũng là trợ lý đắc lực cho các bác sĩ, dược sĩ và chuyên gia huyết học trên khắp cả nước, giúp họ nâng cao chuyên môn bằng cách kết nối và phục vụ bệnh nhân không giới hạn về không gian hay thời gian.

E-Blood gồm các hệ thống hỗ trợ

- 1** Hệ thống xét nghiệm mỡ máu tại nhà
- 2** Hệ thống xét nghiệm đường huyết tại nhà
- 3** Hệ thống xét nghiệm Acid uric tại nhà
- 4** Hệ thống xét nghiệm HIV tại nhà

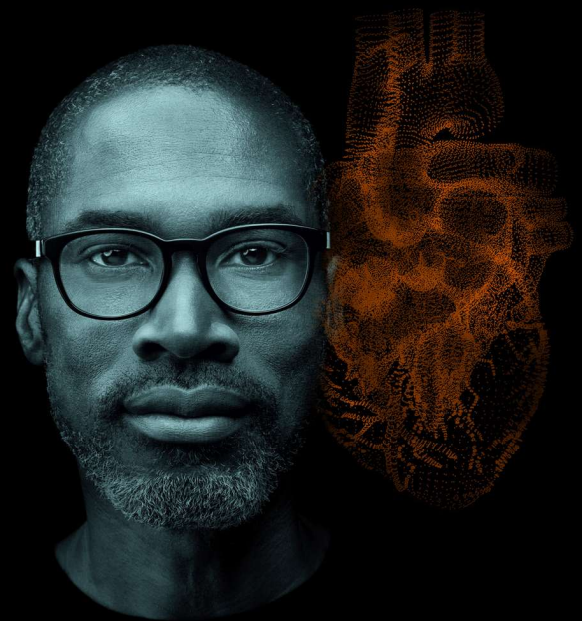
Hệ sinh thái E-Blood Kết nối các mảnh ghép giúp người dùng hiểu rõ bản thân, và sống chủ động hơn mỗi ngày!



Máy phân tích Atellica IM và Atellica CI

Xét nghiệm Troponin I tim độ nhạy cao

siemens-healthineers.com/atellica-ci-analyzer



Troponin tim là các dấu ấn sinh học được khuyến nghị ưu tiên sử dụng để khẳng định hoặc loại trừ tổn thương cơ tim, từ đó xác định nhồi máu cơ tim (MI) và từng phân nhóm cụ thể của MI.

Troponin I tim (cTnI) là một protein ức chế trong phức hợp troponin–tropomyosin. cTnI là dạng TnI duy nhất có mặt trong cơ tim và không được biểu hiện ở bất kỳ giai đoạn phát triển nào của cơ vân. Việc phát hiện sự tăng và/hoặc giảm nồng độ troponin tim là yếu tố thiết yếu và then chốt trong giai đoạn sớm, cùng với các yếu tố lâm sàng khác, để chẩn đoán nhồi máu cơ tim cấp (AMI).¹⁻⁴

Mục đích sử dụng

Xét nghiệm Atellica® IM High-Sensitivity Troponin I (TnIH) dùng trong chẩn đoán in vitro, nhằm định lượng troponin I tim trong huyết thanh hoặc huyết tương người (heparin lithium) trên hệ thống Atellica® IM hoặc Atellica® CI. Xét nghiệm này hỗ trợ chẩn đoán nhồi máu cơ tim cấp (AMI).

Mô tả xét nghiệm

Xét nghiệm Atellica IM/CI TnIH là miễn dịch kẹp 3 vị trí (3-site sandwich immunoassay) sử dụng công nghệ hóa phát quang trực tiếp. Pha rắn: các hạt latex từ tính liên hợp với streptavidin, gắn 2 kháng thể đơn dòng bắt giữ có biotin hóa, mỗi kháng thể nhận diện một epitope khác nhau của cTnI. Thuốc thử phát sáng (Lite reagent): gồm một phức hợp chứa ester acridinium độc quyền và mảnh Fab kháng cTnI người (nguồn gốc cừu tái tổ hợp) gắn cộng hóa trị với albumin huyết thanh bò (BSA), phục vụ cho phát hiện tín hiệu hóa phát quang.

Có mối quan hệ trực tiếp giữa lượng troponin I trong mẫu bệnh phẩm của bệnh nhân và số đơn vị ánh sáng tương đối (RLUs) được hệ thống phát hiện.

Siemens Healthineers cung cấp một xét nghiệm troponin I tim độ nhạy cao thực sự, đã được chứng minh, với kết quả xét nghiệm nhanh chóng, chính xác và có giá trị lâm sàng:

- Dữ liệu lâm sàng cho thấy xét nghiệm Troponin I độ nhạy cao Atellica IM/CI thực sự đáp ứng tiêu chuẩn “high sensitivity troponin I assay” theo hướng dẫn của IFCC.⁵
- Xét nghiệm có khả năng đo lường những thay đổi nhỏ nhưng quan trọng giữa các giá trị troponin I liên tiếp, giúp triển khai các phác đồ chẩn đoán nhanh hơn.
- Các nghiên cứu lâm sàng ủng hộ việc áp dụng các phác đồ 0h/1h, 0h/2h và 0h/3h để khẳng định hoặc loại trừ nhồi máu cơ tim.⁶⁻¹¹
- Độ tin cậy của kết quả được đảm bảo nhờ khả năng chịu nhiễu cao trước các yếu tố gây nhiễu thường gặp.

Tán huyết có thể nhìn thấy bằng mắt thường	Nồng độ Biotin (ng/mL) cao hơn mức bổ sung thông thường
Độ chênh lệch <10% ở nồng độ Hb 500 mg/dL	Độ chênh lệch <10% ở nồng độ Hb 3500 mg/dL

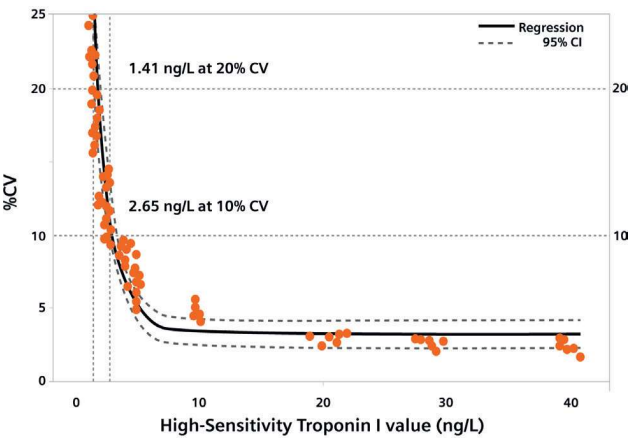
Xét nghiệm Troponin I tim độ nhạy cao Atellica IM/CI

Đặc tính xét nghiệm

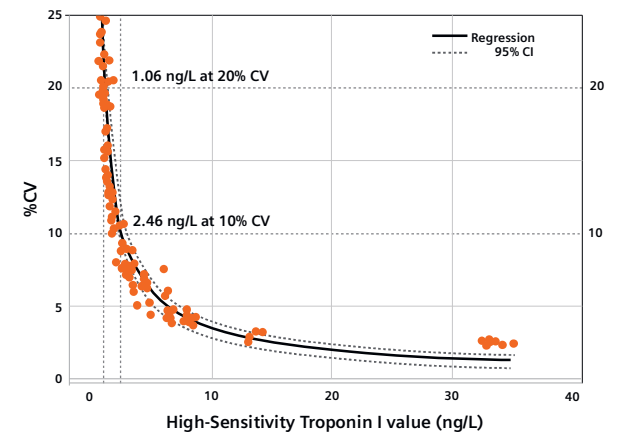
Hồ sơ độ chính xác của Atellica IM TnIH

Xét nghiệm	Loại mẫu bệnh phẩm	Thể tích mẫu (μL)	Thời gian có kết quả đầu tiên (phút)	Khoảng đo lường	Khả năng phát hiện	Atellica IM		Atellica CI Model	
						Độ ổn định trên máy (Ngày)	Khoảng hiệu chuẩn theo lô (Ngày)	Độ ổn định trên máy (Ngày)	Khoảng hiệu chuẩn theo lô (Ngày)
High-sensitivity Troponin I	Huyết thanh, huyết tương Li-heparin	100	10	2.5–25,000 pg/mL	LoB 0.5 pg/mL LoD 1.6 pg/mL LoQ ^{CV20%} 2.5 pg/mL LoQ ^{CV10%} <6.0 pg/mL	28	47	90	47

Hồ sơ độ chính xác của Atellica IM TnIH



Hồ sơ độ chính xác của Atellica CI TnIH tại mức CV 10% và 20%



So sánh phương pháp

Xét nghiệm	Mẫu bệnh phẩm	Xét nghiệm so sánh (x)	Phương trình hồi quy	Thời gian lấy mẫu	n	r
High-sensitivity Troponin I	Huyết tương Li-heparin	Atellica IM TnIH	$y = 1,00 x + 0,04$ pg/mL	2,66-23.395,95 pg/mL	170	0,996

$y = \text{Atellica CI TnIH}$

Thông tin đặt hàng

Atellica CI Analyzer dùng chung công nghệ, thuốc thử, vật tư và phần mềm với Atellica Solution, giúp chuẩn hóa tồn kho, quy trình và tính tương đương lâm sàng trong toàn hệ thống.

Xét nghiệm	Số SMN	Số xét nghiệm/bộ kit	Thành phần
Atellica IM TnIH	10997840	100	1 gói thuốc thử chính Atellica IM TnIH ReadyPack 1 lọ chuẩn hiệu chuẩn thấp (Atellica IM TnIH CAL low calibrator) 1 lọ chuẩn hiệu chuẩn cao (Atellica IM TnIH CAL high calibrator)
	10997841	500	5 gói thuốc thử chính Atellica IM TnIH ReadyPack 2 lọ chất chuẩn hiệu chuẩn thấp (Atellica IM TnIH CAL low calibrators) 2 lọ chất chuẩn hiệu chuẩn cao (Atellica IM TnIH CAL high calibrators)

Tại Siemens Healthineers, chúng tôi tiên phong tạo ra những đột phá trong chăm sóc sức khỏe. Cho tất cả mọi người. Ở mọi nơi. Bằng việc liên tục đưa các đổi mới mang tính đột phá ra thị trường, chúng tôi giúp các chuyên gia y tế cung cấp dịch vụ chăm sóc chất lượng cao, mang lại kết quả tốt nhất cho bệnh nhân.

Danh mục giải pháp của chúng tôi trải dài từ chẩn đoán in-vitro và in-vivo, đến liệu pháp can thiệp có hướng dẫn hình ảnh và chăm sóc ung thư tiên tiến, đóng vai trò thiết yếu trong quyết định lâm sàng và xây dựng phác đồ điều trị. Với thể mạnh trong mô hình song sinh bệnh nhân (patient twinning), liệu pháp chính xác (precision therapy) cùng với công nghệ số, dữ liệu và trí tuệ nhân tạo (AI), chúng tôi có vị thế vững chắc để đối mặt với những thách thức lớn nhất trong y tế. Chúng tôi sẽ tiếp tục phát huy các thể mạnh này để góp phần chống lại những căn bệnh nguy hiểm nhất, nâng cao chất lượng điều trị và mở rộng khả năng tiếp cận dịch vụ chăm sóc sức khỏe.

Chúng tôi là một đội ngũ gồm 66.000 nhân viên tận tâm tại hơn 70 quốc gia, luôn nỗ lực không ngừng để mở rộng giới hạn của những gì có thể trong chăm sóc sức khỏe, nhằm cải thiện cuộc sống con người trên toàn thế giới.

Atellica, ReadyPack và tất cả các nhãn hiệu liên quan là nhãn hiệu thương mại của Siemens Healthcare Diagnostics Inc. hoặc các công ty liên kết. Tất cả các nhãn hiệu và thương hiệu khác là tài sản của các chủ sở hữu tương ứng.

Khả năng cung cấp sản phẩm có thể khác nhau giữa các quốc gia và phụ thuộc vào các yêu cầu quản lý tại từng nơi. Vui lòng liên hệ đại diện địa phương của bạn để biết thêm chi tiết.

Tài liệu tham khảo:

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Tên sản phẩm: Thuốc thử, chất hiệu chuẩn xét nghiệm định lượng troponin I tim
Chủng loại: Atellica IM TnIH
Mã sản phẩm: 10997840/ 10997841
Hãng/ Nước sản xuất: Siemens Healthcare Diagnostics Inc., UNITED STATES
Số lưu hành: 2405224DKLH/BYT-HTTB
Tính năng, tác dụng: Xét nghiệm Atellica IM High-Sensitivity Troponin I (TnIH) được dùng cho chẩn đoán in vitro trong định lượng troponin I tim trong huyết thanh hoặc huyết tương người (lithium heparin) bằng Atellica IM Analyzer và Atellica CI Analyzer. Có thể sử dụng xét nghiệm này để hỗ trợ việc phát hiện tổn thương cơ tim và chẩn đoán bệnh nhồi máu cơ tim cấp (AMI). Xét nghiệm Atellica IM TnIH có thể được sử dụng để phát hiện tổn thương cơ tim và có thể hỗ trợ việc phân tầng nguy cơ đối với tỷ lệ tử vong do mọi nguyên nhân (ACM) trong 30, 90 và 365 ngày, cũng như các biến cố tim mạch quan trọng (MACE) ở các bệnh nhân có dấu hiệu và triệu chứng của hội chứng mạch vành cấp tính (ACS). MACE bao gồm: nhồi máu cơ tim, tái tạo mạch khẩn cấp, tử vong do tim hoặc nhập viện do suy tim.
Chủ sở hữu số lưu hành: CÔNG TY TNHH SIEMENS HEALTHCARE, Số 33, Đường Lê Duẩn, Phường Sài Gòn, Thành phố Hồ Chí Minh

Công ty TNHH Siemens Healthcare

TP. Hồ Chí Minh

Tòa nhà Deutsches Haus, Tầng 7
33 Lê Duẩn, Phường Sài Gòn,
TP. Hồ Chí Minh, Việt Nam
SĐT: +84 283 825 1900
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Tòa nhà Ocean Park, Tầng 9
1 Đào Duy Anh, Phường Bạch Mai,
Hà Nội, Việt Nam
SĐT: +84 243 557 5588
Fax: +84 243 577 6699

Thông tin chi tiết xin liên hệ bộ phận chăm sóc khách hàng 24/7

SĐT: 1800 585 850 (Miễn phí cước gọi)

SGTi Allergy Screen

Hệ thống xét nghiệm dị ứng

S-Blot Series

Sugentech cung cấp một giải pháp xét nghiệm dị ứng đa dạng và linh hoạt, phù hợp với nhu cầu của khách hàng.



S-Blot 2

Mã sản phẩm: SBTD001E
Số lưu hành: 240001848/PCBB-HCM



S-Blot 2 Easy

Mã sản phẩm: SEYD001E
Số lưu hành: 240001849/PCBB-HCM



S-Blot 3

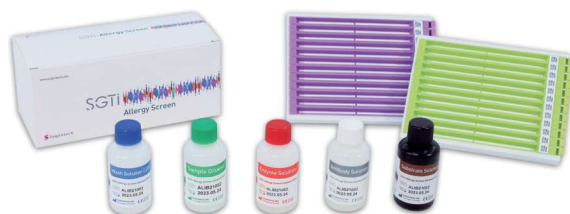
Mã sản phẩm: SBFD001E
Số lưu hành: 240001850/PCBB-HCM

▪ Thông số kỹ thuật

	S-Blot 2	S-Blot 2 Easy	S-Blot 3
Mô tả hệ thống	Quy trình bán tự động	Quy trình bán tự động	Quy trình tự động hoàn toàn
Công suất tối đa (Mẫu trên một lần chạy)	48	12	48
Khay ủ	Khay lắc / 7.5° +/- 0.5 / 20 RPM		
Phương pháp sấy	Bộ gia nhiệt có quạt		
Nguồn điện	AC 100-240V 50/60Hz, 300VA	AC 100-240V 50/60Hz, 300VA	AC 100-240V 50/60Hz, 800VA
Thời gian chạy mẫu	~ 3 giờ	~ 3 giờ	4 giờ
Hệ điều hành	Window 10 64bit trở lên, RAM 4 GB, ổ cứng 250 GB trở lên		
Kích thước (LxWxH mm)	886 x 540 x 560	450 x 400 x 400	968 x 616 x 609
Trọng lượng (kg)	70	22	80

SGTi Allergy Screen

Bộ kit xét nghiệm dị ứng



Hệ thống xét nghiệm dị ứng đa thông số sử dụng phương pháp miễn dịch điện di để chẩn đoán các bệnh dị ứng dựa trên sự phát hiện IgE đặc hiệu với các loại dị nguyên (thực phẩm/hô hấp) trong huyết thanh hoặc huyết tương.

Thể tích mẫu nhỏ

- 50µl huyết thanh hoặc huyết tương
- Phù hợp cho bệnh nhi

Hiệu chuẩn lô bằng QR code

- Quản lý thay đổi lô

Tăng hiệu năng sử dụng

- Khay mẫu 1 lần chạm
- Phần mềm thân thiện với người dùng

▪ Xét nghiệm hơn 100 IgE đặc hiệu với dị nguyên

50 dị nguyên hô hấp

- Cỏ & Cây**
- Phấn cỏ**
Orchard, Bermuda, Cỏ Ngọt, Timothy, Redtop-Bent, Lúa mạch đen
 - Cây**
Bạch dương, Phỉ, Sồi trắng, Oliu, Sung dầu, Liễu dê, cây Bông, Tần bì, Thông, Tuyết tùng Nhật, cây Keo, cây Bách
 - Cỏ dại**
Phấn hương, Bồ công anh, Mã đề, Cúc Hoàng Anh, Cúc mắt bò, rau dền, ngải cứu, cây kế Nga, Hoa bia Nhật Bản

- Động vật & Mạt bụi**
- Da và Protein**
Mèo, Chó, Chuột lang, Chuột hamster, Ngựa, Thỏ
 - Mạt bụi**
D.p, D.f, Mạt bột, Mạt kho, Bụi nhà

- Nấm mốc & Côn trùng khác**
- Nấm mốc**
Candida albicans, Alternaria alternate, Cladosporium notatum, Penicillium herbarum, Aspergillus fumigatus
 - Côn trùng**
Gián, Ong mật, Ong bắp cày
 - Khác**
Mủ cao su, Kiểm soát dương tính, IgE toàn phần

52 dị nguyên thực phẩm

- Rau củ, Trái cây**
- Trái cây**
Táo, Chuối, Kiwi, Xoài, Cam, Đào, Dâu tây
 - Thịt & Hải sản**
 - Thịt**
Bò, Gà, Cừu, Lợn
 - Hải sản**
Nghêu, Cua, Tôm Hùm, Sò điệp, Hàu, Cá cơm, Cá tuyết, Vẹm xanh, Cá bơn, Lươn, Cá hồi, Cá thu, Cá ngừ, Mực Thái Bình Dương
 - Hạt & Ngũ cốc**
 - Hạt, Quả hạch, Cây họ đậu**
Hạnh nhân, Cacao, Hạt phỉ, Đậu phộng, Hạt thông, Đậu nành, Quả óc chó
 - Hạt**
Lúa mạch, Bắp, Gạo, Lúa mì, Kiểu mạch, Mè
 - Bơ, Sữa & Khác**
 - Bơ, sữa**
Phô mai cheddar, Lòng trắng trứng, Sữa
 - Khác**
CCD, Kiểm soát dương tính, IgE toàn phần, Men bánh

Máy phân tích POCT thể hệ mới **OPTICAL Q**

Xét nghiệm Miễn dịch Huỳnh quang

POCT System



Powered by

BILL & MELINDA
GATES foundation

Certified by



Thông số kỹ thuật

Phương pháp	Định lượng miễn dịch huỳnh quang
Kích thước	357 mm (D) × 284 mm (R) × 156 mm (C)
Trọng lượng	2.6 kg
Nguồn điện	DC 12V/5A, AC/DC adaptor
Kết quả đầu ra	LCD / Máy in tích hợp/ USB / LIS / HIS
Bộ nhớ	999 kết quả bệnh nhân

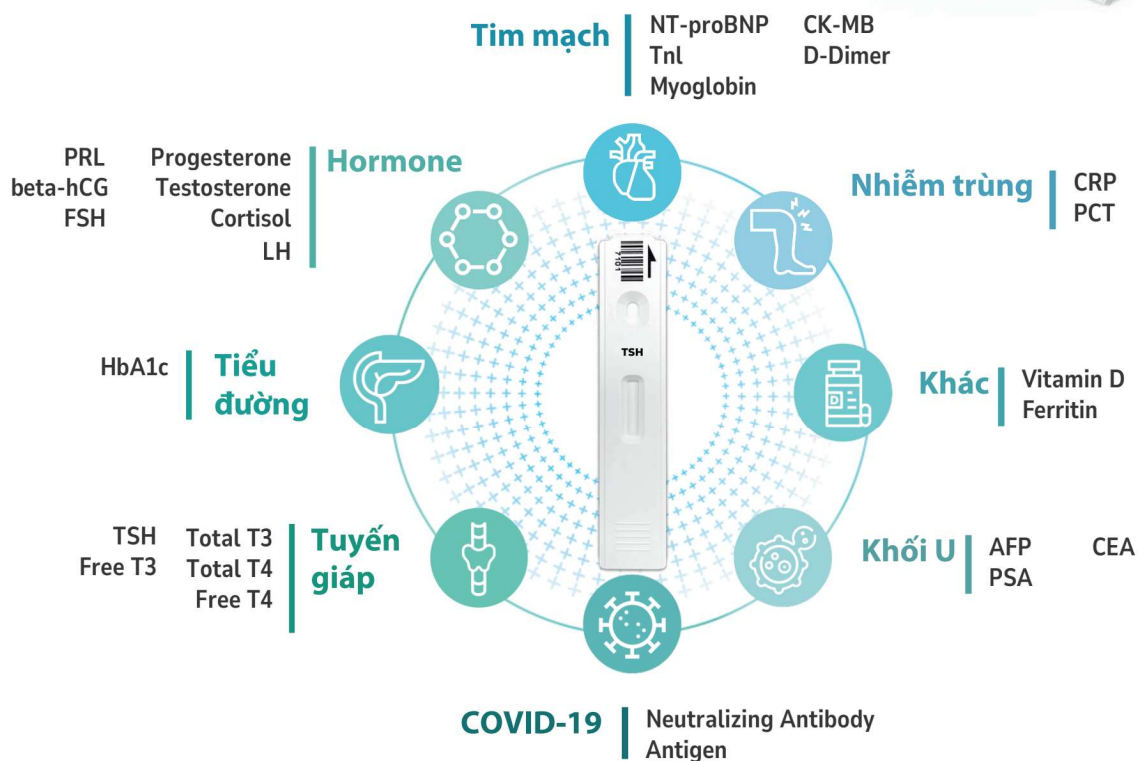


Scan để biết
thêm thông tin

OPTICALQ

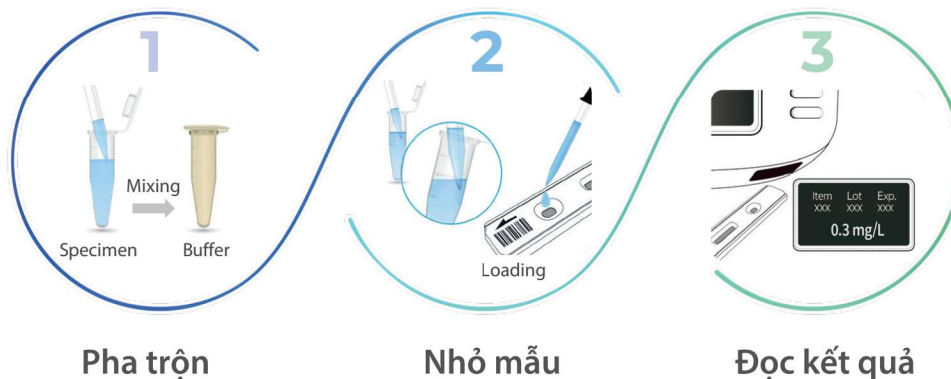
Bộ kit xét nghiệm chuyên biệt

ĐA DẠNG CHỈ SỐ XÉT NGHIỆM



QUY TRÌNH XÉT NGHIỆM

Chỉ trong
3 bước



TOÀN CẢNH ỨNG DỤNG GIẢI TRÌNH TỰ OXFORD NANOPORE TRONG CHẨN ĐOÁN VÀ GIÁM SÁT VI SINH LÂM SÀNG

Giải trình tự toàn bộ hệ gene (WGS) vi khuẩn/nấm phân lập



- Vi khuẩn lao (*MTB*), *Klebsiella pneumoniae*, *Staphylococcus aureus*, *Candida parapsilosis*...
- Xác định đặc tính di truyền: genotyping, *Salmonella* serotyping, MLST
- Phát hiện và phân tích gen kháng thuốc (AMR)
- Dịch tễ học phân tử, điều tra/truy vết ổ dịch

Xác định thành phần loài (Full-length 16S/ITS)



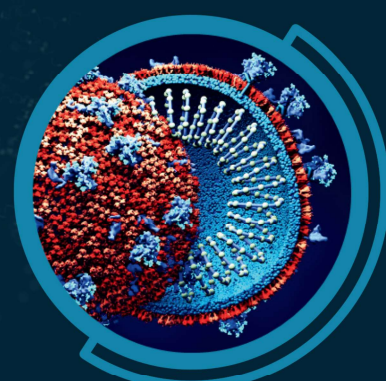
- Phân tích cấu trúc quần thể vi sinh vật
- Độ phân giải phân loại cao (chi/loài)
- Đa dạng nguồn mẫu, không cần nuôi cấy
- Phù hợp mục tiêu định danh và sàng lọc trong vi sinh lâm sàng

Phân tích hệ vi sinh (Metagenomics)



- Giải trình tự trực tiếp không cần nuôi cấy
- Phát hiện không định hướng, đa tác nhân (vi khuẩn, nấm, virus DNA/RNA) theo thời gian thực
- Lắp ráp bộ gen (MAGs)
- Phân tích gen kháng thuốc và độc lực
- Ứng dụng trong ca nhiễm trùng không rõ nguyên nhân, đa tác nhân hoặc sau điều trị kháng sinh

Giải trình tự WGS virus (PCR-tiling amplicon)



- SARS-CoV-2, cúm (influenza A/B), RSV, Dengue, HIV, Enteroviruses (A-D)...
- Phân loại chủng virus, phát hiện biến thể mới
- Hỗ trợ giám sát dịch, điều chỉnh chiến lược vắc-xin và ứng phó y tế công cộng

GIẢI PHÁP PHÁT HIỆN VÀ ĐÁNH GIÁ TÌNH TRẠNG KHÁNG THUỐC MỘT SỐ TÁC NHÂN GÂY BỆNH NGUY HIỂM

(Được khuyến cáo sử dụng bởi WHO)

- Sử dụng công nghệ lai phân tử để phát hiện các đột biến gen cụ thể, đảm bảo độ tin cậy trong chẩn đoán.
- Đánh giá nhanh, chính xác tình trạng nhiễm khuẩn & kháng thuốc ở các vi khuẩn lao (MTB), vi khuẩn lao không điển hình (NTM) và vi khuẩn viêm dạ dày *Helicobacter pylori*.
- Nguồn mẫu: Mẫu bệnh phẩm lâm sàng (dịch đờm, dịch dạ dày, mẫu dịch phổi...) hoặc mẫu nuôi cấy
- Đạt tiêu chuẩn **CE-IVD**



MỘT SỐ BỘ KIT NỔI BẬT:

Genotype/Flurotype MTBDR	Phát hiện lao kháng Rifampicin và Isoniazid
GenoType MTBDRsl VER 2.0	Phát hiện lao kháng fluoroquinolones (ofloxacin và moxifloxacin) và aminoglycosides/cyclic peptides (kanamycin, amikacin, capreomycin, và viomycin)
GenoType Mycobacterium CM/NTM-DR	Phát hiện lao không điển hình kháng macrolides và aminoglycosides
GenoType HelicoDR	Phát hiện vi khuẩn HP kháng clarithromycin và fluoroquinolones



CÁC PANEL THIẾT KẾ SẴN CHO qPCR:

- Tùy chọn linh hoạt – 211 mục tiêu, 12 nhóm tác nhân, 4 màu thuốc nhuộm (Cy5, FAM, SUN, TexRd).
- Mỗi và probe đóng gói trong một ống duy nhất.
- Tương thích với nhiều hệ thống realtime PCR
- Tiết kiệm thời gian, chi phí

Target Category	# Targets
Urinary tract infections (UTI)	23
Antimicrobial resistance (AMR)	42
Respiratory pathogen infections (RPP)	32
Sexually transmitted infections (STI)	16
Gastrointestinal infections (GI)	15
Vaginitis	29
Wound infections	31
Human Papillomavirus (HPV)	12
North American Tick	17
Human Herpesvirus (HHV)	27
Additional pathogens	23



HÓA CHẤT PCR/REALTIME PCR

Mẫu	Hóa chất PCR
DNA	Đơn tác nhân (Singplex) • OneTaq® 2X Master Mix • Q5® High-Fidelity 2X Master Mix (Có sẵn dạng Hotstart)
	Đa tác nhân (Multiplex) • Multiplex PCR 5X Master Mix
RNA	• Kit khuếch đại RNA 1 bước: OneTaq® One-Step RT-PCR Kit • Kit tổng hợp cDNA: ProtoScript® II First Strand cDNA Synthesis Kit

Mẫu	Hóa chất Realtime PCR
DNA	Đơn tác nhân (Dye based: FAM/SYBR) • Luna® Universal qPCR Master Mix
	Đa tác nhân (Probes – based) • Luna® Universal Probe qPCR Master Mix
RNA	Đơn tác nhân (Dye based: FAM/SYBR) • Luna® Universal One-Step RT-qPCR Kit
	Đa tác nhân (Probes – based) • Luna® Universal Probe One-Step RT-qPCR Kit



Email: infors@bcevietnam.com.vn Hotline: 0942 975 624/ 0913 526 170

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Tel: (+84-4) 3234 5666 - Fax: (+84-4) 32345 668

HCMC: No 49/3 Hoang Du Khuong, Hòa Hưng Ward, HCM
Tel: (+84-8) 6290 5623/24 - Fax: (+84-8) 6290 5622

CHEMISTRY MENU

Our broad and growing portfolio of high-performing Six Sigma assays is compatible with AU Chemistry Analyzers — and it offers the exceptional clinical quality you've come to expect from Beckman Coulter.

General Chemistry

Alanine Aminotransferase
Albumin BCG
Albumin BCP
Alkaline Phosphatase
Amylase
Angiotensin Converting Enzyme (ACE)
Aspartate Aminotransferase
Bicarbonate
Calcium Arsenazo
Cholesterol
Creatinine
Creatine Kinase
Direct Bilirubin
Gamma-glutamyltransferase
Glucose
HDL Cholesterol
Iron
LDL Cholesterol
Lactate Dehydrogenase (IFCC)
Lipase
Lipase NG
Magnesium
Phosphorus (inorganic)
Total Bilirubin
Total Protein
Triglyceride
Unsaturated Iron-Binding Capacity
Urea Nitrogen
Urea Nitrogen STAT
Uric Acid
Urinary/CSF Protein

Esoterics

Ammonia
Cholinesterase
Creatine Kinase MB
Cystatin C
D-dimer
Fructosamine
HbA1c (IFCC/NGSP)
HbA1c Advanced†
Homocysteine
Lactate
Lithium
Pancreatic Amylase
Procalcitonin
Total Bile Acids

Proteins/Serology

Alpha-1-acidglycoprotein
Alpha-1-antitrypsin
Antistreptolysin O
Apolipoprotein A1
Apolipoprotein B
Beta-2 Microglobulin
Ceruloplasmin
Complement 3
Complement 4
C-Reactive Protein
C-Reactive Protein, High Sensitivity
Ferritin
Haptoglobin
Immunoglobulin A
Immunoglobulin E
Immunoglobulin G
Immunoglobulin M
Kappa Free Light Chains
Lambda Free Light Chains
Prealbumin
Rheumatoid Factor
Transferrin
Urine/CSF Albumin

✓ LOAD IT AND LEAVE IT

with liquid ready-to-use reagents

✓ TRUST YOUR RESULTS

with standardized test menus, assay protocols and reference ranges providing commutable patient results across AU analyzers

✓ SELECT YOUR SIZE

with a variety of kit sizes, so you can choose just the right size for your test volume

CHEMISTRY MENU

Therapeutic Drug Monitoring (TDM)

Acetaminophen
Amikacin
Caffeine
Carbamazepine
Clozapine
Digoxin
Disopyramide
Ethosuximide
Gentamicin
Lidocaine
Methotrexate
N-Acetylprocainamide
Phenobarbital
Phenytoin
Primidone
Procainamide
Quinidine
Salicylic Acid
Theophylline
Tobramycin
Valproic Acid
Vancomycin

Drugs of Abuse Testing (DAT)

6-Acetylmorphine (qualitative)
6-Acetylmorphine (semi-quantitative)
Amphetamines (300 cutoff)
Amphetamines (500 cutoff)
Amphetamines (1,000 cutoff)
Amphetamines (300 cutoff/
semi-quantitative)
Amphetamines (500 cutoff/
semi-quantitative)

Amphetamines (1,000 cutoff/
semi-quantitative)
Barbiturate (200 cutoff)
Barbiturate (300 cutoff)
Barbiturate (semi-quantitative)
Barbiturate, Tox
Benzodiazepine (200 cutoff)
Benzodiazepine (300 cutoff)
Benzodiazepine (semi-quantitative)
Benzodiazepine, Tox
Buprenorphine (qualitative)
Buprenorphine (semi-quantitative)
Cannabinoid (20 cutoff)
Cannabinoid (50 cutoff)
Cannabinoid (100 cutoff)
Cannabinoid (50 semi-quantitative)
Cannabinoid (100 semi-quantitative)
Cocaine Metabolite (150 cutoff)
Cocaine Metabolite (300 cutoff)
Cocaine (semi-quantitative)
Ecstasy (300 cutoff)
Ecstasy (500 cutoff)
Ecstasy (300 cutoff/semi-quantitative)
Ecstasy (500 cutoff/semi-quantitative)
Ethyl Alcohol
Fentanyl (qualitative)
Fentanyl (semi-quantitative)
Hydrocodone (qualitative)
Hydrocodone (semi-quantitative)
LSD (0.5 cutoff)
LSD (semi-quantitative)
Methadone (150 cutoff)
Methadone (300 cutoff)
Methadone (semi-quantitative)
Methaqualone (300 cutoff)
Methaqualone (semi-quantitative)

Opiates (300 cutoff)
Opiates (2,000 cutoff)
Opiates (300 cutoff/
semi-quantitative)
Opiates (2,000 cutoff/
semi-quantitative)
Oxycodone (100 cutoff)
Oxycodone (300 cutoff)
Oxycodone (semi-quantitative)
Phencyclidine (25 cutoff)
Phencyclidine (semi-quantitative)
Propoxyphene (300 cutoff)
Propoxyphene (semi-quantitative)
Tricyclics, Tox

Immunosuppressant Drugs (ISD)

Cyclosporine
Everolimus
Mycophenolic Acid
Tacrolimus

ISE

Chloride
Potassium
Sodium

Thyroids

Thyroxine
T-Uptake

Contact your local Beckman Coulter representative with questions,
or keep learning at [BeckmanCoulter.com/Chemistry](https://www.beckmancoulter.com/Chemistry)

*Available for use on select analyzers

For distribution in the United States, Canada and Latin America.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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FL-570401 | 2023-12194



Giới thiệu

Công ty TNHH Thương mại Y tế Phú Gia là đơn vị hoạt động trong lĩnh vực dược phẩm và thiết bị y tế, là nhà phân phối đạt chuẩn GDP (Good Distribution Practice).

Công ty được thành lập bởi những thành viên nhiệt huyết và sự tận tâm trong lĩnh vực chăm sóc sức khỏe người bệnh. Trải qua hơn 19 năm xây dựng và phát triển, Phú Gia đã gặp phải nhiều khó khăn và thách thức, nhưng với tinh thần đoàn kết, sự sáng tạo, sự nỗ lực của Ban Giám Đốc cũng như năng lực của tập thể cán bộ công nhân viên, Phú Gia đã từng bước khẳng định vị trí của mình trên thị trường.



Sản phẩm

THIẾT BỊ Y TẾ

NHÓM MÁY HUYẾT HỌC



Máy Neo Iris
Immucor GmbH - Đức



Máy Echo Lumena
Immucor Inc - Mỹ

NHÓM MÁY DỊ ỨNG



Máy Helia
Aesku - Đức



Máy R2L
BioScitec - Đức

NHÓM MÁY KHÁC



Máy FLEXMAP 3D
Lumindex - Mỹ



Máy SQA-Vision
MES Global - Israel



Máy KU-F40
Keyu - Trung Quốc



Máy Alethia
Meridian - Mỹ

VẬT TƯ TIÊU HAO



- Đầu côn pipet tự động 300
- Đầu côn pipet tự động 1100
- Đĩa pha loãng mẫu

NHÓM MÁY MIỄN DỊCH



Serion Immunomat
VirionSerion - Đức



Máy Gemini
Stratec SE - Đức



Máy đọc ELISA
Meril - Ấn Độ



Máy rửa ELISA
Meril - Ấn Độ

NHÓM MÁY C13



Máy Fan HP
Fischer - Đức



Máy Heli Fan plus
Fischer - Đức

NHÓM MÁY KHÍ MÁU



Máy Prime ABG
Nova Biomedical - Mỹ



Máy Prime CCS
Nova Biomedical - Mỹ



Máy Prime Plus
Nova Biomedical - Mỹ

NHÓM MÁY NƯỚC TIỂU



Máy H 1600
Dirui - Trung Quốc



Máy FUS 3000 Plus
Dirui - Trung Quốc

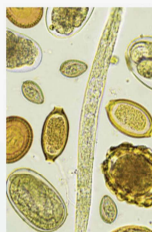
NHÓM VI SINH

- Epstein Barr Virus VCA IgG/IgM
- Epstein Barr Virus EA IgG
- Cytomegalovirus IgG/IgM
- Enterovirus IgA/IgG/IgM
- Dengue virus IgG/IgM
- HAV Ab
- HAV IgM
- HBc Ab
- HBc IgM
- Hbe Ag&Ab



NHÓM KÝ SINH TRÙNG

- Echinococcus IgG/IgM
- E. Histolytica IgG/IgM
- Schistosoma IgG/IgM
- Taenia Solium IgG/IgM
- Toxocara IgG/IgM
- Trichinella IgG/IgM
- Fasciola hepatica IgG/IgM
- Strongyloides IgG/IgM
- Ascaris IgG/IgM
- Clonorchis IgG/IgM



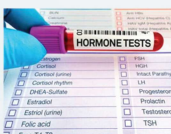
NHÓM SÀNG LỌC SƠ SINH

- Neo-Natal 17-OH Progesterone
- Neo-Natal MSUD
- Neo-Natal PKU
- Neo-Natal Galactose
- Neo-Natal T4
- Neo-Natal TBG
- Neo-Natal TSH
- Neo-Natal IRT
- Neo-Natal Biotinidase
- Neo-Natal G6PD



NHÓM NỘI TIẾT

- Normetanephrine Plasma ELISA
- Normetanephrine Urine ELISA
- Metanephrine Plasma ELISA
- Metanephrine Urine ELISA
- 2-MET Plasma ELISA
- Active Renin ELISA
- Aldosterone ELISA
- Adrenaline ELISA
- Histamine ELISA
- 3-CAT ELISA



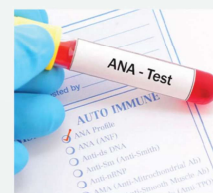
NHÓM HUYẾT HỌC

- Anti-s IgM
- Anti-A IgM
- Anti-B IgM
- Anti-A,B IgM
- Anti-D fast IgM
- Anti-E IgM
- Anti-K (Kell) IgM
- Anti-H IgM
- Anti-Cw IgM
- Anti-P (1) IgM



NHÓM DỊ ỨNG - TỰ MIỄN

- ANA-8S
- ANA-8Pro
- ENA-6S
- ENA-6Pro
- snRNP-C
- Sm
- SS-A
- SS-B
- Scl-70
- Jo-1
- ANA HEP-2
- Nucleo-h



NHÓM C13



NHÓM KHÍ MÁU



NHÓM SOI PHÂN

- FOB multi-level indefinite value controls
- Formed Element Analysis Calibrator
- Feces analyzer Cleaning Solution
- Concentrated Cleaning Solution
- Feces Formed Element Control
- Sample Diluent



NHÓM NƯỚC TIỂU

- Que thử nước tiểu nhiều thông số
- Triiodothyronine Detection Kit
- Thyroxine Detection Kit
- Thyroid Stimulating Hormone Detection Kit
- Free Thyroxine Detection Kit
- Dehydroepiandrosterone Sulfate Detection Kit
- Estradiol Detection Kit
- Prolactin Detection Kit



NHÓM TINH TRÙNG ĐỒ

- QwikCheck™ Beads
- QwikCheck™ Test Strips
- QwikCheck™ Dilution
- QwikCheck™ Liquefaction
- QwikCheck™ Vitality Kit
- Capillaries for SQATM IIC-P
- Capillaries for SQATM - Vision
- Capillaries for SQATM
- Cleaning Kit for SQATM IIC-P
- Cleaning Kit for SQATM-Vision



NHÓM TEST NHANH

- H.Pylori Antibody Rapid Test
- FOB Rapid Test
- Dengue NS1 Rapid Test
- Astrovirus Rapid Test
- Norovirus Rapid Test
- D-Dimer Rapid Test
- Dengue Rapid Test
- Dengue Combo Rapid Test
- NT pro-BNP Rapid Test
- Influenza A Rapid Test



Liên hệ

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Phú Mỹ Hưng, P. Tân Hưng, TP. HCM

Website

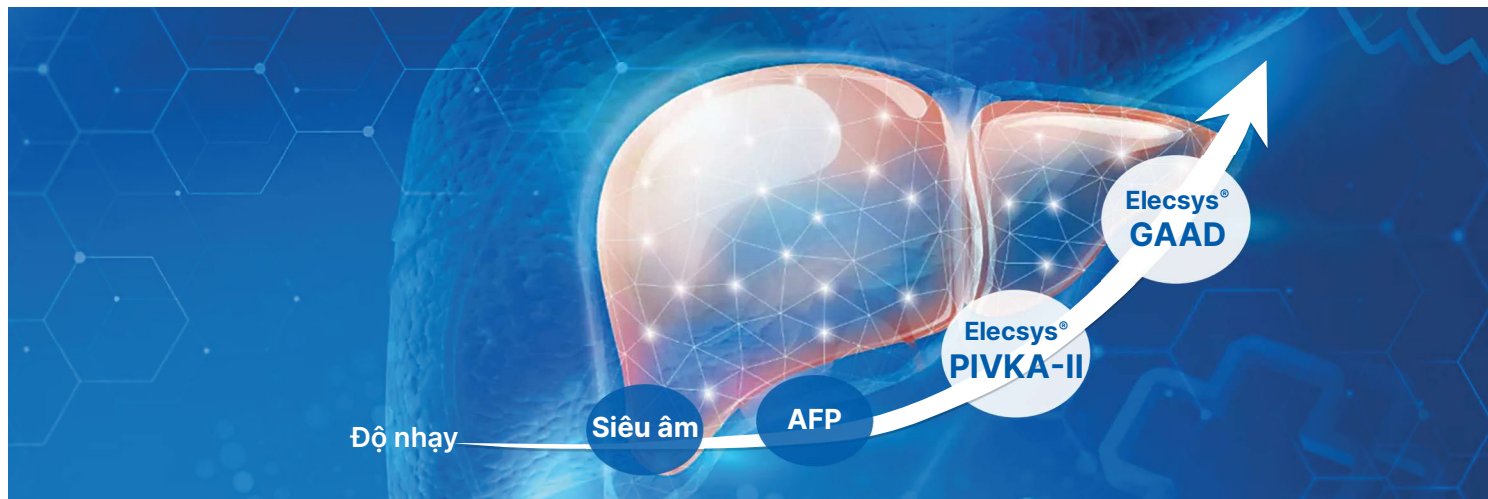


Facebook



Elecsys PIVKA-II & Elecsys GAAD

Xét nghiệm có độ nhạy và độ chính xác cao trong hỗ trợ chẩn đoán ung thư biểu mô tế bào gan nguyên phát (HCC)



Phối hợp PIVKA-II và AFP tăng độ nhạy trong phát hiện HCC giai đoạn sớm

HCC giai đoạn sớm chưa có triệu chứng. Giám sát định kỳ rất quan trọng cho phát hiện sớm và điều trị thành công



Siêu âm

Độ nhạy cho phát hiện HCC giai đoạn sớm

45%



Siêu âm + AFP

Độ nhạy cho phát hiện HCC giai đoạn sớm

63%



AFP + PIVKA-II

Độ nhạy cho phát hiện HCC giai đoạn sớm

87%



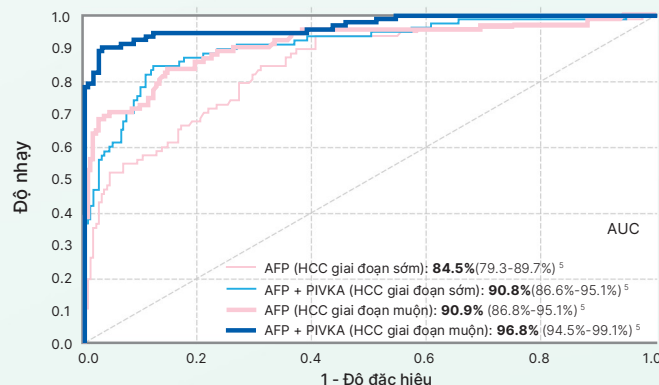
Tài liệu tham khảo: 1. Kao Wei-Yu, et al. *Medicine* Baltimore 2015;94(43):e1929. 2. Fitzmaurice T, et al. *JAMA Onco* 2017;3(12):1683–1691. 3. Henry L Y Chan et al. *JGH Open: An open access journal of gastroenterology and hepatology* 2022;6 292–300

Phối hợp PIVKA-II và AFP cho độ nhạy tốt hơn trong phát hiện HCC²

So sánh giữa phối hợp PIVKA-II + AFP và AFP

	AFP ³	AFP + PIVKA-II ⁴
Độ nhạy (tất cả các ca HCC)	51.8%	91.7%
Độ nhạy (HCC giai đoạn sớm) ^{a)}	36.4%	87%
Độ nhạy (HCC giai đoạn muộn) ^{b)}	64.8%	95.6%
Độ đặc hiệu	98.1%	82.2%

Giá trị điểm cắt AFP: 20 ng/ml; Giá trị điểm cắt PIVKA-II: 28,4 ng/ml



Thuốc thử xét nghiệm định lượng PIVKA-II
Elecsys PIVKA-II

Mã sản phẩm: 09015043190

Số lưu hành: 2301678ĐKLH/BYT-HTTB

Hãng sản xuất, nước sản xuất: Roche Diagnostics GmbH, Đức

Chủ sở hữu, nước chủ sở hữu: Roche Diagnostics GmbH, Đức

Chủ sở hữu số lưu hành: Công ty TNHH Roche Việt Nam
Tầng 27, Tòa nhà Pearl Plaza, 561A Điện Biên Phủ,
Phường 25, Quận Bình Thạnh, Tp. Hồ Chí Minh
Số văn bản công khai nội dung và hình thức quảng cáo:
132/24/QC/RV
Mã số tài liệu: MC-VN-01276

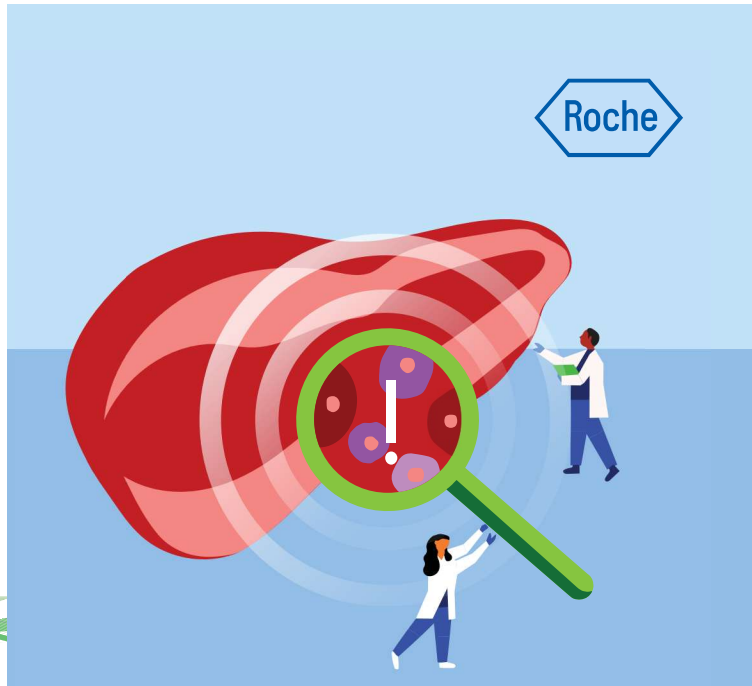
Tài liệu tham khảo:
Henry L Y Chan et al. *JGH Open:*
An open access journal of
gastroenterology and hepatology
2022;6 292–300



Elecsys® PIVKA-II

Thuật toán xét nghiệm GAAD

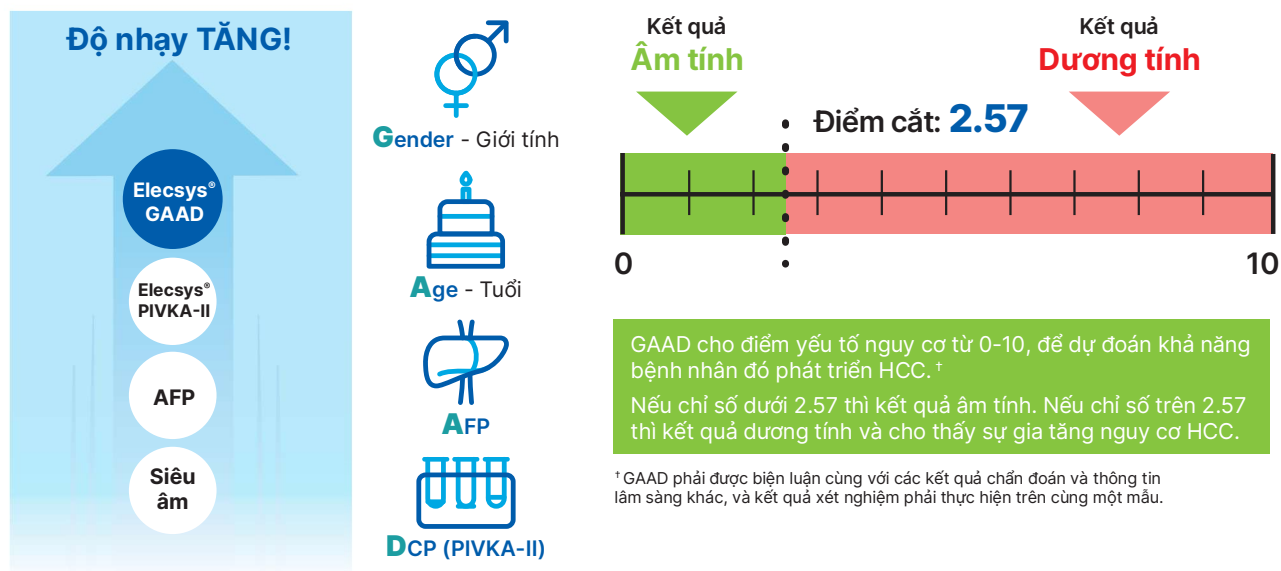
Thuật toán xét nghiệm IVD đầu tiên hỗ trợ chẩn đoán sớm ung thư biểu mô tế bào gan nguyên phát (HCC)



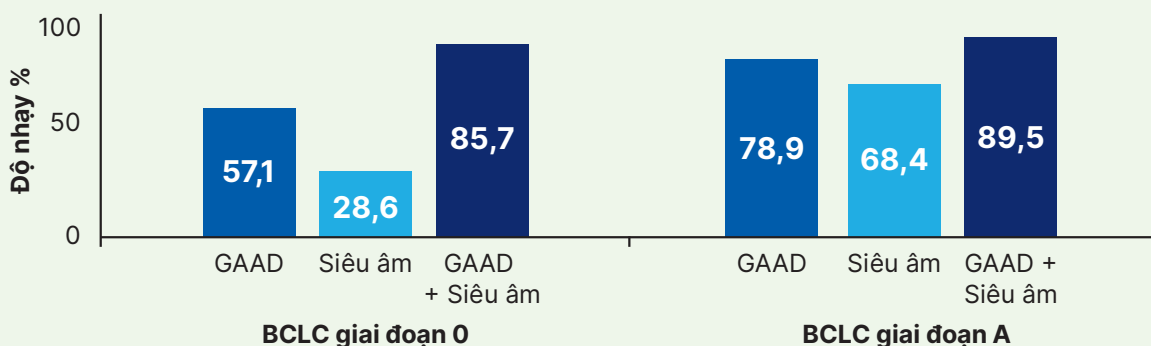
Giới thiệu GAAD

- GAAD - thuật toán chẩn đoán kết hợp các kết quả xét nghiệm AFP và PIVKA-II cùng với giới tính và độ tuổi để hỗ trợ chẩn đoán ung thư biểu mô tế bào gan (HCC) giai đoạn sớm.³
- GAAD được chỉ định cho người trưởng thành đáp ứng các tiêu chuẩn sau: đã được chẩn đoán bệnh gan mạn tính và được khuyến cáo giám sát do tăng nguy cơ phát triển HCC.³
- GAAD phải được biện luận cùng với các kết quả chẩn đoán và thông tin lâm sàng khác theo khuyến cáo quản lý thực hành lâm sàng chuẩn.³

Tài liệu tham khảo 3. Elecsys GAAD Method Sheet. Reference: 09342192001



Kết hợp GAAD với Siêu âm cải thiện phát hiện HCC ở giai đoạn sớm⁴



Tài liệu tham khảo 4. The clinical utility of Elecsys GAAD score in the diagnosis of hepatocellular carcinoma, Ming-Lung Yu, APASL STC HCC 2022



BỘ Y TẾ
ĐẠI HỌC Y DƯỢC THÀNH PHỐ HỒ CHÍ MINH
TRUNG TÂM KIỂM CHUẨN CHẤT LƯỢNG XÉT NGHIỆM Y HỌC
CHƯƠNG TRÌNH NGOẠI KIỂM QCC UMP



Đạt tiêu chuẩn:

- ✓ ISO/IEC 17043:2023
- ✓ ISO 9001:2015
- ✓ ISO 13485:2016

1. HUYẾT HỌC – TRUYỀN MÁU

- Tổng phân tích tế bào máu ngoại vi
- Phết máu ngoại biên
- Định nhóm máu
- Truyền máu cơ bản
- Truyền máu toàn diện

2. HÓA SINH

- Hóa sinh
- HbA1c
- Tổng phân tích Nước tiểu

3. HUYẾT THANH HỌC

- Huyết thanh học Viêm gan siêu vi B và C
- Huyết thanh học Ký sinh trùng
- Huyết thanh học Helicobacter pylori
- Huyết thanh học Dengue virus (*)

4. VI SINH

- Vi sinh lâm sàng
- Vi khuẩn nhuộm soi

5. KÝ SINH TRÙNG

- Phết máu tìm Ký sinh trùng Sốt rét (*)
- Soi phân tìm Ký sinh trùng Đường ruột (*)

6. SINH HỌC PHÂN TỬ

- Đo tải lượng HBV
- Đo tải lượng HCV
- Phát hiện HPV
- Xác định HPV genotype
- Phát hiện Mycobacterium tuberculosis – DNA (*)

(*): Chương trình duy nhất tại Việt Nam

BIO-RAD

18 Chương trình

RANDOX

32 Chương trình



1 Chương trình



BỘ Y TẾ
ĐẠI HỌC Y DƯỢC THÀNH PHỐ HỒ CHÍ MINH
TRUNG TÂM KIỂM CHUẨN CHẤT LƯỢNG XÉT NGHIỆM Y HỌC

CHƯƠNG TRÌNH ĐÀO TẠO
Quản lý chất lượng & Kỹ thuật y học

Các khóa Quản lý chất lượng

- ◆ Quản lý chất lượng theo Tiêu chí 2429 và tiêu chuẩn ISO 15189
- ◆ Nội kiểm & Ngoại kiểm chất lượng XNYH – Điều tra nguyên nhân sai số
- ◆ Đánh giá nội bộ – Xác định SKPH – Cải tiến liên tục
- ◆ Xác nhận giá trị sử dụng phương pháp xét nghiệm
- ◆ Mua sắm và quản lý TTB, hóa chất, sinh phẩm, vật tư tiêu hao
- ◆ An toàn sinh học trong phòng xét nghiệm
- ◆ So sánh liên phòng xét nghiệm Hóa sinh, Vi sinh, Giải phẫu bệnh
- ◆ Ứng dụng Six Sigma trong nội kiểm kiểm soát chất lượng XN
- ◆ Đào tạo Đánh giá viên hệ thống quản lý chất lượng xét nghiệm



Điểm nổi bật

- ✓ Cập nhật xu hướng mới
- ✓ Giảng viên giàu kinh nghiệm, thực chiến
- ✓ Học đi đôi với hành – dễ áp dụng
- ✓ Đào tạo theo nhu cầu, tại địa phương
- ✓ Hình thức đào tạo linh hoạt

Các khóa Kỹ thuật y học

- ◆ Kỹ thuật y học chuyên ngành xét nghiệm, Vi sinh, SHPT ứng dụng
- ◆ Nhận diện hình thái tế bào máu trên phết máu ngoại biên và lam tủy
- ◆ Truyền máu hiện đại: những thách thức và xu hướng mới
- ◆ Cấy, kháng nấm đồ, phiên giải kết quả
- ◆ Khảo sát tiêu bản máu

**Liên hệ
đăng ký!**



TRUNG TÂM KIỂM CHUẨN CHẤT LƯỢNG XÉT NGHIỆM Y HỌC

131 Nguyễn Chí Thanh, Phường An Đông, Thành Phố Hồ Chí Minh
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