

Attention for the extra analytical phase

EXTRA



Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

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SKML mission

To develop the tools for medical laboratory diagnostics with unequivocal interpretation.

SKML achievements over the years

EQA fit for purpose to check metrological traceability of results

1. Value assignment in reference methods
2. Commutable materials
3. Actionable reports with multi sample evaluation
 - Bias
 - Imprecision

Is that enough?

Purpose:

Exchangeability or results that are **relevant** for the **medical question** behind the test request

Medical question

- Translate medical question into test request
- Pre-analytical responsibility
- ISO 15189 requirement for laboratory professional

Relevant results

- Translate data into information
- Answer to the medical question behind the request
- Post analytical responsibility
- ISO 15189 requirement for laboratory professional

Exchangeability

- Harmonized results deserve harmonized reference intervals

ISO 15189 requirement

5.6.3 Interlaboratory comparisons

5.6.3.1 Participation

The laboratory shall participate in an interlaboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results. The laboratory shall monitor the results of the interlaboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled.

NOTE The laboratory should participate in interlaboratory comparison programmes that substantially fulfil the relevant requirements of ISO/IEC 17043.

The laboratory shall establish a documented procedure for interlaboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison programme.

Interlaboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.

SKML organization

- Our own process has analytical and extra analytical phases
- Analytical phase:
 - samples and reports
- Extra-analytical phase:
 - infrastructure, process, quality management system
- People make the organization
- Dedication
- People at the CFB
- People in the SKML sections
- ISO 17043 accreditation applied, incremental approach

ISO 17043 accreditation

Incremental approach

Poll

Accreditation applied for how many schemes

- A. 1 scheme
- B. 5 schemes
- C. 30 schemes



<https://skmlcongres.participoll.com/>



ISO 17043 accreditation

- Incremental approach
- CFB: process, software, statistics, reports
- Sample preparation laboratories
 - MCA Winterswijk: general chemistry, plasma proteins
 - MMB Laurentius Roermond: bacteriology
 - MMB Erasmus MC, Rotterdam: blood parasites, fecal parasites
- Sections:
 - General chemistry
 - Humoral Immunology
 - Bacteriology
 - Parasitology



Next steps

- Increase scope
- Adding schemes
 - Same section and preparation laboratory: 30
 - Add sections and preparation laboratories: ultimately: >130 schemes

Back to the theme of today

- Set your own goals
- SKML section member:
- What can my section add to current schemes to challenge the entire process from pre-post-analytical phase?
- SKML participants:
- How can I make my participation more relevant and representative for my entire process from medical question to answer?



Program

- Morning (English)
- Inspirational examples of pre- and post analytical challenges in EQA

- Afternoon (Dutch)
- Case based cross section examples on extra analytical relevance
 - To inspire future EQA challenges by the SKML
 - To make participants aware of the purpose of EQA: it's not a game!

- Bonus: Prof. dr. Jan Kluytmans: Extra analytical lessons learned from the Covid crisis

Thank you for collaborating

- Thank you to the speakers for sharing
- Thank you to the audience for learning
- Thank you to the scientific committee
- Thank you to the organizing committee
- Thank you to the sponsors

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