EQALM SYMPOSIUM 2024

Hotel Savoyen, Vienna, Austria,
16 – 18 October

Program and Abstracts v.2

Program

Wednesday, October 16th

09.00 – 11.30 Registration

11.30 - 12.20 Lunch

Room Olympia Mancini 1

Time	Lecture	Speaker
Session: Clinical Impact of EQA		
Chair Gro Gidske		
12.30	Opening of the Symposium	Gro Gidske (EQALM chair)
12.30 - 13.10	Future of EQA	Mario Plebani (Italy)
13.10 - 13.50	Clinical Impact of EQA	Michael Spannagl (Germany)

Working group (WG) and task and finish group (TFG) - open meetings

Time	WG / TFG	Chair	Room
14.10 - 14.55	WG: Microbiology	Jaap van Hellemond	Olympia Mancini 1

The EQALM Microbiology Working Group meeting will focus on the restart of the working group. An update will be presented on the current status, after which a discussion will follow on potential new projects and the recruitment of additional members of the working group. We look forward to your participation and valuable contributions.

14.10 - 14.55	WG: Hemostasis	Ann Helen Kristoffersen	Paris&Wien

The Haemostasis working group will present results from a survey on Data evaluation and reporting of EQA results for routine coagulation parameters, give a short update on the HIL survey, and give information about the ISTH/IFCC project on the standardisation of the INR. In addition, potential new projects in EQA for coagulation parameters will be discussed.

14.55 - 15.40	WG: Virtual Microscopy	Istvan Juhos	Olympia Mancini 1

The EQALM Virtual Microscopy working Group meeting will focus on key ongoing projects and initiatives:

EQALM VM Sharing Platform: Overview and updates. Discussion on status and next steps
EQALM VM Image Database: Current progress and plans for expansion and enhancement
EQALM VM Collaborative Network: Introduction and goals. Opportunities for collaboration and engagement

We look forward to your participation and valuable contributions.

Working group (WG) and task and finish group (TFG) - open meetings

Time	WG / TFG	Chair	Room
14.55 - 15.40	WG: Immunohaematology	Richard Haggas	Paris&Wien
The Immunohaematology working group meeting will focus on discussing the progress against the antibody screening sensitivity exercise and any initial results we have received.			
15.40 - 16.00	*Break*		
16.00 – 16.30	WG: Haematology	Barbara De la Salle	Olympia Mancini 1
The Haematology working group committee will present the summary of the work undertaken during the year, including the outcome of the survey on normal ranges planned at the 2023 meeting. Delegates will be invited to propose new work items for the group. We welcome any new interest in joining the Haematology WG steering committee.			
16.00 – 16.30	WG: Frequency	Wim Coucke	Paris&Wien
A brainstorm will be held to collect ideas to work on, around the following topics: *More samples are a cost for the EQA provider and the participating laboratories, but more samples lead to more information. How do we find a trade-off?* *How do we find evidence for best frequency apart from theoretical models?* *Do we all need to optimize frequency, or can we collaborate and share data?*			
16.30 - 17.00	WG: EQA for POCT	Tony Badrick	Olympia Mancini 1
The EQA for POCT working group meeting will provide feedback on a pilot project to measure the performance of PoCT in non-laboratory situations using EQA data. The discussion will concentrate on the difficulties of providing EQA for PoCT.			
16.30 - 17.00	TFG: ISO/IEC 17043:2023	Stephanie Albarede	Paris&Wien
The revised standard ISO/IEC 17043:2023 is now available! The ISO/IEC 17043 TFG will now be looking at different approaches to managing the major differences between the 2010 and the 2023 versions of the standard. A number of EQA/PT providers have already transitioned to the revised standard and the TFG meeting will be a unique opportunity to share experiences.			
17.00 - 17.45	WG: Performance Specifications	Dalius Vitkus	Olympia Mancini 1
Results of EQALM survey “Identification of exchangeability of results. The role of EQA organisations” will be presented. Progress on the project “How equal is equal enough to allow combination of data within one health record” will be discussed.			

Working group (WG) and task and finish group (TFG) - open meetings

Time	WG / TFG	Chair	Room
17.00 - 17.45	WG: Immunology	Dina Patel	Paris&Wien

The aim of the Immunology working Group is to collaborate with other EQALM members to try to understand how immunology practices for anti-nuclear testing (ANA) tests are utilised within member countries. A survey was circulated to EQALM members in summer 2023 and results analysed by the group in autumn 2023. The results from the survey will be presented and discussed with EQALM members during the EQALM annual Meeting in Vienna in October 2024.The Immunology WG will publish a paper using the data from the survey.

Room Olympia Mancini 1
Meeting regarding feedback on EQALM's potential transition to an international organization
18.00 - 18.30
Chair *Barbara De la Salle*

During this meeting, we will review the proposal documents, the proposed amendments to the Articles of Association, and address any questions on the voting procedures.

/EQALM Board

Thursday, October 17th

Room Olympia Mancini 1

Time	Lecture	Speaker
COMET project: Manufacturing of commutable calibrators and quality control materials *Chair Wim Coucke*		
08.30 - 08.50	TraceLabMed survey	Gavin O'Connor (Germany)
08.50 - 09.10	Presentation of the COMET project	Vincent Delatour (France)
09.10 - 09.30	The role of EQALM	Piet Meijer (The Netherlands)
09.30 - 09.45	*Short break*	
Session: Follow-up from Symposium 2023 *Chair Wim Coucke*		
09.45 - 10.15	Outcome of last years' breakout discussion session: Use of statistics, commutability testing and education in EQA	Barbara De la Salle (United Kingdom)
10.10 - 10.30	IVD-R and EQA	Paolo Mellino (Germany)
10.30 – 11.00	*Break*	
Session: (Personal) Competence, Image-based EQA *Chair Pierre-Alain Morandi*		
11.00 - 11.20	Image based EQA	Emilia Svala (Sweden)
11.20 - 11.40	EQALM Virtual Microscopy Collaborative Network	Istvan Juhos (Hungary)
11.40 - 12.00	Nordic immunohistochemical Quality Control (NordiQC)	Rasmus Røge (Denmark)
12.00 - 13.00	*Lunch*	

Room Olympia Mancini 1

Time	Lecture	Speaker
Session: News from working groups/task and finish groups *Chair Gitte Henriksen*		
13.00 - 13.15	Normal ranges in automated blood counting	Barbara De la Salle (United Kingdom)
13.15 - 13.30	Sensitivity of antibody screening tests – the 2024 EQALM Super Challenge	Christoph Buchta (Austria)
13.30 - 13.50	Projects in EQALM Central Database	Wim Coucke (Belgium)
13.50 - 14.10	ISO/IEC 17043:2023. Suggestions for implementation	Olivier Pierson (France)
14.10 - 15.00	*Break*	
14.20 – 14.40	*Meet the poster presenters*	
15.00 - 16.00	General Assembly	Gro Gidske (Norway)

Adam Uldall Lecture

Chair Gro Gidske

16.00 - 17.00	EQA and its ”abilities”	Anja Kessler (Germany)

Social Event

Dinner in the historic Heurigen (wine tavern) on the outskirts of Vienna

The buses will pick us up at 18.00 in front of the Hotel Savoyen

EQALM Symposium 2024
Hotel Savoyen, Vienna, Austria
October 16th-18th

Friday, October 18th

Room Olympia Mancini 1

Time	Lecture	Speaker
Abstract session *Barbara De la Salle*		
09.00 - 09.15	Setting up an External Quality Assessment Scheme for the microbiology aspects of heart valve banking	Nita Patel (United Kingdom)
09.15 - 09.30	Proposal for harmonized method classification system for external quality assessment schemes	Stephanie Albarede (France)
09.30 - 09.45	Measurement Uncertainty in Clinical Biochemistry and ISO/IEC 17043:2023	Rachel Marrington (United Kingdom)
09.45 - 10.00	Artificial intelligence determined reference value (rAIght value) included in virtual histopathology EQA scheme: comparison of participating pathologists and a trained image analysis algorithm	Jonna Pelanti (Finland)
10.00 - 10.15	18 years of performance evaluation of molecular detection of enteroviruses by QCMD	Oliver Donoso (United Kingdom)
10.20 - 10.50	*Break*	
Session: Clinical performance specifications and misclassification of patients *Chair Rachel Marrington*		
10.50 - 11.10	Commutability of reference materials – perspective of the clinical laboratory	Michael Vogeser (Germany)
11.10 - 11.30	Analytical performance specifications - are we providing clinically appropriate EQA?	Annette Thomas (United Kingdom)
11.30 – 11.50	Serological misclassification	Lukas Weseslindtner (Austria)
11.50 - 12.10	How EQA performance can be used in simulation studies to check whether laboratory performance is clinically appropriate	Marc Thelen (The Netherlands)
12.15	*Closing of the symposium*	*Gro Gidske, EQALM Chair*

EQALM Symposium 2024

Hotel Savoyen, Vienna, Austria

October 16th-18th

The Symposium is supported by IFCC

GH 2024-09-30
Subject to change

Adam Uldall Lecture

EQA and its ‘abilities’

Anja Kessler

Speaker Abstracts

Future of EQA

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Introduction

Inter-laboratory comparisons are a mandatory requirement for accreditation to the international Standard specifically developed for medical laboratories (ISO 15189: 2022). External quality assurance (EQA) programs offer an organized and valuable approach to these appraisals, allowing large-scale statistical comparisons to be made. Therefore, first and foremost there is the need to maintain and improve the link between the two already mentioned professional and fundamental professional activities of laboratory professionals.

Aims

Currently, EQA programs are at the crossroads of many challenges:a) first, after some decades the discussion between the regulatory and educational programs needs to be clarified and the main question is if EQA are still adopted “by tradition” rather than as effective tools for improving analytical quality and reliability of laboratory results. b) second, EQA programs should investigate not only the analytical phase but the quality of laboratory information; c) third, in the era of metrological traceability, EQA programs should investigate not only a few number of clinical chemistry measurands, but all available laboratory tests in haematology, coagulation, serology, molecular diagnostics and genetics

Methods

The most interesting advancements in EQA programs regard: (a) the nature of control materials, namely their commutability and value assignment; (b) establishment of analytical performance specifications (APS) for results evaluation; (c) the introduction of extra-analytical performances evaluation; (d) harmonization among existing EQAs and EQAs providers

Results

In the era of standardization, the implementation of an optimal EQA program is based on the use of commutable samples that have target values assigned by high-order reference measurement procedures which are available for less than 20% of the measurands analyzed in current medical laboratories. Therefore, there is the need to provide guidelines and recommendations to improve EQA programs dealing with hematology, coagulation, serology, molecular and genetic tests. In addition, EQA programs should evaluate the quality and integrity of samples (pre-analytical phase) and the main comparators (measurement units, reference intervals, decision limits, interpretative comments (post-analytical phase)

Conclusions

There are many barriers to better implementation of valuable EQA programs at an international level, including limited resources in low- and middle-income countries. Harmonization of EQA programs requires a closer collaboration between many stakeholders including professional bodies (EQALM), national and international scientific societies and federations, accreditation agencies, regulators and manufacturers. However, EQA programs are a fundamental tool for improving harmonization in laboratory medicine.

Clinical Impact of EQA

Michael Spannagi

Improved patient outcome at acceptable cost is the ultimate goal of further development of healthcare systems. Laboratory results have an important impact on diagnosis, treatment and monitoring of patients but also on prevention of disease. EQA allows for comparison of available test systems but also for comparison of laboratories in respective ring trials. Assuming the ring trials collect real word data EQA allows for effectiveness perspective in the comparative assessment of laboratory test systems.

Cross sectional and longitudinal comparability of lab values is of utmost importance for national and global healthcare structures. Most consensus documents and guidelines aimed for harmonization and standardization of diagnostic and/or therapeutic pathways rely on direct comparability of laboratory results obtained in different clinical situations. Meanwhile this claim is extended to results obtained from lay users in a point of care setting.

This extended use of laboratory tests has to be recognized in the further development of external quality assessment. Programs and perspectives focusing analytical procedure and/or the extended view on interpretation and outcome may be different depending on the individual structure and responsibility of the different organizations.

The role of metrological traceability in external quality assessment schemes and calibration laboratories – Results of a survey conducted by the EMN-TLM

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Introduction

Clinical laboratory testing forms a critical part of the decision-making process for disease diagnosis and patient care. The development of reference ranges that inform on reliable and safe patient diagnosis requires the measurement results used in establishing these ranges to be comparable. Also, for effective individual patient diagnosis, the results from the individual patient samples must also be comparable. An established approach for improving the comparability of measurement results is the concept of metrological traceability. For well-defined measurands, this often involves the development of reference measurement procedures, that provide results that can be directly linked to the international system of units (SI), with fit-for-purpose uncertainty estimates to act as a reference. These procedures are then used for the characterisation of matrix certified reference materials or materials used in external quality assessment schemes.

Aims

The European Association of National Metrology Institutes, EURAMET, has recognised the strategic importance of laboratory diagnostics as a key backbone for safe and reliable patient diagnosis in Europe. In response to this heightened regulatory focus and recent advancements in metrological applications within the field, the European Metrology Network (EMN) on Traceability in Laboratory Medicine (TLM) was established. A survey was conducted to understand the growing needs regarding the traceability of in-vitro diagnostics under the reinforced rules on clinical evidence and performance evaluation of the IVDR and to gain a comprehensive understanding of the current and future needs of EQA providers' for engaging with the broader metrology community.

Methods

The survey was conducted using LimeSurvey (v3.26.1) hosted on the EURAMET server. Participants' exposure to some questions was contingent upon their responses to prior items, with certain questions being revealed or concealed accordingly.

Results

A total of 29 participants responded to the study. These included 25 EQA providers, 1 calibration laboratory, and 3 participants engaged as both EQA providers and calibration laboratories. EQALM currently has 31 European members, 5 non-European members and 3 associate members, corresponding to a response rate of 74 %. All those who responded had prior knowledge of the concepts of traceability in clinical measurement results. 69% of the respondents thought it vital that the assigned values of EQA materials should be traceable to the SI while the same percentage thought evaluation of participant performance against SI traceable assigned reference values as being more reliable than the use of study consensus values. Most respondents reported using measurement uncertainty estimates with just 31% failing to do so. A variety of reasons as to why this was not performed were provided.

Conclusions

There was a unanimous understanding among respondents about the vital importance of traceability in clinical measurements, highlighting its crucial role in maintaining accuracy and reliability across different laboratories and IVD manufacturers. Respondents have emphasized that commutability is a critical aspect for establishing metrological traceability of patient results. To support establishing a higher number of category 1 EQA schemes, it is crucial to address challenges like cost, availability, commutability, and to provide tailored training. Establishing such schemes seems also necessary considering the impact of the IVDR.

COMET project : Manufacturing of commutable calibrators and quality control materials

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Introduction

Medical decisions often depend on accurate, informative and comparable biomarker measurement results from commercial in vitro diagnostic (IVD) tests. According to the in vitro diagnostic regulation (IVDR) EU/2017/746, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures (RMPs) and/or suitable Certified Reference Materials (CRMs) of a higher metrological order. Due to a lack of biological CRMs and RMPs, IVD manufacturers are often unable to fully comply with regulation.

Aims

The COMET project will enable the IVD industry to better meet the requirements of the IVDR EU/2017/746 regarding metrological traceability and performance verification of IVD tests. This will be achieved by establishing the necessary metrological infrastructure to provide cost-effective calibration services to IVD manufacturers to properly establish calibrated IVD tests and better monitor their performance.

Methods

New certified reference materials and quality control materials will be produced for IVD tests which are in need for standardisation and post-market surveillance. By developing more efficient ways to conduct commutability studies, the project will identify common causes of poor commutability and improve the manufacturing process.

The role of EQALM in the COMET project

Piet Meijer
on behalf of the TFG COMET project (Gitte Henriksen, Wim Coucke and Piet Meijer)
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Introduction

The COMET project focusses on the manufacturing of commutable calibrators and quality control materials for standardisation and post-market surveillance of IVD tests. The total project exists of 6 working packages and 23 tasks. Each task exists of a variety of activities.
EQALM is an associate partner in this project and is involved in over 40 different activities. This may vary from distributing questionnaires to EQALM members, collecting data from different EQA programmes to developing protocols for performance verification and harmonisation monitoring of IVD tests through EQA data aggregation.
An important contribution of EQALM in the COMET project is the use of the EQALM Central Database.
During the presentation details will be provided of the role of EQALM in this COMET project Also the benefits for EQALM to participate in this project will be discussed.

Outcomes from the 2023 Symposium breakout session

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Introduction

The EQALM 2023 meeting included a new, interactive breakout session, which had the intention of encouraging us to share knowledge, obtain new ideas and, above all, make new friends. Three topics were presented to the session: 1) The Use of Statistics, 2) Commutability Testing and 3) Education in EQA, and delegates discussed pre-set questions selected from a brief survey circulated in advance of the Symposium. A report of the session was shared with EQALM members earlier this year. Today's presentation will review the outcomes of the breakout session and the feedback received on this innovative addition to the EQALM Symposium programme.

IVD-R and EQA

Paolo Mellino

Image-based EQA

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Introduction

Equalis, a Swedish not-for-profit organization, provides a variety of external quality assessment (EQA) schemes. Several of the EQA schemes are focusing on medical imaging and cover areas such as vascular ultrasound, echocardiography, point-of-care ultrasound, radiology, nuclear medicine (e.g., whole-body bone scintigraphy), lung physiology diagnostics, diagnostic cancer pathology, and digital cell morphology. The accuracy of these examinations relies heavily on the knowledge and expertise of the individual, making EQA essential for evaluating and enhancing personal competence.

Aims

Present the process of Equalis' image-based EQA schemes.

Methods

Images used in the EQA schemes are either authentic clinical images or images closely resembling them, aiming to match the characteristics of real-life clinical settings as accurately as possible. These images are distributed via digital imaging systems, developed either in-house or in collaboration with external partners. Participants are required to evaluate the images using various methods, including performing measurements, classifying cells, identifying pathology, answering multiple-choice questions, or providing clinical diagnostic opinions. Each participating unit (e.g., laboratory, department, clinic) has access to two types of user accounts for result submission. A single shared user account is used to register either a representative response (where an individual is selected to represent the entire unit) or a consensus response (discussed and agreed upon within the unit). The other type of user accounts is the personal user accounts that are anonymous, meaning that Equalis cannot access information about which individual has submitted results from a specific user account. Depending on the specific EQA scheme, additional information about the individual participant may be requested, such as the number of years of experience with the specific examination, academic degree, professional title, or whether the participant has the authority to examine these images in a real-life clinical setting.

Results

Results are presented to easily distinguish between the individual responses and the representative/consensus response. Within Equalis' EQA schemes, the participants are responsible for assessing their own results and for taking appropriate actions if necessary. In the area of personal competence, a corrective action may include the need for professional development or skills enhancement. The outcomes of the image-based EQA schemes are also discussed at the annual Equalis' user meetings, providing a platform for participants to engage with the Equalis' advisory group and peers, encouraging improvement of knowledge.

Conclusions

Equalis' image-based EQA schemes play an important role in assessing and enhancing personal competence, thereby improving the quality of examinations that are highly dependent on the individual'sexpertise.

EQALM Virtual Microscopy Collaborative Network

Dr István Juhos
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Introduction

This talk covers the development of the EQALM Virtual Microscopy Collaborative Network, detailing its journey from vision to action.

Aims

Vision
In 2016, the EQALM Virtual Microscopy Working Group (VM WG) identified a key challenge: although virtual microscopy offers significant advantages for External Quality Assurance (EQA), many EQALM members lacked essential resources like scanning infrastructure, high-resolution digital images, and specialised software. This led to the vision of creating a collaborative network to share VM resources and expertise, improving EQA across the network.

Methods

Action
To bring this vision to life, the following initiatives were launched by the EQALM VM WG:
EQALM VM Sharing Platform: developed with the University of Szeged, this platform enables members to share resources, including scanning services, digital images, and expertise, making virtual microscopy accessible for use in EQA practices by all EQALM members.
EQALM VM Guidelines: scientific and technical standards were created to ensure consistency and efficiency in the use and exchange of shared resources, as well as to harmonise EQA and educational programs.
EQALM VM Image Database: a shared database of high-quality digital images allows members to access and contribute to a repository of VM resources for EQA and education.
EQALM VM Collaborative Network: the platform, image database, and guidelines enable EQALM members to strengthen knowledge exchange and collaboration on EQA and educational programs, while advancing AI-driven initiatives in both areas and healthcare.

Results

Legal framework
As these initiatives expanded, the need for a formal structure to oversee the EQALM Virtual Microscopy Collaborative Network became clear. To ensure long-term sustainability, a non-profit organisation will be established, maintaining a strategic partnership with EQALM. This organisation will manage the legal, administrative, and technical aspects of the network, facilitating the sharing and exchange of resources and knowledge on healthcare quality, particularly in virtual microscopy. The network will primarily support external quality assurance (EQA), educational programs, and advancements in artificial intelligence on a global scale.

Conclusions

This network is a crucial step toward enhancing global healthcare quality through collaboration, standardisation,andinnovation.

Nordic Immunohistochemical Quality Control (NordiQC)

Rasmus Røge, NordiQC scheme organizer, MD, PhD
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Introduction

Immunohistochemistry (IHC) plays a critical role in diagnostic pathology, enabling visualization of specific antigens in tissue samples. However, accuracy and reproducibility of IHC results can be influenced by numerous factors, including the choice of primary antibodies, staining protocols, and interpretation criteria. The Nordic Immunohistochemical Quality Control (NordiQC) is an independent external quality assurance (EQA) program working to ensure high standards in IHC across laboratories.

Aims

The primary aim of NordiQC is to improve the quality of IHC staining in diagnostic pathology laboratories by providing objective assessments of submitted IHC stains, constructive feedback, and guidance on optimal staining protocols. By regularly participating in NordiQC, laboratories can identify suboptimal procedures. Due to high number of participants using different staining protocols, data analysis allow identification of optimal staining protocol parameters and control tissues.

Methods

NordiQC operates by distributing tissue microarrays containing well-characterized tissues with known antigen expression levels to participating laboratories. Laboratories perform IHC staining using their routine protocols and return the stained slides to NordiQC for evaluation. The slides are assessed by a panel of expert pathologists and technicians who review the quality of the staining reaction based on predefined criteria such as specificity, sensitivity, and signal-to-noise ratio. Detailed reports are published on the NordiQC homepage. Additionally, each laboratory receive individual results with recommendation for improvement if needed. The published reports offers recommendations for control tissue and optimized staining protocols, including the selection of primary antibodies, antigen retrieval methods, and detection systems.

Results

Over the years, significant improvements has been demonstrated in the quality of IHC staining among participating laboratories. Feedback from the program has led to the adoption of more standardized and effective staining protocols, resulting in enhanced diagnostic accuracy. However, around 25% of all IHC slides submitted to NordiQC are still assessed as technical insufficient for clinical use. The insufficient results in NordiQC are primarily due to a combination of factors, including the use of less successful or poorly calibrated antibodies, particularly in Ready-to-Use (RTU) solutions, and the dependency of some antibodies on specific stainer platforms. Additionally, insufficient or erroneous epitope retrieval and less sensitive visualization systems further contribute to suboptimal outcomes. Technical issues such as impaired morphology and excessive counterstaining also play a role in compromising the quality of immunohistochemical staining. The IHC quality is better in modules with predictive markers (e.g. HER2, PD-L1).

Conclusions

External Quality Assurance (EQA) programs like NordiQC provide critical objective evidence of laboratory performance, identifying methodological errors and offering clear guidance for improvements and quality control measures. The results from NordiQC highlight a significant need for the improvement of immunohistochemistry (IHC) practices. To achieve optimal IHC performance, there must be a stronger alignment between EQA schemes, industry standards, and IHC experts.

Normal ranges in automated blood counting

Barbara De la Salle

Sensitivity of antibody screening tests - the 2024 EQALM Super Challenge

Christoph Buchta

- Antibodies against blood group antigens can cause serious or even fatal incidents if they react with antigens on erythrocytes during a transfusion or during pregnancy, for example.
- To prevent such reactions, antibody screening is carried out before transfusions and during pregnancy and, if necessary, suitable blood products are selected or treatments carried out.
- The patient's serum is mixed with erythrocytes with known blood group antigens, and it is observed whether reactions in the form of agglutinations occur.
- While there are some publications on the specificity of antibody screening tests (antibodies against which blood group characteristics are detected), no reports could be found on their sensitivity (detection limit that an antibody must exceed to be detected).
- To investigate the sensitivity of different antibody screening tests in practice, we prepared EQA sample materials with the antibodies against the blood group antigen D (= “Rhesus positive”) in four different low concentrations. These samples were sent from 8 EQA providers to the participants in their respective schemes.
- The results of this “EQALM Superchallenge” will be presented in this lecture.

Projects in EQALM Central Database

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Introduction

Introduction

The EQALM central database has been used for various projects dealing with EQA data.
The HALMA project is still using the data that were collected in 2023 to find similarities between data from various EQA providers.
Two projects organized by the EQALM working groups have used the EQALM central database as well: a pilot project in the POCT working group and as a database to collect data from the international anti-D study run by the immunohaematology working group

Aims

The HALMA project aims at assessing harmonisation between laboratory methods by aggregating EQA data.
The project from the POCT working group aimed at establishing a proof of concept for assessing performance of POCT methods for CRP, and the international anti-D study aimed at assessing performance of methods for detection of the anti-D antibody at different concentration levels.

Methods

A reflection on the data was made in the HALMA project, since data from different EQA providers did not always show comparable differences between laboratory methods. A method has been developed to find a threshold that can be used as a maximum difference between samples from different EQA providers to consider them as similar and containing the same laboratory method harmonisation information. In addition, a method has been developed to help establishing homogeneous method groups.
For the POCT pilot study, the characteristic function was used to model the variability of various POCT devices.
A new infrastructure of the EQALM database will also be presented to answer to future needs, in particular the variety in data structures of the data that are being transferred to the EQALM central database.

Results

For the HALMA project, thresholds will be presented to help identifying similarities between samples arising from different EQA providers.
For the POCT project, noticeable differences were found between POCT devices.

Conclusions

The EQALM central database has proven its ability to collect EQA results to draw useful information that could not be derived from data from one single EQA provider.

ISO/IEC 17043:2023. Suggestions for implementation

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Introduction

The last edition of ISO 17043 standard “General requirements for the competence of proficiency testing providers” was published in may 2023 and has to be implemented within three years in the context of accreditation.

Aims

Although this new version does not introduce major changes regarding the proficiency testing (PT) process, the new structure of the standard, aligned on ISO 17025 and consistent with the new ISO 15189, provides an opportunity to rethink the architecture of existing PT management systems and to implement process approach more efficiently.

Methods

Suggestions for the implementation of the new requirements will be presented, with emphasis on the concept of surveillance of the PT processes and on new clauses also introduced in order to promote the risk approach.

Results

Examples of solutions will be given. Recommandations will be providef for some requirements of the previous standard that have been strengthened, such as those concerning impartiality, complaints and appeals, information management systems, which induce the need for the definition of explicit processes.Several clauses which have been simplified or deleted will also be addressed.

Conclusions

As a conclusion, the revision of ISO 17043 allows to challenge external quality assessment programmes and PT provider management systems in terms of performance

Commutability of reference materials – perspective of the clinical laboratory

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Commutability has been highlighted as one of the most fundamental requirements for quality assessment (QA) materials in laboratory medicine. However, it is important to emphasize that commutability in a given constellation does not necessarily mean that a material is suitable for its intended purpose in internal or external QA of a clinical laboratory.
The definition of commutability according to the International Vocabulary of Metrology makes it clear that commutability is not an “absolute”, inherent property of a material, but always a “relative” property attributed to a material in a specific constellation related to two or more distinct measurement procedures. These procedures, however, may vary greatly in their performance characteristics, especially regarding selectivity and specificity.
Formal commutability of a QA material can suggest close between-method agreement of different analytical methods - although results of real patients’ samples may differ substantially. This is most evident in the field of therapeutic drug monitoring, where the presence of related drug metabolites is common. For a QA material that is spiked only with the respective target analyte - and not simultaneously with the drug metabolites generated from this compound in vivo - commutability can be observed with respect to several routine analytical methods, which in turn indeed differ significantly in their respective analytical sensitivity to metabolites, leading to discrepant clinical results in patient samples.
Commutability of a QA-material related to a wide range of assays may be convenient for manufacturers – since no method-specific target ranges have to be specified. However, such “commutable” materials may fail to display specificity-related differences between routine analytical methods. Metabolite-free – but thus widely commutable - QA materials may also fail to display specificity issues in long-term assay monitoring by internal QA.
Accordingly, the relevance and meaning of commutability need to be thoroughly considered in relation to specific analytical constellations and diagnostic requirements – indeed, in group-tests (e.g. for growth-hormone isoforms) high specificity may not be desired clinically. In conclusion, prudent and correct use of the term and concept of commutability is essential for meaningful communication between QA institutions, manufacturers and clinical laboratories.

Analytical performance specifications (APS) - are we providing clinically appropriate APS for External Quality Assessment (EQA)?

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Introduction

In terms of EQA, APS is defined as a range of values around the target which is considered acceptable for the performance of that test. A result outside the acceptable range should alert the laboratory that that their assay may produce results that are at risk of detrimentally affecting clinical decision making. It provides a simple tool to allow a rapid, standardized assessment of EQA results in both numerical and graphical report formats. Laboratories and Point of Care (POCT) users must ensure that the analytical quality attained for that test is appropriate for the needs of the clinical service and the clinical utility of the test. It is therefore essential that EQA performance specification also reflect the clinical need and utility of the test. Various strategies have been proposed over the last 25 years, including the Consensus hierarchy from the Stockholm Conference in 1999, and the simpler EFLM Milan strategy in 2014.

Aims

To review the strengths and weaknesses of the various models in the Milan strategy and propose an APS for routine chemistry analytes. Analytes were assessed against:
Model 1. Based on the effect of analytical performance on clinical outcomes. This model is the most rationale since it is based on the actual clinical outcome; however, in practice it is applicable only to a few tests since it is difficult to show the direct effect of laboratory tests on medical outcome.
Model 2. Based on components of biological variation of the measurand. This model seeks to minimize the ratio of the analytical noise to the biological signal. Its applicability can however be limited by the validity and robustness of the data on biological variation.
Model 3. Based on the state of the art. This model is the one where data is most easily available. It is linked to the highest level of analytical quality achievable with the currently available techniques.

Methods

Laboratory and Point of Care method performance data from Weqas in the UK was collected over the last five years across a wide clinical concentration for the common analytes in Clinical Biochemistry. The data covered 60 distributions using 240 samples, assayed by 200 laboratories for a range of analytes. Precision profiles were calculated for each analyte and for each of the major methods used for that analyte. These were represented as Standard Deviation (SD) against analyte concentration. For certain analytes the data was also assessed according to whether the analyte was used for laboratory diagnosis or POCT monitoring.

Results

The strengths and weaknesses of the various models were reviewed and compared with what was achievable in a real-world environment. There was little published data on APS from clinical outcome studies and this was only achievable for HbA1c. Although Model 2 was achievable for a number of analytes, it was rarely achievable across the full pathological range. The relationship between Standard deviation (SD) and analyte concentration was rarely linear, and a hybrid (mixed) model of Model 2 and 3 was proposed in this situation.

Conclusions

APS for routine chemistry analytes is proposed based on real life data.

Serological misclassification

Lukas Weseslindtner

How EQA performance can be used in simulation studies to check whether laboratory performance is clinically appropriate

Marc Thelen

Poster and Oral Abstracts

Proposal for harmonized method classification system for external quality assessment schemes

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Introduction

The various associations (non-profit associations) External Quality Assessment (EQA) programs providers in France have formed a federation (FAEEQ) with the aim of harmonizing their practices. Two lines of action have been developed, one concerning the coding of the various elements essential to characterizing the results supplied by participants in these programs, the other concerning the establishment of performance specifications designed to assess the quality of results in terms of accuracy.

Aims

The international LOINC system was found to be inadequate for characterizing the results observed during the EQA evaluations, identical codes providing non-comparable results.
For appropriate evaluation of EQA results supplied by the participating laboratories, identification of measurands, units, biological matrices, In Vitro Medical Device (IVD) principle, manufacturer reagent and instrument is necessary, especially where it contributes to between results discrepancies.
Need for a database linked to harmonized system of all the IVDs available on the market, applicable to all disciplines of medical laboratories (biochemistry, hematology, microbiology, and immunology) was obvious for a long time.

Methods

Working groups have been set up to cover all specialties and elements of the database.
Manufacturers have been involved to provide information about commercialized In vitro medical devices (IVD) used in France.
The identification system proposed by FAEEQ includes identification of measurand, units, IVD medical devices including analytical general principle, manufacturer reagent, instrument, and calibrator/standardisation.

Results

In vitro medical devices (IVD) used in France have been identified and classified according to a table of general principles as Chromatography (affinity, ions exchange, HPLC, CPG, CCM, gel filtration according to the detection system), Electrophoresis, Electrochemistry (Amperometry, Coulometry, Conductimetry, Polarimetry, Potentiometry…), Spectrometry (Atomic Absorption, Atomic Emission, ICP, Mass Spectrometry), Spectrophotometry applied to substrate or enzymes measurement, Flow cytometry, genetics (amplification systems, karyotype, MLPA, NGS sequencing, DNA chips, CGH array, RFLP, Sanger sequencing, STR, PCR, RT PCR…), Immuno-analysis (Agglutination, Hemagglutination, Chemiluminescence, Immunofluorimetry, immunochromatography, immunodiffusion, Radioimmunology, Nephelometry, Turbidimetry) and so on…
The analytical principle of the method is also associated to the manufacturer IVD reagent, instrument and calibrator identification.
The identification system proposed by FAEEQ includes several tables: Analytes table (measurand or qualitative analyte), Units table (g/L, mmol/L, IU/L…), Matrices table (serum, urine, blood, sweat…) analytical principle, IVD manufacturers table for reagents and instruments
This system has been adopted under the auspices of the National Health Agency for safety (ANSM), by the National Digital Agency for Health (ANS) to identify patient results within the interoperability framework of exchanges from different national laboratories.

Conclusions

Constant updating of this database is one of the major difficulties encountered and stay a challenging issue.

The extension of the field of application of this database to identifying patient results for interlaboratory exchanges is the key to the success of this work.

The identification system described could be an asset for the development of the Harmonization of Measurands in Laboratory Medicine through Data Aggregation (HALMA) project.

EQA schemes may give a contribute to assess the quality of clinical pathways: the case of colorectal screening in Tuscany

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Introduction

Tuscany is an Italian region traditionally oriented to public welfare; public health is a key point in local governance and oncological screenings are offered to general population of appropriate age. The screening programs are constantly monitored by specific indicators of compliance, efficiency and efficacy, gathered by public agencies.

Aims

To get further insights on the screening programs, the Centro Riferimento Regionale VEQ - CRRVEQ, a public EQA provider, launched in January 2024 an initiative, named" Focus on colorectal cancer", in order to assess the analytical quality of laboratory tests involved in the Tuscany colorectal cancer screening, based on performances obtained in "Fecal Occult Blood EQA" and "Human Pathology EQA".

Methods

The first scheme is managed according to ISO 17043:2010 and underwent minimal changes: the samples number was increased to 8 sample/cycle. The second scheme was redefined to propose digitalized histological samples representative of the possible finding during colonoscopy and, moreover, of colorectal cancer spectrum of disease. Participants were asked to define the lesion according to WHO 2019 classification.

Results

In itinere evaluation of both EQA schemes results was performed and major findings were the following: public laboratories offering FOB measure, either to answer unspecified clinical questions or to accomplish a screening initiative, applied the same analytical methodology, adopted the same cut off value and, consequently, were consistent in test interpretation (positive vs. negative). Private laboratories were not homogeneous neither in analytical methodology, nor in cut off values used and the majority expressed results merely as qualitative data. The Pathology Units performing histological samples evaluation were exclusively public and showed a good concordance in diagnosis, although the adherence to the WHO 2019 classification was poor.

Conclusions

The initiative is in progress and results are preliminary; the "focus initiative" will be completed in December 2024. A meeting with all the laboratories involved and with representatives of Tuscany Region council is already planned, in the form of a "consensus conference", aimed to define a strategy to harmonize both analytical and interpretative results, as well as to encourage the adoption of current terminology for lesion classification.

Identification of polyclonal Vs monoclonal samples within the UK NEQAS for Monoclonal Protein Identification EQA Scheme

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Introduction

Monoclonal gammopathies range from asymptomatic, benign disorders, such as monoclonal gammopathy of undetermined significance (MGUS) to malignant plasma cell and lymphoid disorders, including multiple myeloma and Waldenstrom's macroglobulinaemia.
Laboratories use a variety of methods, to detect, quantify, characterise and monitor monoclonal gammopathies.
Serum protein electrophoresis, which may be conducted using either Agarose Gel (AGE) or Capillary Zone (CZE) methods are commonly used to screen for monoclonal proteins (M protein/paraprotein). These methods are also used to quantify the amount of M protein present when performed in conjunction with scanning densitometry and total protein measurement. Clonal characterisation of identified M proteins is typically performed using Immunofixation or Immunosubtraction capillary electrophoresis.

Aims

Determine whether laboratories can correctly identify the presence of raised polyclonal gamma and the absence of a monoclonal band.

Methods

A serum sample containing a raised polyclonal IgG was distributed within the UK NEQAS for Monoclonal Protein Identification EQA Scheme.
Participants processed the serum sample within their laboratory and interpreted the resulting pattern. Their results were reported back to the EQA scheme.
All the participant's results that were returned to the EQA scheme were analysed, and the report was produced.

Results

Majority of laboratories 89% (465/524) correctly reported the absence of a monoclonal protein.
10% (52/524) of laboratories misidentified a polyclonally raised gamma sample as a monoclonal component in this sample.
67 laboratories submitted a free text comment to highlight the presence of polyclonal IgG within the sample.
Misidentification was more common with CZE users (15.8 %) compared to AGE users (2.1 %)

Conclusions

It is concerning that a significant number (1 in 6) of laboratories using CZE have over-interpreted a polyclonally raised gamma sample as a monoclonal protein sample.

Incorrectly reporting the presence of monoclonal proteins can lead to unnecessary additional investigations (some of which are invasive) and in the most extreme cases, inappropriate treatments. The inappropriate labelling of a patient as MGUS is not without consequence and is a difficult label

to remove. Patients may interpret being labelled as MGUS as a pre-cancerous state which may result in significant unnecessary stress and anxiety and could require lifelong monitoring.

Misidentification of monoclonal proteins is worrying and has the potential for serious consequences and patient harm.

Laboratories need to review their practice to minimise the misidentification of monoclonal gammopathies when using protein electrophoresis techniques.

Evaluating the accuracy of multiple rapid diagnostic tests for HIV detection in serum samples analysed during point-of-care proficiency testing assessments

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Introduction

HIV rapid diagnostic tests (RDTs) are vital for decentralised testing, offering immediate results essential for the timely initiation of antiretroviral therapy (ART). To comply with World Health Organization (WHO) standards, RDTs must achieve a sensitivity of ≥99% and a specificity of ≥98%.

Aims

This study aims to assess the performance of HIV RDTs across nine South African provinces to ensure diagnostic accuracy and reliability.

Methods

Between April and June 2023, the NHLS Quality Assurance department conducted a proficiency testing (PT) assessment. A total of 4,243 panels, each containing six blinded serum samples (three HIV-negative and three HIV-positive), were distributed to HIV testing facilities in nine provinces: Eastern Cape, Free State, Gauteng, KwaZulu-Natal, Limpopo, Mpumalanga, Northern Cape, North West, and Western Cape. Out of 25,458 serum samples distributed, 25,012 responses were received. The assessment outcomes were analysed to determine key metrics including accuracy, sensitivity and specificity.

Results

Six different HIV RDT kits were used for screening and confirmatory testing across the provinces. Of the 25,012 responses, 98% were accurate, with most provinces meeting or exceeding WHO-recommended sensitivity and specificity levels. Gauteng, KwaZulu-Natal, and Limpopo exhibited high sensitivity and specificity rates above 99%, while Mpumalanga achieved 100% accuracy. The Northern Cape had the lowest sensitivity (94.23%) and specificity (91.98%). False negative and false positive rates varied, with Gauteng and Mpumalanga reporting the lowest rates, and Northern Cape the highest.

Conclusions

This evaluation underscores the overall reliability of HIV RDTs in South Africa, with an agreement rate of 98.53% and a Cohen Kappa coefficient of 0.97. Despite regional variations, RDTs proved effective for rapid and accurate HIV diagnosis. The observed discrepancies, especially in the Northern Cape, highlight the need for targeted interventions to improve diagnostic accuracy and reliability. Continuous quality assurance, professional development, and systematic monitoring are crucial for enhancing diagnostic outcomes and ensuring effective HIV management nationwide.

Use of Point of Care (POCT) C-Reactive Protein (CRP) to support antibiotic prescribing in primary care – Are they good enough? A Review of Performance on the Weqas POCT CRP Programme

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Introduction

Antimicrobial resistance is a major global healthcare problem. Antibiotics for respiratory infections account for around 60% of all primary care prescriptions, which in turn comprise 80% of the total antibiotic burden. In the UK, the National Institute for Health and Care Excellence guidelines for suspected acute respiratory infection in over 16s, recommend that antibiotics are not routinely offered if CRP 100 mg/L. In Wales, the guidelines for the management of acute COPD exacerbation recommends alterative threshold in this cohort of 20-40 for antibiotic consideration and a lower threshold of > 40 mg/L to prescribe antibiotics. POCT CRP has increasingly been used in primary care to support prescribing in suspected acute respiratory infection and in 2017, Weqas developed an EQA programme to assess and monitor the performance of these devices in primary care.

Aims

To assess the performance of POCT devices compared with Laboratory methods

Methods

Samples were collected from volunteers and patients and a panel of linearly related samples were produced from spiking base serum with a purified source of human CRP to provide an extended clinical range. Two samples were distributed to the primary care sites bimonthly, with the same samples distributed to Laboratories each alternate month as part of the monthly Weqas Laboratory EQA CRP programme. This allowed for a comparison of POCT performance against laboratory methods.

Results

Overall CVs on the POCT CRP programme ranged between 5 – 10 % for CRP > 20 mg/L, with slightly higher CVs of 7-15% for CRP nce specification (APS) of +/- 15% was used for both programmes, compared with the optimal Total Error of 25.4%, EFLM biological goals database. A bias of < 3 mg/L was observed at CRP concentration 0-50 mg/L for most POCT devices compared with the Laboratory programme overall mean.

Conclusions

Data from the Weqas POCT CRP EQA programme suggests that the performance of POCT devices compare well with Laboratory methods and are well within the recommended APS for both imprecision and bias according to the EFLM biological goal database.

A Review of Lactate Performance on the Weqas Blood Gas External Quality Assessment (EQA) Programme – A comparison of POCT and Lab Instruments and their suitability for use in Sepsis Management.

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Introduction

Sepsis is defined as a life-threatening organ dysfunction due to a dysregulated host response to infection and septic shock as persisting hypotension requiring vasopressors to maintain a mean arterial pressure of 65 mmHg or more and having a serum lactate level of greater than 2 mmol/l despite adequate volume resuscitation. National Institute for Health and Care Excellence (NICE) Guideline [NG51] Sepsis: recognition, diagnosis and early management recommends lactate measurement as part of risk stratification and management of suspected sepsis in acute hospital settings. Lactate was introduced as part of the Weqas Blood Gas EQA programme in 2001, with 33 laboratory enzymatic methods and 295 blood gas analysers in use at the end of the first 5 years compared with 43 enzymatic and 2116 blood gas or lactate meters used in 2023.

Aims

To assess the current performance of both laboratory and POCT lactate methods at clinical decision thresholds.

Methods

Three samples were distributed monthly with a lactate range of 0.4 to 6.4 mmol/L provided over the year. The programme assessed both laboratory and method performance, including linearity, bias, within and between batch imprecision.
The performance of participants in 2023 using 11 different POCT instruments, 1 handheld lactate specific instrument, and 6 different laboratory instruments were assessed.

Results

At an all method mean of 4.17 mmol/L, a mean of 4.17mmol/L, SD 0.09, CV 2.2% (n=44) was observed for the enzymatic method, mean 4.17 mmol/L, SD 0.08, CV 1.9% (n=977) for ABL 90 flex, mean 4.13 mmol/L SD 0.14 CV 3.4% (n=481) for Gem 5000, mean 4.02 SF 0.18 CV 4.5 (n=256) for the Rapidpoint 500 and a mean of 4.54 mmol/L SD 0.21, CV 4.6 (n=83) was observed for the EPOC. A bias of < 0.3 mmol/L was observed for the majority of POCT instruments.

Conclusions

The mean bias of the POCT and laboratory instruments were not significantly different across a range of samples. The CV for most of the POCT instruments compared well with the enzymatic methods. An identical analytical performance specifications was used within the programme for both POCT and lab instruments. Most instruments performed well at the clinical decision thresholds of 2 mmol/L and 4mmol/L suggesting that lactate measurement on POCT blood gas analysers are suitable for use in sepsis management.

A Review of Performance on the Weqas Quantitative Faecal Haemoglobin (FIT) EQA Programme – Are current analysers 'FIT' for purpose?

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Introduction

Faecal immunochemical tests (FIT) are designed to detect small amounts of blood in stool samples using antibodies specific to human haemoglobin (Hb). In the UK, these tests are recommended by NICE to guide referrals for suspected colorectal cancer in symptomatic patients using a threshold of 10 µg Hb/g of faeces (DG30 and NG12). FIT is also recommended as part of the testing strategy for the UK Bowel Cancer Screening Programmes although much higher thresholds are used. In 2016, Weqas developed an EQA programme to assess and monitor the performance of these tests.

Aims

To assess laboratory and method performance, including linearity, bias, and within batch imprecision at concentrations around 10 µg Hb/g of faeces.
To assess laboratory and method performance for non-spiked EQA samples.

Methods

Organic material, closely mirroring the basic constituents of human faeces was spiked with a known quantity of Hb. A range of concentrations were prepared to cover the pathological range including negative samples, at or near the clinical cut-off used for symptomatic testing pathways and at the higher cut offs used in asymptomatic population screening programmes. The homogeneous material was dispensed aseptically into buffered collection devices specific to each manufacturer. Three samples per month were distributed to all participants within the EQA programme.

Results

For a non-spiked sample, 8 laboratories reported 0, 7 at 0-1, 3 or 18 laboratories reported 0, 2 at 0.4, 1 at 1, 1 oratories correctly identified the negative sample as g matrix, a mean of 11.68 µg Hb/g matrix (SD 2.41, CV 20.6%, n = 35) was observed for the HM-JACKarc with a mean of 4.85 µg Hb/g matrix (SD 1.1, CV 22.7%, n=39) for the OC Sensor.
A wide variation in lower reporting limits was observed which were not associated with test utility. A 2.4 X difference in result was observed at the 10 µg Hb/g threshold for the two analysers.

Conclusions

This study suggests that a universal cut-off of 10 µg Hb/g for suspected colorectal cancer in symptomatic patients may not be appropriate when such large method biases exist at low concentration. Until such time a reference standardisation system is developed, it may be more appropriate for laboratories to use manufacturer specific cut offs.

A commutability evaluation approach based on retrospective data for infectious serology EQA samples

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Introduction

EFS Réactifs manufactures infectious serology samples (Hepatitis, HIV, Syphilis,…) dedicated to EQA schemes. Samples are designed in serum or plasma diluants. An industrial manufacturing process has been set up to guarantee batches homogeneity, samples safety and performance stability all over product shelf-life.

Aims

To present a commutability evaluation approach of EQA samples based on retrospective data and compared to patient clinical results.

Methods

Some patient samples screened positive for serological markers (Ag HBs, Ac anti-HBc, Ac anti-HCV, Ac anti-HIV-1, Ac anti-Syphilis Tp,...) by two analytical methods (Abbott Architect and Roche Cobas) have been analyzed to establish the method correlation with 95% confidence interval.
A representative sampling of EQA samples to cover manufacturing influence parameters limits has been established to evaluate the matrix effect.
Produced samples results, from several years EQA schemes, have been positioned on a correlation graph.

Results

The manufactured EQA samples are confirmed within 95% confidence interval from method correlation on patient data.

Conclusions

According to retrospective data analysis, manufactured samples do not present any matrix effect questioning commutability, which confirms sample matching with EQA scheme objectives.

The standardization of the manufacturing process enables us to be responsive in offering commutable infectious serology samples, and to provide flexibility for EQA organizers.

Setting-up a multi-parametric samples production for External Quality Assessment – Serology/Microbiology area

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Introduction

The French blood bank – l'Etablissement Français du Sang (EFS) – is the legal manufacturer for reagents and EQA samples provider since 2004. EFS Réactifs, based in Lille, manufactures control samples for microbiological serology (VIH, Hepatitis, Syphilis, Chagas, Toxoplasmosis, Rubella, Malaria,…).

Aims

To illustrate the development steps of a multi-parametric range for Hepatitis B, Hepatitis C and HIV serologies through an example of EQA organizer specifications.

Methods

The initial specifications are including requirements regarding the serological markers (HBs Ag HBs Ab, HBc Ab, HBe Ag, HBe Ab, HCV Ab et HIV Ab), the signal level (low, medium and high), as well as the reference method (Abbott Architect and Roche Cobas).
The multi-parametric samples offer has been proposed as following:

- In vitro compatibility of expected markers
- Signal level review in respect to the analytical sensibility of methods
- Raw material selection
- Result confirmation for each marker

Results

10 multi-parametric samples corresponding to different clinical profiles for Hepatitis B, Hepatitis C and HIV infection were proposed and accepted by the EQA organizer.

Conclusions

The reagent production by EFS is based on an internal supply in order to guarantee ethical blood sampling, inventory securing, as well as raw material characterization, including on rare specificities.

The raw material availability, the standardization of the manufacturing process, the expertise and flexibility of EFS Réactifs allow to quickly respond to customer specifications for multi-parametric EQA samples.

These elements taken together illustrate EFS Réactifs flexibility in order to address specific requirements of EQA organizers.

Is our ICT infrastructure secure enough? An analysis of software and hardware vulnerabilities in the cloud computing and ChatGPT times.

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Introduction

Although the totality of our operations assumes uninterrupted provision of IT resources, we are facing numerous attacks on our systems that are often neglected. Data breaches and unauthorized access are primary concerns in cloud environments. Weak authentication mechanisms and misconfigured access controls can expose sensitive data to unauthorized users. To mitigate these risks, EQA organizations should implement multi-factor authentication (MFA) and role-based access control (RBAC), ensuring least privilege access. Encrypting data at rest with AES-256 and in transit with TLS/SSL further enhances security. Cloud computing offers significant benefits for EQA applications, including scalability, cost-efficiency, and accessibility. However, it also introduces various security challenges that need to be addressed to protect sensitive data.

Aims

Highlighting the importance of protecting our systems from hackers and how this can be achieved.

Methods

A literature search of articles related to hacking and cybersecurity, consultation with bioinformatics experts, and study of real cases of hacking EQA websites.

Results

Compliance with regulations like HIPAA is crucial for sensitive EQA applications. Compliance management tools from cloud providers help ensure adherence to standards. Continuous monitoring and logging of access and data usage using specialized tools are essential for compliance.
Data sovereignty and jurisdictional issues arise when data is stored across multiple regions. Geo-fencing and data residency controls can restrict data to specific geographic areas, ensuring compliance with local laws. Consulting with legal experts regularly helps navigate the complex landscape of data sovereignty.
Shared infrastructure risks in multi-tenant cloud environments can lead to data leakage. Using virtual private clouds (VPCs) and network segmentation helps isolate sensitive workloads. Regularly updating and patching hypervisors and container runtimes is critical to prevent exploits like Spectre and Meltdown.
Insider threats from cloud service provider employees pose significant risks. Implementing strict access control policies, monitoring user activity, and using customer-managed encryption keys (CMKs) can mitigate these threats. Encrypting data ensures that even if accessed, it remains unintelligible.
Data loss and availability concerns can be addressed by implementing automated backups and multi-region redundancy. Regular testing of disaster recovery plans ensures readiness. High-availability solutions including Database Geo-Replication provide additional safeguards.
Evaluating cloud providers' security measures is essential. Reviewing certifications, compliance reports, and using advanced security services ensures robust security. Augmenting these with third-party solutions enhances protection.

Application vulnerabilities require secure development practices, regular code reviews, and using tools like SAST/DAST. Securing APIs with OAuth 2.0 and input validation prevents common attacks. Centralized logging, monitoring with SIEM solutions, and using Cloud Security Posture Management (CSPM) tools provide visibility and control.
The complexity of cloud security necessitates automated configuration management with tools like Terraform and continuous security audits. Regular training for development and operations teams on cloud security best practices is vital to maintaining a secure environment.

Conclusions

We have to consider these issues and take action promptly because our continuity of operations and our reliability that affects our clients (laboratories) quality performance and accreditation status depends on this. By addressing these challenges with robust technical countermeasures, EQA organizations can securely leverage cloud computing, ensuring the protection of sensitive laboratory data.

Change in tests from manual to automated for Thrombotic Thrombocytopenic Purpura diagnostics, what can external quality data tell us about this change?

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Introduction

Thrombotic thrombocytopenic purpura (TTP) is caused by a deficiency in ADAMTS13 (a disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13). ADAMTS13 is functioning as von Willebrand factor (VWF) protease. It can modulate VWF activity, which is important for primary haemostasis. For decades a manual performed FRET (fluorecscence resonance energy transfer) based technology utilizing recombinant VWF substrate is used to determine ADAMTS13 deficiency, with a clinical decision level of

Aims

In the present study, it is evaluated whether new automated ADAMTS13 assays show better performance compared to manual FRET assay.

Methods

ADAMTS13 activity results were evaluated derived from EQA plasma samples with various ADAMTS13 levels in combination with various assay types (FRET, Enzyme Immunoassay (EIA) and Chemiluminescent Immunoassay (CLIA)) used for measurement. EQA data of approximately 180 laboratories for the period 2020 – 2024 is used. In addition, for two assay groups (FRET and CLIA) also a comparison was made between both EQA and clinical samples derived from patients with suspected TTP.

Results

Over the last five years an increase of 64% in number of laboratories is observed performing ADAMTS13 activity tests and a shift in more automated tests is seen. The automated methods show a lower between-laboratory imprecision of more than 2-fold compared to the FRET method (e.g. CVCLIA=18% versus CVFRET=52%). Furthermore, positive correlations were observed between the total group consensus values and the various assay group consensus values for ADAMTS13 levels in the range between 0.3 and 90 IU/dL, with a small systematic and proportional difference (EIA: y=1.00x+0.83, FRET: y=1.03x-0.42, CLIA: y=0.98x-0.59). The correlation FRET-CLIA resulted in y=0.90x+1.44 using EQA samples and y=0.87x-2.21 using clinical samples. The distribution of the clinical samples and EQA samples matched fairly well.

Conclusions

The results of the EQA data demonstrated an improved performance of the automated ADAMTS13 methods compared to the manual performed method. Comparison of the EQA results with clinical results suggest acceptable commutability of the samples.

Reference versus consensus values in proficiency testing of clinical chemistry: a comparison based on laboratories' results in Palestine

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Introduction

Proficiency testing (PT), or external quality control, provides additional means to ensure the quality of laboratory testing results. The most applied methods of achieving this objective are the comparison of laboratory results with reference values (RVs) or consensus values (CVs). The Center for Quality in Medical Laboratories (CQML) – Al-Quds University is the only Palestinian provider of PT. The results of participants at the CQML are compared with CVs calculated based on Algorithm A of ISO 13528. Given the wide range of equipment and reagents employed in laboratories, it might be risky to make conclusions based on CVs exclusively

Aims

In this work, we compare CVs obtained from data collected by the CQML for 11 analytes corresponding to clinical chemistry with certified RVs and compare PT results obtained under both criteria (CV and RV).

Methods

A lyophilized human serum sample was prepared and tested in a certified laboratory to determine RVs. Two samples were distributed to the Palestinian laboratories participating in the CQML. CVs and the allowable limits of performance (ALP) were calculated from the obtained data based on Algorithm A of ISO 13528 and the standards provided by the certified laboratory. The deviation between CVs and RVs was calculated for each analyte using the formula [(Consensus mean – reference mean) X 100/reference value]. The percentage of laboratories that met the ALP criteria was then compared using both criteria for each analyte.

Results

The deviation between CVs and RVs for the evaluated analytes ranged from -0.56% for Calcium to -14.3% for Aspartate Aminotransferase. The percentage of laboratories that met the allowable limits of performance ranged between 69.3-91.7% when CVs were used for comparison, whereas the range was 59.6-89.5% when using RVs.

Conclusions

The deviation between CV and RV could vary depending on the analytes under investigation. The adoption of a combined approach of these schemes in PT should be considered as a more practical approach to evaluating the performance of laboratories in Palestine.

1. ISO/IEC 13528, Statistical methods for use in proficiency testing by interlaboratory comparison
2. ISO/IEC 17043, Conformity assessment — General requirements for the competence of proficiency testing providers

Analyzes of Immuno-Hematology's non-compliant results causes.

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Introduction

UCIL is the inter-laboratory comparison unit of the Etablissement Français du Sang (French Blood Establishment). We organize EQA campaigns in the field of Immune Hematology, for EFS laboratories as well as for public and private laboratories. More than 200 laboratories are currently taking part in UCIL comparisons, in France and abroad.
When results are published, we ask laboratories with non-compliant results to fill in a questionnaire to analyze the cause of the non-compliant result.

Aims

Identify recurring causes of non-conforming results and find a way to reduce non-conforming EQA results.

Methods

For the year 2023, we have extracted the causes of non-compliant results for ABO-RH-KELL, antibody screening, antibody identification and DAT, analyses for which we have the majority of participants.

Results

We found that 60% of non-compliant results were due to human error (data entry, transcription, etc.), 23% to the equipment, 10% to the method, 3% to misinterpretation of the hardware/software and 3% to the reagents. No erroneous results led to reactovigilance.

Conclusions

Although the software offers different levels of authorization for data entry and validation, human error remains high. There is no real failure of reagents or methods.

A question arises as to the need for double blind entry of results.

Integrated EQA Data Management for EQA Providers

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Introduction

External Quality Assessment (EQA) is crucial for ensuring the reliability of clinical laboratory results. However, managing data from multiple EQA programs can be challenging. QuoData, a leading provider of solutions for clinical EQA providers, is developing an innovative platform to address this issue and enhance quality assurance.

Aims

To create a hub that integrates historical and current data from various EQA programs, empowering EQA providers to comprehensivegain in-depth knowledge, and data-driven understanding of EQA data.

Methods

The web-based EQA data management platform is currently in the prototyping stage, incorporating three key features:
• EQA Progress Monitoring: Tracking the pass rates and performance drifts of different EQA schemes, enabling EQA providers to identify trends and areas for improvement on scheme, peer group or laboratory level. By incorporating granular filters, trend detection, combination scores and graphical tools.
• Cross-Round Comparison: Analyze and compare the performance of instruments, methods and combinations therof across multiple rounds. Get valuable insights on the performances of analytical procedures that are highly valuable for laboratories and manufacturers alike.
• Sample analysis: Enhance the reliability of EQA programs by ensuring sample traceability and commutability as well as homogeneity and stability, through validated statistical tools.

Results

The system is designed to seamlessly import existing data from various formats, ensuring that EQA providers can access all necessary information by consolidating data from multiple EQA programs in a single platform.
While the platform is still in the prototype stage, it demonstrates potential for:

- Streamlined data management across multiple EQA programs
- Enhanced ability to identify trends and areas for improvement
- Easy-to-use sample monitoring

Conclusions

This prototype platform aims to revolutionize EQA data management. QuoData, seeks partners to refine and develop this innovative solution, benefiting across the EQALM community

18 years of performance evaluation of molecular detection of enteroviruses by QCMD

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Introduction

Human enteroviruses (EVs) can cause a wide range of diseases such as acute flaccid paralysis/myelitis; aseptic viral meningitis; and hand, foot and mouth disease. The gold standard for EV detection is reverse transcription polymerase chain reaction (RT-PCR) based on the conserved 5' untranslated region (5' UTR) which can detect all known types. Detection of EVs is crucial to enable poliovirus exclusion and assess epidemiological circulation of different non-polio EV types. This requires high sensitivity and specificity and should be routinely evaluated to maintain an acceptable level of diagnostic quality.

Aims

To evaluate the performance data from external quality assessment (EQA) schemes for molecular EV detection that were distributed between 2005 and 2022, and tested by diagnostic and public health laboratories using either in-house or commercial assays.

Methods

Performance data from a total of 32 EQA schemes were evaluated that were returned by 699 registered laboratories worldwide regardless of their participation frequency during the 18 years of observed study period. Of these 621 were diagnostic and 78 were public health laboratories. A total of 44,434 samples were included in the study, which accounted for 41,087 core and 3,347 educational samples analyzed by the participants using their routine molecular assays and workflows (classified as in-house or commercial). Overall performance is defined as the combined percentage correctly identified true positive samples as positive, the true negative samples as negative, and the specificity samples containing parechovirus or rhinovirus as negative. A separate analysis was conducted on the performance in relation to true positive (sensitivity), true negative (false positivity) and specificity samples.

Results

Overall performance increased over the years for both laboratory types using either in-house or commercial assays with rates >94.8% since 2013. In general, diagnostic laboratories performed significantly higher than public health laboratories (odds ratio= 1.26 (95% CI: 1.14 - 1.40); p.18 (95% CI: 1.10 - 1.27); p laboratories.

The sensitivity for the different EV types varied with the lowest sensitivity reported for samples containing EVD68 B3 strain (86.8%), echovirus 11 (85.2%) and poliovirus 3 (79.7%). Both, commercial and in-house assays showed similar sensitivity for the majority of the types, with the exception of echovirus 9, EVD68 B3, and poliovirus 3 positive samples where a lower sensitivity was observed when using a commercial assay.

Conclusions

The data details the performance of commercial and in-house assays used in diagnostic and public health laboratories, and shows the value of performance evaluating EQA schemes over time where

low sensitivity should encourage further optimization of the assays. Inclusion of different EV types of clinical and public health relevance remains a crucial part of the EQA, as differences between these types should be regularly evaluated in light of their varying disease patterns, changing epidemiology and the emergence of new strains.

Measurement Uncertainty in Clinical Biochemistry and ISO/IEC 17043:2023

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Introduction

Laboratories accredited to ISO 15189 are required to calculate Measurement Uncertainty (MU) for all measurands (analytes). ISO/IEC 17043:2010 required Proficiency Testing (PT) providers to give participants the option of reporting uncertainties [4.6.1.2 (f)]. In practice, at Birmingham Quality, no laboratory has ever requested to report MU back to us, therefore it had not been included as part of the Scheme Design. The revised version of ISO/IEC 17043 (2023) takes MU one step further and not only allows PT providers the option to allow participants to record and report results and associated uncertainties, but also to consider how this uncertainty will be used to evaluate the participant's performance [7.2.2.3 (g)].

Aims

The aim of this study was firstly to assess the current state of play of MU calculation and management within clinical biochemistry, and then to provide evidence and justification for the Scheme design at Birmingham Quality with regard to MU.

Methods

In April 2024, an online survey using MS Forms was made available to all Birmingham Quality (UK NEQAS) participants including non-UK. The demographics of participants to whom the survey was offered was mainly UK based clinical laboratories or POCT sites.
The survey consisted of 14 questions auditing current practice relating to MU. A single analyte, Sodium, was chosen to assess the variation in reported MUs.

Results

In total there were 252 laboratory registration responses. The UK contributed to 86% of data. MU is calculated for all/most analytes on their main chemistry/immunoassay analyser by 96% of respondents. The 4% who hadn't calculated MU were a mixture of non-UK and POCT sites.
100% of respondents do not report MU on every single patient result. Thirteen different permutations of SD and CV were given as the calculation used determining MU with Internal Quality Control being the main data set used to determine MU, but some respondents do combine with EQA, biological variability.
79% of respondents reported that they would find it useful to report MU on their EQA report, even if only for benchmarking. However, on further probing only 8% of respondents would want to report MU on every EQA result. The majority 73%, would like to report once per year in defined bins.
As a proof of concept, we gathered information on MU for Sodium. We evaluated the data and sorted MU into three bins 'low', 'normal' and 'high' concentration and wide variation was seen in the reported MU.

Conclusions

Our survey has shown that there is considerable variability in all aspects of MU, whether it is the equation used, the frequency of evaluation or even the result produced. Laboratories spend a lot of time and resource calculating MU.

Birmingham Quality (UK NEQAS) will use this study as evidence to not change its EQA Scheme Design. However, we will be offering an annual benchmarking exercise for selected analytes.

Two-year review of the HEV detection EQA scheme

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Introduction

Hepatitis E Serology and Molecular Detection of HEV RNA EQA schemes were launched by UK NEQAS for Microbiology in 2018. Participants reported on the presence or absence of anti-HEV IgM and IgG (Hepatitis E Serology) and HEV RNA (Molecular Detection of HEV RNA). In 2022 the two schemes were merged into the Hepatitis E Detection EQA with participants given the opportunity to report on all three analytes. This is the first EQA scheme for UK NEQAS Microbiology to combine serological and molecular testing.

Aims

As the first EQA scheme to combine serological and molecular testing the success of the Hepatitis E Detection EQA would serve as proof-of-concept for similar future EQA schemes where clinically relevant. The review focuses on analysing reporting rates for different analytes and giving an overview of the performance of serological and molecular assays.

Methods

During the review period 28 specimens were distributed with participants reporting on anti-HEV IgM and IgG and HEV RNA status. Distribution reports were reviewed to determine the numbers of participants reporting on each of the analytes and to analyse specimens for which at least one analyte was not scored due to lack of participant and reference testing consensus. For the analysis of reporting on HEV RNA status one specimen in the first distribution of the review period and one specimen in the last distribution of the review period was analysed.

Results

Compared to reporting for the last year of Hepatitis E Serology and Molecular Detection of HEV RNA EQA schemes, reporting on anti-HEV IgM, anti-HEV IgG and HEV RNA increased throughout the review period for Hepatitis E Detection EQA. The most reported analyte was anti-HEV IgM report with on average 86.5% of participants returning results for it across distributions. Anti-HEV IgG report was the second most reported analyte with on average 81.0% of participants returning results across distributions. HEV RNA report was the least reported, however, the reporting rate for this analyte increased from 20.2% for the first distribution to 30.5% for the last distribution under review. Analysis indicates that the increase in participants reporting on HEV RNA is largely due to participants previously only reporting on serology results starting to report on molecular testing. Out of 28 distributed specimens, 8 specimens (28.6%) had at least one analyte not scored due to lack of consensus with all but one of the not scored analytes being serology analytes. Analysis of results submitted for the not scored analytes revealed differences between the sensitivities of assays used.

Conclusions

The introduction of the combined serology and molecular EQA scheme has led to increased participation in HEV EQA, including increased reporting on HEV RNA status. This is a good indication that similar schemes could be successful where clinically relevant. As differences in the sensitivities of different serological assays were observed inclusion of RNA results alongside serology results will allow participants to better understand the performance of their assays.

Hair analysis performance for illicit drugs detection tests: results from the External Quality Assessment of Lombardy Region

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Introduction

The Regional Reference Center for the Quality of the Laboratories of the Lombardy Region (Center) manages External Quality assessment (EQA) program for the analysis of illicit drugs in hair

Aims

Describe the state of the art of performance VEQ results for illicit drug detection tests

Methods

All laboratories analyzed the same control material. The hair undergoes an artificial incorporation of drugs refer to 7 classes for a total of 22 metabolites. The 7 classes of substances were opiates, methadone, amphetamines and methoxyamphetamines, cocaine, cannabinoids, ketamine, Buprenorphine and were alternately positive or negative. Center processed the quantitative results with a statistical algorithm conform to according to the international standard ISO 13528. The methods used by laboratories were: GC-MS, GC-MS/MS, HPLC-HRMS and HPLC-MS/MS. Laboratories performances were evaluated by comparison with the expected outcome defined by the manufacturer of control material. The expected outcome must be confirmed by most frequent result

Results

A total of 14 exercises were submitted by the Center, 6 in 2022, 6 in 2023 and 2 in 2024 for a total of 4127 results. 17 laboratories participated in both 2022 and 2023, 19 laboratories in 2024. A total of 77 results, 1,86%, were classified as false-negative and 4 results, 0,09%, were classified as false-positive. The substances/metabolites with the highest number of false-negative results were codeine, dihydrocodeine, norbuprenorphine and buprenorphine, respectively 14, 8, 7 and 6 results. The substances/metabolites with false-positive were THC-COOH, MBDB, cocaine and Benzoylecgonine. The coefficient of variation (CV) was analysed for each exercise and for each metabolite. The CV varies from 47,6% for THC-COOH to 8,2% for ecgonine methyl ester. The average CV was 30,7%.

Conclusions

The performances of laboratories were satisfactory, the 98% of results were in agreement with expected outcome. The CV of each substances/metabolites requires an in-depth analysis of instruments performance

Setting up an External Quality Assessment Scheme for the microbiology aspects of heart valve banking

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Introduction

Heart tissue products donated usually after death are banked worldwide in order to support reconstructive cardiac surgery, to treat both congenital and acquired cardiac defects. Donations of substances of human origin can include a risk of transmitting infection to recipients. One of the steps taken is to test the tissue for the potential presence of contamination and to decontaminate the heart tissue often using an antibiotic cocktail. This area of clinical practice does not have an established EQA.

Aims

To ensure the quality and safety of transplanted heart valves, it is crucial to establish an EQA scheme which involves regular testing and evaluation of tissue banks' processing methods for the detection of contamination and subsequent decontamination. This unique pilot EQA was undertaken in January 2024 and provides an insight into the gaps that need addressing.

Methods

UK NEQAS for Microbiology in collaboration with the Scottish National Blood Transfusion Service (SNBTS) conducted this EQA exercise to determine the processes employed by three tissue establishments in their isolation, identification and decontamination of microorganisms present in heart valve tissue designated for transplantation.
The heart tissue used for this pilot was sourced from deceased donor heart tissue that failed to meet the quality criteria required for clinical use by SNBTS.
Four heart tissues were provided on dry ice and stored locally by UK NEQAS. The heart tissues were checked for contamination, antibiotic effect and then neutralised so they could be spiked with a known micro-organism. Only two of these heart tissues were deemed suitable for use.
Once pre-distribution results were acceptable, the heart tissue was segmented into three and suspended in Thioglycollate and dispatched.

Results

Intended as determined by UK NEQAS
Specimen No. 8757 Staphylococcus aureus
Specimen No. 8758 No contamination (sterile)
Reported by laboratories
Specimen 8757
• All three laboratories reported that the specimen was contaminated with Staphylococcus aureus and Streptococcus mitis/oralis at the pre-decontamination stage.
• One laboratory (A) did not detect the growth of the contaminants at their post-decontamination stage, one laboratory (B) reported the growth of S. aureus, and one laboratory (C) reported both S. aureus and S. mitis after their post-decontamination stage.
Specimen 8758
• All three laboratories reported no contamination in the specimen at both pre and post decontamination stage.
A method questionnaire was also undertaken and clearly shows that the three laboratories testing the tissues follow no standardise method and their methodology varied.

Conclusions

The results highlight the differences in practice between different tissue banks further supporting the need for setting up this very niche and unique EQA on a regular basis and to produce a best practice method document to attempt harmonisation of the testing. In addition it also highlighted that our own procedures need to be adapted so that another specimen can be provided should laboratories fail to obtain the correct EQA result and to review our own testing algorithms as only one of the organism was isolated prior to dispatch when there were two in specimen 8757.

Methods used for lipemia evaluation require more attention and quality control processes

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Introduction

In Labquality's integrated external quality assessment service (EQA3) pre- and postanalytical cases are added to traditional schemes to assist clinical laboratories in meeting end-to-end requirements of the ISO 15189 standard, which states that all steps of the laboratory process should be monitored. Here we present the results of a lipemic sample sent with regular samples in the general clinical chemistry round 6-2023.

Aims

The aim of this study was to gain knowledge on how the participants evaluate and handle lipemic samples.

Methods

A lipemic sample was sent to the participants in addition to traditional samples. The laboratories were asked to analyze and report results for sodium, potassium, chloride, creatinine, urea, glucose, phosphate, and triglycerides and furthermore they were asked to answer questions related to lipemia handling. In the final report, the response distribution was presented along with expert comments.

Results

112/182 laboratories responded to the preanalytical questionnaire. 88 laboratories declared their accreditation status: 55 (63 %) were accredited according to ISO 15189. 75 (67 %) evaluate lipemia using lipemic index, while 31 (28 %) still use visual inspection. 77 (70 %) had not validated their lipemia evaluation method and 76 (70 %) used cut-off values provided by the manufacturer.
127/182 analyzed the lipemic sample. The triglyceride concentration was almost twice as high as the recommended upper reference limit (mean value 3.255 mmol/L) and such concentration might be found in quite many clinical samples. 77 % responded that they would release the triglyceride result without or with comment.
The creatinine performance of all methods in the lipemic sample was different compared to the presumed commutable sample analyzed on the same round. The enzymatic method coefficient of variation (CV) was 6.8 % (vs. 3.6), Jaffe 12.1 % (vs. 7.4), and Vitros 5.4 % (vs. 1.7) for the lipemic sample compared to the regular sample. The all method mean of the lipemic sample was 64.4 µmol/L.
Potassium and chloride concentrations were low, sodium concentration was high. The trend in chloride testing wa similar to regular samples: ISE direct results circa (ca.) 2.0 % higher than ISE indirect, but CVs were ca. 2.5 times higher in the lipemic sample. Because of the dilution used in indirect ISE, significant difference between direct and indirect was observed for sodium: 148.3 mmol/L ISE direct and 170.5 mmol/L ISE indirect. For sodium and chloride about half would release their results and almost 10 % would not release their results at all.
No significant difference was noted in method performance for glucose, phosphate, and urea.

Conclusions

Based on the results of this study, methods used for lipemia evaluation require more attention from the laboratories: less than half (48 %) participate in lipemia index EQA and 80 % do not have an

internal quality control procedure for their lipemia evaluation method. 70% use lipemia cut-off values provided by the manufacturer without validating the method for lipemia evaluation. The results indicate that there is a need for harmonization on how lipemic sample handling should be performed and monitored in clinical laboratories.

Artificial intelligence determined reference value (rAIght value) included in virtual histopathology EQA scheme: comparison of participating pathologists and a trained image analysis algorithm

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Introduction

Correct identification of prostate cancer is important to help patients correctly and on time. Prostate cancer samples are evaluated with the Gleason score. The most common and most aggressive grades are added together, resulting in an overall Gleason score for the sample. The overall Gleason score determines the Grade Group (GG) from 1 to 5, where 5 is the most aggressive. Labquality organizes a virtual histopathology external quality assessment (EQA) scheme twice a year. In round 2-2023, the topic was prostate cancer and participants were given 7 whole specimen scanned slide for analysis.

Aims

The development in the area of digital pathology and artificial intelligence (AI) has made it possible to utilize whole slide images (WSI) in addition to an expert evaluation of a pathology slide. We compared the image GG analysis done by Aiforia's AI model to the scheme participants' visual GG analysis.

Methods

Participating clients were provided with relevant clinical patient history and instructed to analyze 7 scanned virtual microscopy images of prostate biopsies. The samples were formalin fixed and stained with hematoxylin and eosin. 149 individual participating pathologists were requested to grade the samples according to the most common Gleason score, most aggressive Gleason score and the GG. On this round, the analyses conducted by Aiforia's AI model were used as a "rAIght" values as additional information, however, the evaluation of the participant performance was based on a reference diagnosis by the scheme expert. The Aiforia's AI model automatically detects the tumor epithelium and Gleason patterns from the WSIs.

Results

The AI-produced results were in alignment with the results reported by the participants regarding most common and aggressive Gleason scoring and GG in 3/7 cases (cases 1, 2 and 6). For the other cases, the participants reported slightly different Gleason scores and grade groups. For case 3, the majority (49%) of the participants graded it to GG2 and whereas 28% graded it to GG3 which was the AI-produced grading. Case 4 was graded to GG3 by 55 % of the participants whereas AI determined it to be GG5. Case 5 grading had the most discrepancy among the participants with grading varying roughly even from GG2-5 and 19% graded it to GG2 which was the AI-grading. Case 7 was graded as GG1 by 61% of the participants whereas AI-produced grading was GG2 agreeing with 32% of the participants.

Conclusions

Artificial intelligence tools can support the user's visual interpretation and assist the pathologist in making a diagnosis. As AI models are able to analyze the WSIs quickly, they can help to reduce the workload of the medical professionals. In this study, the grading of the samples differs somewhat between the participants and the AI model, however, there is also variability in Gleason scoring and GG between the participants indicating that there are challenges in making a diagnosis. In all cases, both the participants and the AI model graded the clinical outcome of the samples such that the patient could have received similar treatment.

Hints from the italian thin layer PAP test EQA scheme

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Introduction

The “Centro regionale di riferimento per la VEQ (CRRVEQ)” is a public italian EQA provider located in Tuscany and provides services to local and national laboratories. In 2020 the “cervical screening-PAP test” EQA program was established thanks to the collaboration with “Istituto per lo Studio, la Prevenzione e la Rete Oncologica (ISPRO)”, the Tuscany oncological screening center. The scheme can be described “educational” and it is accredited ISO 17043:2010 since 2023; participation is open to all health care structures analysing cervical smears, either as part of a screening program, or as occasional provision of services.

Aims

The scheme aim is to improve the quality of laboratory testing and the harmonisation of results, also offering support to participants in the form of EQA commented report including, beside the laboratory proficiency, smear description, clinical reasoning and information on the clinical outcome. Routinely the provider select different clinical cases in order to cover the full spectrum of disease, but occasionally repeated samples are proposed. We presently show laboratories performances on repeated samples.

Methods

In the EQA scheme participants need to evaluate digitalized thin layer cervical smears along with selected pictures, according to the Bethesda 2014 classification. For each annual cycle, 12 cases are proposed, data are collected and laboratory proficiency is determined according to a score system, conceived by ISPRO, taking into account the clinical risk of misclassification. In May 2022 and in September 2023 the same digitalized case was proposed (Low-grade squamous intraepithelial lesion LSIL, confirmed by histology) and results were compared.

Results

A subgroup of 35 laboratories participated in both 2022 and 2023 cycles and evaluated respectively EQA sample C5 and C9. We observed an improvement in the correct classification: in 2022 cycle “ LSIL” represented the 68.6% of identification (n= 24) vs 80.0% in 2023 cycle (n= 28), with 11.4% improvement of correct classification. Reporting of “ ASC-US” and “ASC-H” are to be considered as an underestimate of the lesion; in the 2022 cycle, the laboratories that provided an underestimation were 17.2% (n= 6), while in the 2023 cycle they decreased to 8.6% (n= 3).
It should be noted that in the 2023 cycle no laboratory has reported the severe misclassification “ Negative”, unlike in 2022.
The 17 new laboratories unrolled in 2023 , viewing for the first time EQA case 9, indicated LSIL as 88.2%, while the overall percentage of correct classifications, in the 2022 cycle, was 70.5%.

Conclusions

To evaluate the impact of a EQA program is not an easy task and caution needs to be exercised in order not to advocate unreal claims, however we found encouraging that a subgroup of laboratories, exposed to the same EQA case, after an adequate washout time, showed a consistent trend to better performances. We plan to introduce more repeated cases during future cycle in order to monitor the consistency of laboratory performances. We firmly believe that an educational approach is rewarding and highly appropriate to a public provider.

Introducing a clinical question framework in EQA reports

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Introduction

EQAs programs are generally structured according to Laboratory Medicine subspecialties such as: hematology, clinical chemistry and the likes. Although this structure may be coherent with laboratory organization and with analytical platforms, it totally lacks a connection with clinical questions. Diagnostic Clinical reasoning , on the contrary, is based on the integration of information deriving from different sources. Nowadays both clinical guide lines and international regulations such as ISO 15189 encourage professionals to take responsibility for the whole process: from clinical question to clinical outcome

Aims

In an attempt to follow this this inspiring approach, the Centro Regionale Verifica Esterna Qualità CRRVEQ(Careggi Florence -Italy) produced a “sepsis EQA report”. Sepsis was the chosen topic, since Regione Toscana promoted the adoption of a sepsis protocol (1) containing, along with Emergency Department orders to identify potentially septic patients and to perform initial management, a list of blood tests.

Methods

We verify that the relevant analytes were evaluated by means of 7 different EQAS programs: Hematology, Clinical Chemistry, Coagulation, Specific Proteins, Procalcitonin, Cardiac markers and Blood gas analysis. The rational that allowed us to produce an objective summary report, is the following: all EQAs schemes request quantitative data, our statistical approach is based on ISO 13528 and Analytical Performance Specification are defined. To provide, at a glance, an overview of global analytical quality, we gathered all the sepsis protocol tests in just one report and we added an intuitive evaluation based on traffic light code (red, yellow, green), referring to the statistical evaluation customarily performed.

Results

The quarterly reports have been sent to Tuscany clinical laboratories located in acute-care hospitals. The first report has been released in 2020 it is presently ongoing for the 2024 EQA cycle. This sort of cross view allowed us to identify potential pitfalls such as the lack of shared POCT management and the need of a more stringent evaluation of some measurand in our EQA schemes. Critical analytes resulted to be Procalcitonin and Lactate.

Conclusions

This approach, where cross-functional data are shown and can be shared between different professionals working in team to a specific clinical question, is well suited for clinical pathways and may promote a better knowledge of tests use and tests limitations.

Gestione della Sepsi e dello Shock Settico, Identificazione e Trattamento - (PDTA).
http://www.regione.toscana.it/documents/10180/601731/PERCORSO+SEPSI+GRC+TOSCANA_2016.pdf

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