Annual Report

2024

The European Organisation for External Quality Assurance Providers in Laboratory Medicine (EQALM) is an umbrella organization for European EQA organizers in laboratory medicine. EQALM provides a forum for co-operation and exchange of knowledge on quality-related matters especially with regard to EQA programs in Europe.

www.eqalm.org

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The EQALM Executive Board 2024

Executive Board members	First term / second term
Gro Gidske, Chair	2022–2024/2025–2027
Pierre-Alain Morandi, Treasurer	2022–2024/ 2025–2027
Gitte Marie Henriksen, Chair of the Scientific Committee	2020–2022/2023–2025
Rachel Marrington, Secretary	2020–2022/2023–2025
Wim Coucke, Member	2023–2025/2026–2028
Barbara De la Salle	2024–2026/

Activity report of the Executive Board

The executive board held monthly videoconferences for EQALM's agendas. Two face-to-face meetings was held: one in Geneva on 22/23 May 2024, and the other in Vienna on 15 October 2024.

Routine board activities 2024

- Preparation of Annual Report
- Membership management
- Preparation of Symposium in Vienna, Austria
- Swiss Chamber of Commerce and Bank issues
- Cooperation with interested parties
- Monthly meetings of the Executive Board
- Management of the Scientific Committee
- Management of the website and LinkedIn

Special board activities 2024

- Contribution to Published paper: Buchta C, Gidske G, Henriksen GM, Badrick T; European Organisation of External Quality Assurance Providers in Laboratory Medicine (EQALM). The European Organisation of External Quality Assurance Providers in Laboratory Medicine (EQALM) Statement: guidelines for publishing about interlaboratory comparison studies (PubILC). Crit Rev Clin Lab Sci. 2024 Apr 4:1-11. doi: 10.1080/10408363.2024.2335202.
- Established EQALM LinkedIn account (114 followers per February 2025)
- EQALM became Associated Partner in the EU Comet project
- Renewed contract EQALM – CSCQ regarding office services
- Renewed Memorandum of Agreement between EFLM and EQALM for a collaboration of WG-PRE and POST
- Developed a feedback survey from Symposium
- Developed EQALM instructions for how to prepare, submit, and present abstracts, and abstract selection criteria (available at www.eqalm.org > Annual Symposia)
- Prepared documents for General Assembly voting on EQALM European v International
- Several scientific projects progressed
- Further preparation of the EQALM handbook to document and optimize internal routines
- Initial discussions regarding potential collaborative projects with BioMed Alliance.

EQALM Symposium 2024

The annual EQALM Symposium and General Assembly were held in Vienna, Austria on 16–18th October 2024. The Symposium was organized by the EQALM board together with the local organizer ÖQUASTA. The scientific program organizing committee consisted of Christoph Buchta (ÖQUASTA) and Wim Coucke, Istvan Juhos, Tony Badrick and Gitte Henriksen (Scientific committee).

In addition to the many lectures, the symposium included other activities, such as steering committee meetings, scientific committee meeting, board meeting, and working group meetings.

The Adam Uldall Award lecture was given by Anja Kessler (Germany), with the title *EQA and its 'abilities'*.

131 persons attended the EQALM Symposium, and there were 13 sponsoring companies present with their respective booths.

Presentations from the EQALM Symposium are available at EQALM Symposium 2024

Members of EQALM 2024

A detailed member list is available online at EQALM Members

- 39 full members
- 4 non-European members
- 5 associate members

Membership fees are available at Membership fees

Activity plan for 2025

- Preparation of the EQALM Symposium 2025 in Leiden, Netherlands
- Follow up on changes to the Articles of Association
- Run and further optimise routine activities
- Support recognition of EQALM by interested parties
- Promote activities
- Prepare articles
- Support cooperation with other organisations in laboratory medicine and diagnostics

Report of the Chair of the Scientific Committee (Gitte Henriksen)

The EQALM Scientific Committee (SC) consists of the chairs of ten working groups (WGs), two task and finish groups (TFGs) and two WGs in collaboration with other organizations; IFCC and The International Consortium for Harmonization of Clinical Laboratory Results, ICHCLR. There were four virtual meetings in 2024 and one face-to-face meeting at the EQALM Symposium in Vienna. At the SC meetings the chairs shared the progress of ongoing projects within the WGs and TFGs and received announcements from the EQALM board.

There have been a few changes in the SC in 2024; Michael Noble (Microbiology WG) and Dalius Vitkus (Performance Specifications) stepped down as WG chairs. Jaap Van Hellemond (microbiology/Infection diagnostics) and Marc Thelen (Performance Specifications) have taken over the respective chair positions. A TFG was established with Piet Meijer as chair to support the COMET project (Manufacturing of COMmutable calibrators and quality control materials for standardisation and post-markET surveillance of IVD tests). IFCC TF-GLQ and EQALM agreed on establishing a WG on EQA in resource limited countries with Annette Thomas and Tony Badrick as co-chairs.

Reports from EQALM Working Groups

EQA for POCT (Chair: Tony Badrick since 2022)
WG Steering Committee: Tony Badrick, Gitte Marie Henriksen, Buchta Christoph, Barbara Del la Salle, Samantha Jones.

Tasks and purpose:

1. Document performance characteristics of PoCT system as determined by EQA
2. Investigate EQA Analytical Performance Specifications for PoCT systems
3. Serve as a forum for PoCT EQA

Current projects:

2024

1. ***Determine the performance of PoCT systems for selected measurands in primary care settings – Survey of EQA providers.***

Progress: a pilot survey was conducted using data from 4 EQA providers, only 3 provided data from CRP: ÖQUASTA, RCPAQAP and WEQAS. Labquality provided us data from HbA1c, those data are not included in the analysis.

The first table gives the overall numbers of samples and data for the three EQA providers

Number of samples and number of data

	Number of samples	Number of data
Oequasta	16	3113
RCPAQAP	24	14425
WEQAS	5	621

The statistical analysis focused mainly on the EQA variability. Unfortunately, we did not have data about the background of the operator that performed the POCT analysis, this is something that we should pay attention to at a following EQA collection.

We also looked at bias between methods, but these results should be interpreted with caution, since none of the samples had proven commutability. We found that the relation between the bias between methods and concentration is not always linear, which makes us doubt about the commutability of the samples. The results of this analysis of bias should be interpreted with caution.

It is difficult to investigate the issues we wanted using the normal client and site data collected by EQA providers, for example.

- The POCT setting e.g. pharmacy, GP surgery, clinical ward NHS, clinical ward private hospital etc.
- Details of what staff group manages the oversight of the instruments.
- Clinical utility – intended purpose of the testing within each setting.
- Do we want to look at performance at specific cut points?
- Are the clinical decision cut points different from Country to Country?
- Variation observed within each method / instrument group.

We will review and reinvestigate this project in 2025.

2. ***Develop an opinion paper describing EQA providers' risk in primary care settings.***

This paper is underway, and we hope to have it completed by October 2025. It would form the basis of the WG presentation at the EQALM meeting.

2025

The insights uncovered by the pilot and the work on the risk paper have raised some questions that deserve further investigation into PoCT operations in non-laboratory settings. These are:

- Does the level of EQA monitoring and oversight support influence the instrument performance, compliance, and overall management and improvement of POC testing to benefit the patient ultimately?
- Do EQA providers support the participant with managing the instrument library, data entry, and monitoring and troubleshooting poor performance?
- Does this improve compliance and performance?
- Are POCT hospital sites and POCT community sites two separate entities?

- How do we categorise the instrument 'settings'?
- How do we categorise the 'type of user'?
- If instruments are maintained, and EQA assayed, by lab staff does this stop that instrument being part of the 'POCT group'?

EQALM Central Database (Chair: Piet Meijer since 2022)

The Steering Committee (SC) of the Working Group Central Database (CD) exists of Stephanie Albarede (France), Wim Coucke (Belgium), Gitte Henriksen (Denmark), Razvan Popa (Romania) and is chaired by Piet Meijer (The Netherlands).

In December 2024 the SC has agreed to be extended with a new member: Marith van Schrojenstein-Lantman (The Netherlands).

The SC has met two times in 2024, one online meeting and one face-to-face meeting in conjunction with the EQALM symposium in Vienna.

In 2024 the focus of the WG Central Database was mainly on two projects:

1) *Involvement in the HALMA initiative for which the central database is used to aggregate EQA data for albumin, calcium and creatinine. For further details see the section on HALMA.*
2) *The COMET project (Manufacturing of COMmutable calibrators and quality control materials for standardisation and post-markET surveillance of IVD tests). It has been decided by the board to establish a specific Task and Finish Group for the COMET project (TFG-COMET). For details see the report of this TFG.*

A file station for the central database at the CSCQ office is still under development.

Activities on data aggregation and evaluation are performed by Wim Coucke.

In 2025 the major focus will be on how the EQALM CD can become more beneficial for other EQALM working groups.

Frequency (Chair: Wim Coucke since 2017)

The working group continues working on finding evidence of arguments identifying the most optimal frequency of EQA samples, both using theoretical models and collecting opinions.

A working group meeting took place at the 2024 symposium in Vienna. Arguments were collected that will form the basis of an opinion document listing arguments to define optimal frequency. This opinion document will be elaborated and discussed further in the course of 2025.

In addition, work theoretical models to find the most optimal frequency will be further developed.

Haematology (Chair: Barbara De la Salle since 2020)

Works in progress

1. **Article on the Analytical Performance Specifications for Blood Smear Interpretation in Haematology**

   The text of this manuscript has been reviewed prior to submission for publication and substantial updating undertaken.

2. **Survey on Reference Ranges in Haematology Cell Counting**

   The questions for this survey have been tested in a pilot survey to laboratories in the UK. Some additional updates are required, including how the questions are laid out, and assistance is being sought. The outcomes of the questionnaire will be used as the basis for a publication.

3. **Collaboration with the VM WG**

   Steering committee members have continued to work with the VM WG and a new project on VM in Haematology is in development.

Works proposed

1. Post-analytical EQA in Haematology
2. Rare disease EQA in PK deficiency
3. Standardisation of NGS interpretation in Haematology

Additional comments

1. The WG has an established Steering Committee (Barbara De la Salle, Stéphanie Alberède, Erika Sarkany) and a Terms of Reference document.
2. The Steering Committee wishes to recruit at least two additional members. The appeal for volunteers at recent EQALM meetings has been unsuccessful and we should consider direct invitation to appropriate individuals.

Haemostasis (Chair: Ann Helen Kristoffersen since 2017)

Ongoing projects	Status 2024	Responsibility
APTT/PT performance evaluation	Data evaluation and reporting of basic haemostasis parameters. Questionnaire finalized and sent to EQA organizers in 2024. Responses received from 20 EQA organizers. Data evaluation is ongoing. Results were discussed at the EQALM meeting in the WG Haemostasis Steering	Meijer/ Stavelin/ Kristoffersen/others in project group

	Committee meeting and the WG Haemostasis meeting during the EQALM symposium.	
APTT seconds/ratio project	Project cooperation with the EFLM WG-PRE/POST. Final data evaluation is ongoing and a first draft of a publication is in preparation.	Meijer/Kristoffersen/ Hillarp/Cadamuro
Project on pre-analytical variables in haemostasis: HIL survey	Feedback report sent to EQA organisers and laboratories in January -24. Main manuscript for submission almost finished. Discussed at the EQALM meeting. Possibly 1–2 follow-up manuscripts based on data already collected (possibly in cooperation with the WG-PRE in EFLM).	Kristoffersen/Meijer and others in project group
New members of the Steering Committee	Michael Spannagl (INSTAND) and Christopher Reilly-Stitt (UK NEQAS Blood and Coagulation)	

Immunohaematology (Chair: Richard Haggas since 2022)

1. *Steering Committee*

A Steering committee meeting was held on Wednesday 16th October 2024. Discussion took place around the anti-D detection exercise and the issues surrounding declining specialist knowledge in Transfusion Medicine. Discussion on possible future challenging samples that could be sent took place.

2. *Anti-D sensitivity challenge exercise challenge*

- Samples distributed by Antitoxin in July 2024
- Testing all completed by December 2024
- Results now submitted

3. *Immunohaematology Working Group Meeting (Vienna, October 2024)*

- Antibody sensitivity exercise
    - Presentation of the preliminary results from the anti-D antibody sensitivity exercise were presented. Discussion took place around the results.
    - There are still a number of results from some EQA providers to come in.
    - Analysis of the results will take place in 2025.

- The audience were asked to send suggestions for the next workstream to the Working group chair.

Immunology (Chair: Dina Patel since 2019)
The aim of the Immunology Working Group is to collaborate with other EQALM members to try to understand how immunology practices/tests are utilised within member countries.

The group has met several times during 2024 via virtual meetings and a face-to-face meeting was held at the Symposium meeting in Vienna. The main focus of the group has been to analyse and review the data from the Anti Nuclear Antibody survey, which aimed to determine the variation in practice as well as the impact of the ANA ICAP harmonisation initiative. In addition, the survey reviewed whether changes in technology, using machine learning, are reducing or improving skills within the workforce in the sphere of immunofluorescence testing.

The survey was circulated to EQALM members in summer 2023 and results analysed by the group towards the end of 2023 and early 2024. The results from the survey were then reviewed and discussed within the Immunology WG and agreed to produce a publication within a scientific journal. The paper has been submitted and we hope to have a positive outcome shortly. The key findings of the survey were presented and discussed with EQALM members within the Immunology WG session at the EQALM annual Meeting (Vienna) in October 2024.

The Immunology WG has now produced a survey for EQALM members to understand the information covered within various ANA EQA programs to see if this can be harmonised in any way.

Infection diagnostics (Until 2025: Microbiology) (Chair: Jaap Van Hellemond since 2024)
In 2024 the working group (WG) microbiology has made a restart by appointing Prof.dr. Jaap van Hellemond (SKML, the Netherlands) as a new chair. All EQALM members were invited to nominate WG members and during the annual EQALM meeting in Vienna a WG session was organized during which it was discussed how to restart the WG and which topics could be addressed. These activities resulted in the recruitment of a sufficient number of new members for the WG (>10 members from >6 countries that sufficiently cover all disciplines in microbiology). The digital kick off meeting took place on November 28th 2024 during which possible projects were discussed, as well as the name of the WG. The outcome of the meeting was to propose “infection diagnostics” as the new name of the WG (as this better represents all aspects of infectious disease laboratory diagnostics) and to focus on a single and feasible project first. This project will be the “Inventory of EQA schemes of EQALM members for infectious disease” because the information generated by this project will provide a solid base for selection of further projects. The WG plans to prepare a survey among EQALM members in spring 2025.

Performance Specifications (Chair: Dalius Vitkus since 2019)
The main objectives of the WG Performance Specifications are:

− To investigate which performance specifications are currently used by different EQA organisations;

− The rationale behind different performance specifications in use;

− To set-up cooperation with EFLM Science Committee Task Groups “Performance Specifications Based on Outcome Studies” (TG-PSOS) and “Biological Variation Database” (TG-BVD) and the EFLM committee Quality and Regulations and its WGs to come to a division of roles where the science bodies specify how PSs should be specified and quality bodies specify how to check whether PS are met.

Open WG meeting held in Vienna during the annual symposium of EQALM held on October 16th, 2024 was well attended. Marc Thelen presented outcomes of the Survey on current status and future possibilities among EQALM members for the project “How equal is equal enough to allow combination of data within one health record?” (“Exchangeability survey”). According to the feedback received at the Vienna meeting, both at the WG-PS meeting and discussions with other groups (HALMA project in particular), taking into consideration “Exchangeability survey” outcome, project “How equal is equal enough to allow combination of data within one health record?” will be limited to one analyte, at least for the beginning. Particular analyte remains to be defined.

On April 13th together with Portuguese Society of Laboratory Medicine workshop “How to apply performance specifications in daily laboratory practice” was organized. *Piet Meijer, Dalius Vitkus, João Faro Viana, Ana Faria*

Time	Topic	Speaker /Moderator
9.00 – 9.10	General introduction on the scope of the workshop	Piet Meijer
9.10 – 9.25	Results of questionnaire	Dalius Vitkus / Ana Paula Faria
9.25 – 9.55	Theory on Performance Specifications	Piet Meijer
9.55 – 10.15	Break	
10.15 – 11.00	Workshop (4 working groups)	
	- Clinical Chemistry (Creatinine)	João Faro Viana
	- Haematology (Haemoglobin, Iron)	Ana Paula Faria
	- Hormones (TSH, Ferritin)	Dalius Vitkus
	- Coagulation (D-Dimer, Factor VIII)	Piet Meijer
11.00 – 11.45	Presentation of outcome	All
11.45 – 12.00	Final Q+A session	All

Part of ToR has to be re-defined *(to set-up cooperation with EFLM Science Committee Task Groups “Performance Specifications Based on Outcome Studies” (TG-PSOS) and “Biological Variation Database” (TG-BVD) and the EFLM committee Quality and Regulations and its WGs: to come to a division of roles where the science bodies specify how PSs should be specified and quality bodies specify how to check whether PS are met; to distinguish between Analytical Performance Goals (APG), which are ideally met (if not possible now, then in the future) and Analytical performance specifications (which can and must be met today))* due to change of EFLM Functional units structure from the January 2025.

Virtual Microscopy (Chair: István Juhos since 2016)

2024

WG Steering Committee

This section is about the activity and the number of the members of the WG steering committee

Year	Activity
2024	18 participants from 11 countries represented in the VM WG Steering Committee this year supporting ongoing WG projects: Brazil, Croatia, France, Germany, Hungary, The Netherlands, Norway, Portugal, Spain, Switzerland, UK.

WG Terms of Reference

EQALM VM WG Terms of Reference has been updated.

EQALM Symposium WG Session

Ongoing project activities were discussed, and the planned EQALM VM pilot in haematology and parasitology was presented. A total of 26 participants from 19 EQALM members expressed their interest during the WG session.

Grants

Year	Status
2024	● An invitation to participate in an ongoing project related to a WHO initiative, funded by the EU and the Swiss government, has been received. ● New grant opportunities have been identified, and the application preparation has begun.

Projects

This section is about the status of WG projects.

Year	Status

2024	● EQALM VM Guidelines ● EQALM Digital Blood Smear Analysis - Parasitology Scheme Draft has been improved. ● EQALM VM Sharing Platform ● Improvements in the EQA support continued especially for parasitology, haematology and andrology, and more specifically blood smear, bone marrow and semen analysis. ● EQALM VM Image Database ● Pilot VM image database has been extended. ● VM Collaborative Network ● The EQALM Board supports the creation of a new non-profit organisation for VM Collaborative Network. Hence, the preparation of a new non-profit organisation for VM Collaborative Network has been continued.

Scientific activities

This section is about the scientific activities related to the WG.

Year	Scientific activity
2024	● Koelewijn R, Feoktistov I, Tieken C, Albe X, , Albarede S, Juhos I, van Hellemond J.J. (submitted): Digitalization of clinical specimens by microscopic scanners in combination with Artificial Intelligence (AI) provides new tools to improve diagnostics in high-income countries and for virtual training in low-income countries. Abstract submitted for presentation at the Joint Parasitology Societies Meeting 2025. ● Buchta, C, et al. (in review). Behind the Scenes of EQA – characteristics, capabilities, benefits and assets of external quality assessment (EQA). Clinical Chemistry and Laboratory Medicine.

- Juhos, I (2024, October). EQALM Virtual Microscopy Collaborative Network Projects [conference presentation]. EQALM Symposium 2024.

Reports from EQALM Task and Finish Groups

ISO 17043 revision (Stéphanie Albarède)

In 2024, the Task&Finish steering committee met one time (September) in order to define a work strategy to help EQALM members better understand the new version of the standard and respond to non-conformities highlighted during audits. The steering committee set up a survey on the progress of the accreditation of organizations according to the new version of the standard and the problems encountered. The results of this survey were presented at the EQALM meeting in Vienna. Proposals of projects for 2025 were then presented to the whole TF during this meeting and were accepted with enthusiasm:

- Organisation of workshops on specific chapters proposed to exchange of points of view and on the back-up after Audit on the new version of the standard. First chapters chosen are:
    - 8.5 Actions to address Risks and Opportunities
    - 7.5.3 Surveillance of the processes
    - 4.1 Impartiality + 4.2 Confidentiality
- Writing an opinion paper for the field of EQA for medical labs

COMET project (Piet Meijer)

In 2024 the COMET project (Manufacturing of COMmutable calibrators and quality control materials for standardisation and post-markET surveillance of IVD tests) has been started.

In the first half of 2024 a lot of attention has been paid if and how EQALM could participate in this project. The board has finally decided to participate in this important project. Because of the scope of this project (e.g. manufacturing commutable quality control materials) it is important that EQALM is involved.

This project includes 6 working packages of which EQALM is involved in 5 of these working packages. There are in total 23 tasks (EQALM involved in 16 tasks) and 167 activities (EQALM involved in 57 activities). Further information about this project can be found on the following website: https://projects.lne.eu/jrp-comet/. To structure the EQALM activities a special Task-and-Finish Group (TFG) has been established by the board. Members of this TFG are: Gro Gidske, Gitte Henriksen, Wim Coucke and Piet Meijer (chair).

Special attention has been paid how the activities executed by EQALM can be financed. Because EQALM is based in Switzerland, it cannot be a financed partner in this by the European Union granted project. Initiatives for financing are still ongoing.

An important contribution of EQALM is the use of the EQALM Central Database. Because of the central role for the use of the Central Database Sciensano has become a partner in this project to make it possible for Wim Coucke to work on this project.

At the EQALM symposium a special session was organized on this COMET project. This session included the following contributions:

- *TraceLabMed survey* by Gavin O'Connor (Germany)
- *Presentation of the COMET project* by Vincent Delatour (France)
- *The role of EQALM* by Piet Meijer (The Netherlands)

In 2025 the focus will be on the execution of tasks and activities in which EQALM is involved.

Reports from EQALM projects in cooperation with other organizations

IFCC TF-GLQ (Gitte Henriksen)

- **WG on EQA in resource limited countries. (Chairs: Annette Thomas and Tony Badrick as co-chairs).**

16/10 - Joint Working group on EQA in resource –limited countries established after approval from the 2 respective committees. AT and TB appointed as co-chairs.

26/10 - Draft e-mail sent to IFCC TF-GLQ chairs for approval.

04/11 – e-mail notification sent out from EQALM office to ask EQA providers “that if you are currently providing FOC EQA material or services, please let us know the countries involved, any third-party organisations (WHO, Pathologists Overseas), the scope of the support and a contact person form your organisation.”

Expression Of Interest so far

- WEQAS – Provides FOC EQA samples in Clinical Chemistry to Malawi
- RCPAA – Provides FOC EQA samples in Clinical Chemistry to Zambia
- ControlLab - Fully committed to supporting it in 2–3 countries in Latin America. Their team are in the process of preparing a detailed proposal outlining the scope and structure of the program that is on offer.
- INSA PNAEQ has been involved in a project for Portuguese speaking countries (ProMeQuaLab), to improve quality in medical laboratories since 2015. Ana Faria provided a presentation on their activities to TF-GLQ at their November meeting.
- Piet Meijer of ECAT is advisor to ProMeQuaLab project and has given several quality-related courses in Mozambique. Furthermore, although coagulation is probably not one of the top priorities of the

TF-GLQ, he is happy to be involved from this perspective. ECAT is willing to see whether they can provide some material for (small-scale) pilot surveys.

- CRCMedLab (Milan – Italy) - They are prepared to provide free digital exercises related to Peripheral blood smear, Biological Liquid and Somatic Pathology. They also have some material residues for biochemistry analyses but in very limited quantities (10 to 20 bottles per batch).
- UK NEQAS – Have substantial experience in the operation of an EQA programme for less economically developed regions as they offered a haematology programme for almost 50 years through WHO. Their experience would be invaluable in advising the group going forward.

Next Steps

First meeting of the chairs to be held on 11th December 2024 to develop ToR and project plan.

ICHCLR; The HALMA initiative (Gitte Henriksen)

HALMA is “the joint task force to monitor harmonization of measurands in laboratory medicine through data aggregation” and is a collaboration between EQALM and the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR). The HALMA task force was established in 2021.

Besides the steering committee there are currently three specific working groups (WG) in HALMA; WG on Measurands, WG on Commutability and WG on Description of Methods.

The HALMA steering committee and WG chairs had 7 virtual meetings in 2024 and one 2-day physical meeting in Copenhagen, Denmark in March. The aim of the physical meeting was to further discuss and analyse the aggregated EQA data for serum creatinine, calcium and albumin results obtained in 2023; *26099 results from 59 different samples from 11 EQA providers including but not limited to method information, country of origin and target value.*

An initial summary report, attached, was written with a short overview of the relative biases among different IVD measurement procedures for the three measurands. The summary report was sent to EQA providers that sent data for the HALMA project and members of the three WG’s.

Wim Coucke gave a presentation at the EQALM Symposium 2024 about projects in the EQALM Central Database including an overview of the HALMA project. Tony Killeen gave a presentation at the Asia-Pacific Federation of Clinical Biochemistry meeting about HALMA.

Work in progress:

The Measurands WG is developing a list of measurands that can have assumed commutable samples (20-25 measurands). Measurands on the list will be prioritized and the driving factors are clinical needs and measurands with “problems”. However, also considering the feasibility to aggregate data.

The Description of Methods WG is preparing recommendations on what information describing measuring systems is minimally and optimally needed to aggregate data from different EQA schemes given that the EQA control materials are commutable.

The HALMA steering committee and the WG chairs are in the process of preparing a manuscript about approaches to data aggregation and where we see challenges including what information is needed if you want to aggregate EQA results, e.g. knowledge about sample commutability and granularity of method information. This manuscript will be based on the data that we received in 2023.

The HALMA steering committee consists of the following people:
From ICHCLR: Greg Miller and Sverre Sandberg
From EQALM: Piet Meijer, Wim Coucke and Gitte Henriksen (chair)
WG chairs: Tony Killeen, Description of Methods; David Ducroq, Measurands; and Greg Miller, Commutability

For more information about HALMA, please see EQALM.org

HALMA EQA data aggregation summary report

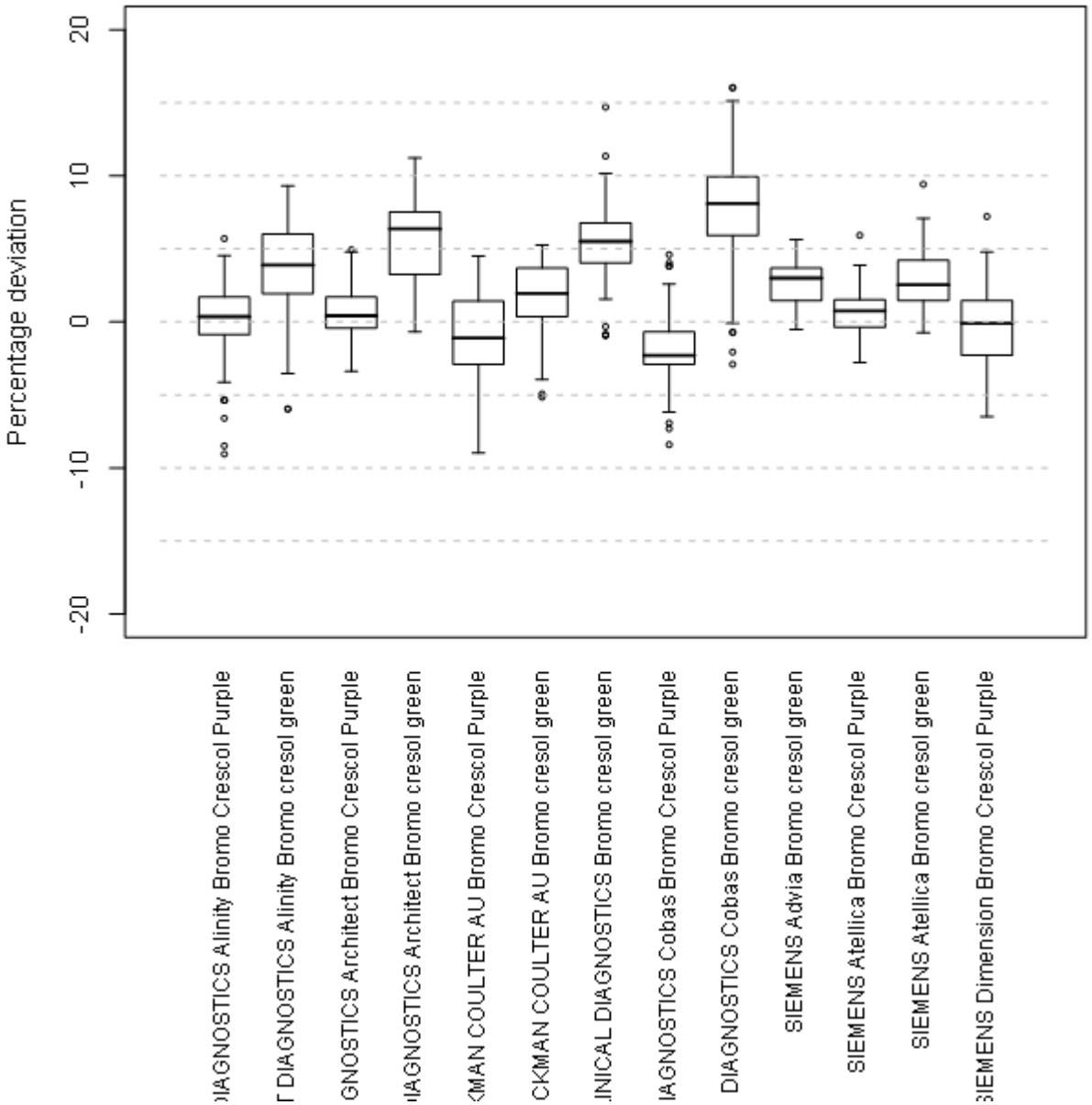
EQA data from 11 providers was reviewed to examine procedures to aggregate the data. The long-term goal is to assess the harmonization/standardization of results among IVD manufacturers using EQA data. The samples submitted were assumed to be commutable based on the way they were prepared. In a few cases there was documentation of a formal commutability assessment for a prior batch. The data in the typical normal concentrations was used to examine serum albumin, calcium and creatinine. The number of samples included were 20 for Albumin, 23 for Calcium and 18 for Creatinine. All combinations of IVD measurement procedures (IVD MPs) were examined in pairs to determine how closely the results from different EQA providers agree. Results that agree were aggregated to assess bias relationships among IVD MPs for the EQA materials. Note that agreement does not ensure commutability with clinical samples.

The figures show the relative biases among different IVD MPs for the three measurands within the typical normal range. The target concentration for each EQA sample for each measurand was calculated as the mean of medians of all results. For albumin the BCP results were used and for creatinine the enzymatic results were used to set the target values. All results were used for the calcium target value.

A publication is in development to explain the details of the data assessment and criteria for aggregation. Preliminary review of the data has identified at least two future needs. One need is to establish the commutability for at least one EQA provider's EQA material for each measurand to link the aggregated samples with a commutable sample to indirectly support the commutability of the group of EQA samples. Another need is to have reference measurement procedure target values assigned for EQA materials to enable assessment of metrological traceability.

April 2024

Albumin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INICAL DIAGNOSTICS Bromo cresol green
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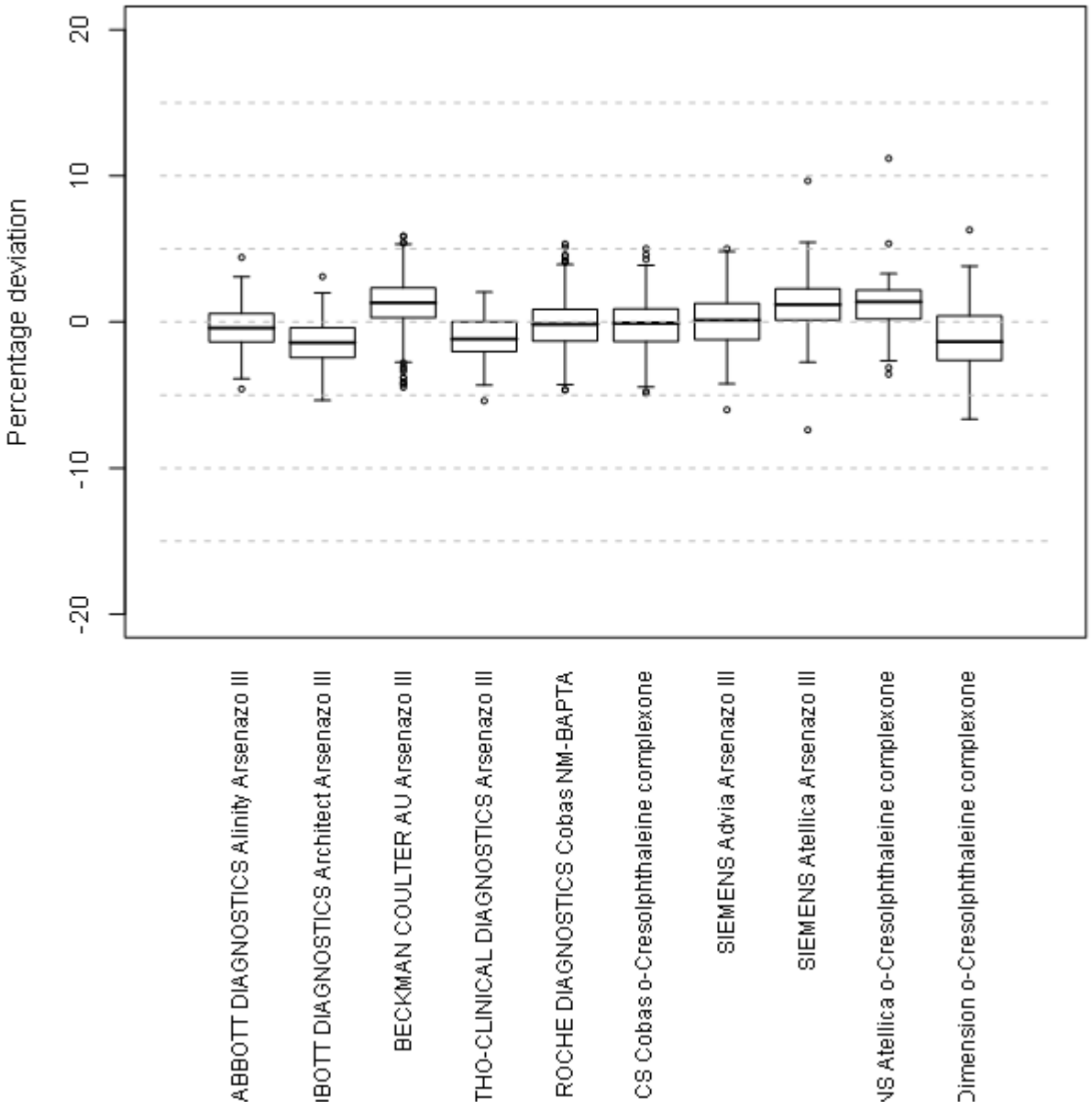
SIEMENS Dimension Bromo Crescol Purple

Calcium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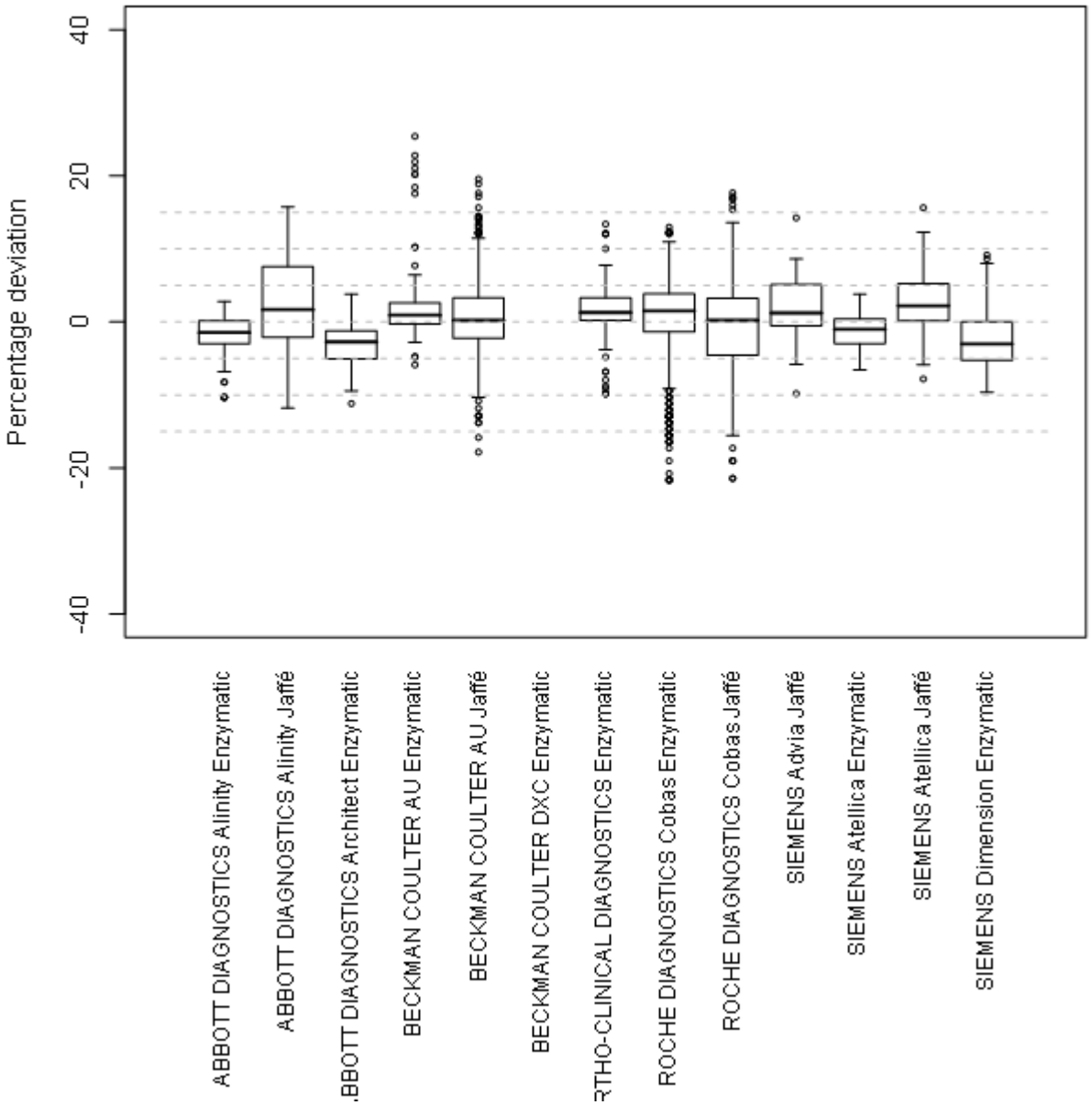
-10
-20
ABBOTT DIAGNOSTICS Alinity Arsenazo III
IBOTT DIAGNOSTICS Architect Arsenazo III
BECKMAN COULTER AU Arsenazo III
THO-CLINICAL DIAGNOSTICS Arsenazo III
ROCHE DIAGNOSTICS Cobas NM-BAPTA
CS Cobas o-Cresolphthaleine complexone
SIEMENS Advia Arsenazo III
SIEMENS Atellica Arsenazo III
NS Atellica o-Cresolphthaleine complexone
Dimension o-Cresolphthaleine complexone

Creatinine


Percentage deviation
40
20
0
-20
-40
ABBOTT DIAGNOSTICS Alinity Enzymatic
ABBOTT DIAGNOSTICS Alinity Jaffé
ABBOTT DIAGNOSTICS Architect Enzymatic
BECKMAN COULTER AU Enzymatic
BECKMAN COULTER AU Jaffé
BECKMAN COULTER DXC Enzymatic
RTHO-CLINICAL DIAGNOSTICS Enzymatic
ROCHE DIAGNOSTICS Cobas Enzymatic
ROCHE DIAGNOSTICS Cobas Jaffé
SIEMENS Advia Jaffé
SIEMENS Atellica Enzymatic
SIEMENS Atellica Jaffé
SIEMENS Dimension Enzymatic

Reports from EQALM in cooperation with other organizations

EA-EUROLAB-EURACHEM: 'Proficiency Testing in Accreditation' (EEE-PT) (Stéphanie Albarède and Erika Sarkani)

The 57th meeting and the the 58th meeting held on 21st – 22nd May 2024 in Morges (Switzerland) and on 14th – 15th November 2024 in Rome (Italy) respectively.

The revision of the Eurachem leaflet on use of ILCs other than PT has been completed and the new version published.

Concerning the Revision of "EA-4/21 INF: 2018 Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation", the document was discussed at the 2 meetings and updated. Comments from Eurachem, Eurolab and EQALM will be reviewed and processed before being sent to the EA-LC for comment and approval.

As discussed in the EA/LC meeting, it was proposed that the EEE PT working group should look at ways in which flexible scopes are currently approached by both PT provider and NAB's and to produce guidance on flexible scopes for accreditation bodies. A task group within EEE PT WG was set up.

EFLM – WG-PRE/POST (Rachel Marrington and Gro Gidske)

WG-Pre/Post have merged into a single group which has progressed to a committee rather than a WG. In future this will be known as C-PRE/POST.

There are no new formal activities from the collaboration with EQALM. A longstanding project which involved EQALM relating to a survey on reflex and reflective testing in clinical chemistry has had draft one of the manuscript written for the chemistry elements. It is hoped that this will be submitted for publication in 2025.

ISO/CASCO (Stéphanie Albarède)

No EQALM activities were conducted following the completion of the ISO 17043 standard in 2023.

JCTLM (Piet Meijer)

A summary of the JCTLM Workshop 2023 entitled: "EQA/PT Harmonisation; EQA schemes elucidating the clinical suitability of laboratory results" has been published in Clinica Chimica Acta:

Theodorsson, E., P. Meijer and T. Badrick, External quality assurance in the era of standardization. Clin Chim Acta, 2024; 557: 117876 (openaccess).

There were no further activities of JCTLM in which EQALM was involved in 2024.