Joint Committee for Traceability in Laboratory Medicine (JCTLM) Workshop

hosted by the

Nicolaus Copernicus University in Torun, Collegium Medicum in Bydgoszcz, Poland

under the auspices of

May 27-28, 2026

Aula 1.4-1.5 (Building A), Collegium Medicum UMK, Bydgoszcz, Poland

May 27, 08:30 – Welcome [Academic Authorities – JCTLM Chair]

Day 1 workshop

HIGH-PRIORITY REFERENCE MATERIALS FOR TRACEABILITY IN LABORATORY MEDICINE – FILLING THE GAP

Field of reference: The total number of clinically relevant analytes measured routinely has been estimated at over 2000. Some analytes are measured very frequently and others less. To adhere to regulatory requirements in vitro diagnostics (IVDs) specific analytes are classified as high or a lower risk determined by the intended purpose of the IVD and the inherent risks of inadvertent false positive or negative results. The global harmonization of laboratory medicine is facilitated by the development and implementation of Reference Measurement Systems including appropriate Certified Reference Materials (CRMs). There are a relatively small but growing number of national laboratories that are able to produce CRMs for these applications worldwide. With these limited resources the prioritization of efforts is key as is the interaction of different producers in meeting global needs for the highest priority CRMs that ensures supply and maximises the number of analytes that can be covered with sufficient redundancy.

Workshop goals:

- Understand the current prioritization exercises that exist and their level of consistency;
- Understand the current activities on-going to meet high priority CRM development and maintenance needs;
- Make recommendations on how optimised efficiency of the processes for filling the gap of missing CRMs, maintenance of CRM supply, and optimised redundancy of CRMs can be achieved.

Day program

09:00-09:15 - Introduction to the day topic (Robert Wielgosz, JCTLM/CCQM Executive Secretary)

Session 1: Prioritization activities and stakeholder needs - Chairpersons: M. Panteghini, R. Wielgosz

09:15-09:35 – The work of ICHCLR in the past and in the future. Presupposition for harmonisation/standardisation of measurement procedures (Sverre Sandberg)

09:35-09:55 - Outcomes of EMN Trace Lab Med questionnaire and EURAMET projects (Vincent Delatour)

09:55-10:15 - CRM needs of reference measurement laboratories (1) (Anja Kessler)

10:15-10:30 – Coffee Break

10:30-10:50 - Review of gaps in the JCTLM database (Mauro Panteghini)

10:50-11:10 - IVD manufacturer approach to meet its needs for CRMs (Christian Vogl)

11:10-11:30 - CRM needs of reference measurement laboratories (2) (Hubert Vesper)

11:30-12:15 - Discussion

12:15-13:00 – Lunch break

Session 2: On-going activities to address needs - Chairpersons: R. Josephs, G. O'Connor

13:00-13:20 - IFCC-SD: CRMs that are expected as outcomes of IFCC-SD projects 2035+ (Christa Cobbaert)

13:20-13:40 - CCQM OAWG: Plans for comparisons on small organic clinical markers and the CRMs they will cover 2035+ (Gavin O' Connor)

13:40-14:00 - CCQM PAWG: Plans for comparisons on protein clinical markers and the CRMs they will cover 2035+ (Claudia Swart)

14:00-14:20 – NIST: CRM development and maintenance plans 2035+ (Karen Phinney)

14:20-14:40 - NIM: CRM development and maintenance plans 2035+ (Dewei Song)

14:40-15:00 – JRC: CRM development and maintenance plans 2035+ (Liesbet Deprez)

15:00-16:00 – Discussion

16:00-16:15 – Coffee break

16:15-17.45 - Session 3: Towards maximised efficiency for gap filling and optimised redundancy for CRMs - Round Table discussion with all speakers on:

- How to reach agreement on a global priority list for CRMs and have an active system for maintaining this?
- How to effectively share the load for high priority CRM development and maintenance?
- How to ensure continuity of supply and avoid unnecessary duplication?
- Proposals for next steps for improvement in the efficiency of the international system?

Day 2 workshop

ESTABLISHING METROLOGICAL TRACEABILITY TO INTERNATIONAL SYSTEM OF UNITS (SI) FOR SERUM AND URINARY ALBUMIN MEASUREMENTS

Field of reference: Albumin measurements in serum and urine have important diagnostic and prognostic roles. However, non-standardized measurement procedures are still used in medical laboratories. While much progress toward providing tools for standardizing urine albumin measurements has been made in the last 15 years, serum albumin still lacks an approach for the implementation of metrological traceability to the SI, starting by employing alternative methods for CRM characterization. This workshop will provide an analysis of the current status of Reference Measurement System components for serum and urine albumin measurements, including discussion on how to improve standardization and highlighting some important aspects that still require clarifications. The discussion will also be useful for IVD manufacturers when introducing changes in metrological traceability of serum and urine albumin measurement procedures to assure traceability to SI.

Workshop goals:

- Provide a comprehensive analysis of metrological traceability tools for standardizing urine albumin measurements;
- Understand the interchangeability of available higher-order CRMs and reference measurement procedures when employed to establish metrological traceability of IVD measurement procedures for urine albumin to SI;
- Discuss about analytical performance specifications that should be fulfilled when using serum and urine albumin measurements for patient management decisions;
- Agree on how to redesign the approach needed for the implementation of metrological traceability to the SI for serum albumin and plan the related studies.

Day program

09:00-09:15 - Introduction to the day topic (Mauro Panteghini, JCTLM Chair)

09:15-11:45 - Morning session: Urine albumin - Chairpersons: G. Miller, M. Panteghini

09:15-09:45 - An overall description of the reference measurement system for urine albumin standardization (Greg Miller)

09:45-10:15 - Primary CRMs and calibrators for urine albumin: intended use and interchangeability (Robert Wielgosz)

10:15-10.45 - An overview of reference measurement procedures for urine albumin (Quinde Liu)

10:45-11:15 - Secondary CRMs for urine albumin: availability and interchangeability (Ashley Beasley Green)

11:15-11:45 - Discussion

11:45-12:15 - Analytical performance specification-driven total measurement uncertainty budget for serum and urine albumin measurements (Mauro Panteghini)

12:15-13:00 – Lunch break

13:00-15:00 - Afternoon session: Serum albumin - Chairpersons: M. Panteghini R. Wielgosz

13:00-13:30 - Current tools for harmonization of serum albumin measurements (Guy Auclair)

13:30-14:00 – External Quality Assessment results for serum albumin with special focus on assay selectivity (Marc Thelen)

14:40-15:00 - A proposal for SI-traceable calibration hierarchy for serum albumin (Liqing Wu)

15:30-16:00 - Discussion

16:00-16:30 - Concluding remarks and future work (Mauro Panteghini)