

# Developments in reference measurement systems for C-reactive protein and the importance of maintaining currently used clinical decision-making criteria

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1 December 2022



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## BACKGROUND AND AIM OF THE WORKSHOP

New C-reactive protein (CRP) candidate reference materials (cRMs) were nominated in the recent Joint Committee for Traceability in Laboratory Medicine (JCTLM) cycles. While characterization of the cRMs were thoroughly carried out, the JCTLM was concerned about the impact of the materials for the laboratory medicine community that the JCTLM database serves. It was unclear in which position of the current traceability chain for CRP should these cRMs be inserted or if they belong to newly proposed traceability chains in which these materials are traced to SI through, e.g., the amino acids RMs and the hydrolysis-IDMS procedure. Overall, it is not clear if the cRM providers propose an alternative traceability chain to that currently used in the clinical community and listed on the JCTLM database. If this is the case, JCTLM recommends that further investigations should be carried out to understand the implications of introducing a new traceability chain for CRP for patient clinical results before proceeding with adoption of newly characterized cRMs and listing them on the JCTLM database.

The workshop will start a discussion with all parties involved in the CRP standardization. JCTLM wishes to encourage the CRP stakeholders and RM providers to initiate an investigation with the clinical community on the possible effects of changing the traceability chain of CRP for patient results.

## TARGET AUDIENCE

The workshop is open to all individuals and groups with an interest in traceability and method standardization. These include laboratory medicine specialists, EQA providers, IVD manufacturers, national metrology institutes, and regulatory agencies.

[www.jctlm.org](http://www.jctlm.org) – The JCTLM is working with many global partners to reduce between-method variability. The production and adoption of reference materials, reference methods and the establishment of reference laboratories are drivers for accurate patient results.

**10:00 Introduction and aim of the meeting**

Mauro Panteghini

**MORNING SESSION: THE STATUS QUO**

Chair: Robert Wielgosz (BIPM)

10:30 Why CRP is one of the most requested test in hospital laboratories?

Mario Plebani (CCLM Editor)

11:00 CRP and clinical outcomes in patients with COVID-19

Elena Aloisio (L. Sacco Academic Hospital)

11:30 History and overview of WHO reference measurement system for CRP

Guy Auclair (JRC European Commission)

12:00 Current performance of CRP determination and derivation of quality specifications for its measurement uncertainty

Francesca Borillo (CIRME)

**12:30 Discussion****13:00 Lunch****AFTERNOON SESSION: FUTURE DEVELOPMENTS**

Chair: Milena Quaglia (London, UK)

14:00 A summary of NIM studies on CRP reference materials and the establishment of a new IVD traceability system

Li Hongmei (NIM)

14:30 Characterization of the new reference material JCCRM 612 and impact of its use on the CRP measurement in human serum

Violeta Raneva (ReCCS)

15:00 Development of NIST SRM 2924 and its potential role in a reference measurement system

Karen Phinney (NIST)

15:30 Discussion, Decisions, and Actions

Chair: Greg Miller (JCTLM Chair)

**CONFERENCE VENUE**

GRAND HOTEL VILLA TORRETTA

Via Milanese 3 – Sesto San Giovanni, Milano, Italy

**The participation is free of charge. However, the organisers are asking for a contribution for the lunch buffet:**  
**€ 70,00 + 22% VAT = € 85,40**

To make your online registration, please access the following link:  
<https://ems.mzevents.it/start/1954/eng>

**ORGANISING SECRETARIAT**  
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Supported by an unconditional grant by:

