

Comparability of Results in Laboratory Diagnostic

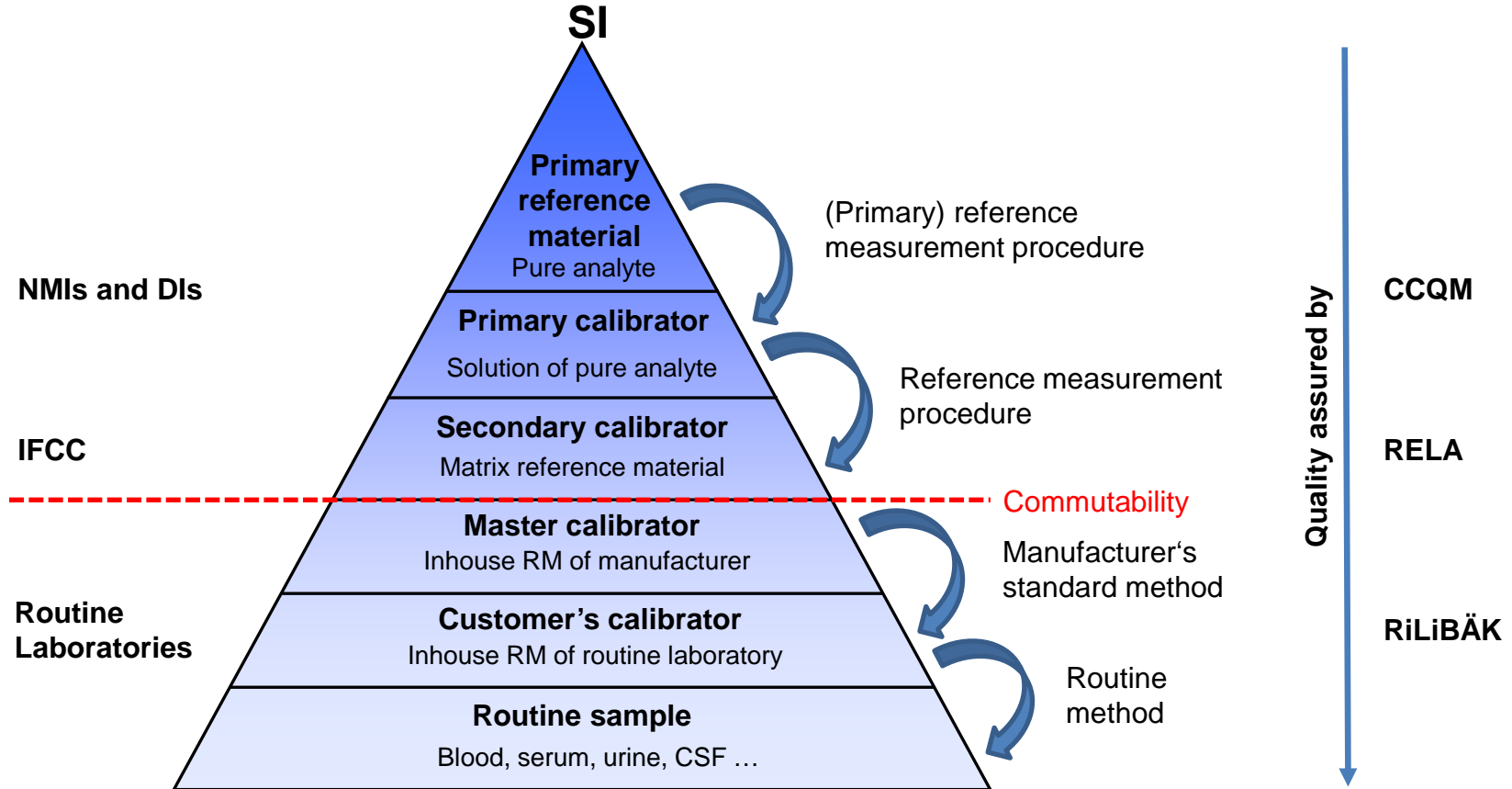
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Traceability chain



EMN Trace Lab Med



12 NMIs/DIs
9 Countries

TRACE LAB MED



EU IVDR (2017/746):
Demand for **metrological traceability**



International standards for medical laboratories:
Demand for **metrological traceability**



EU citizens: metrological traceability
for **patient safety** & public confidence



The EMPIR initiative is co-funded by the European Union's Horizon 2020 research and innovation programme and the EMPIR Participating States



EMN Trace Lab Med - Aims



Support for EU reference laboratories



Metrological traceability for *in vitro* diagnostics



Service-oriented European metrology infrastructure



Coordinated top-down research



Capacity building & knowledge transfer

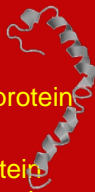
Contact: TraceLabMed@euramet.org

<https://www.euramet.org/laboratory-medicine/>

- 11.3 million new cases of cardiac diseases and 1.8 million deaths/year in the EU with estimated costs of €210 billion/year
- Large between-methods variability due to a lack of reference methods / traceability chains required by Regulation (EU) 2017/746
- Cardiac biomarkers challenging to quantify due to the low concentrations and complex biological matrix

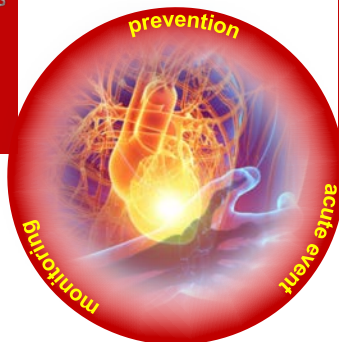
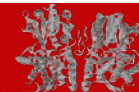
WP1: Biomarkers used in patient stratification and long-term CVD risk assessment

- Defining metrology needs for estimating risk
- Towards worldwide standardisation of apolipoprotein measurements
- Performance specification of advanced lipoprotein testing methods in CVD risk assessment and patient stratification



WP3: Biomarkers for acute and chronic heart failure

- Reference measurement procedure for NT-proBNP
- Application of reference measurement procedure for NT-proBNP to EQA schemes
- Understanding issues for 1-32 BNP measurements in clinics



WP2: Biomarkers for acute myocardial infarction

- Production of reference and spike material
- Development of a suitable quantification method
- Development of a biosensor for the quasi-continuous monitoring of biomarkers
- Method validation
- Application to patient samples



Impact

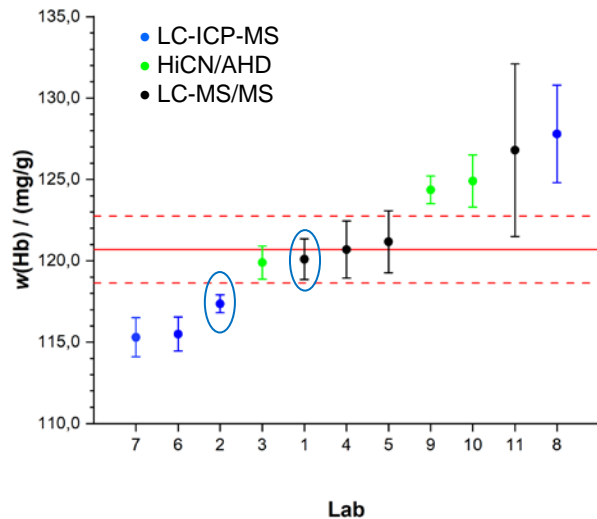
- Close exchange with international committees such as IFCC, JCTLM, EFLM and SFBC
- Cooperation with networks such as CRML and the EMN TLM
- Knowledge exchange with NIST
- Close cooperation with national EQA scheme providers
- Support accreditation through COFRAC

Consortium



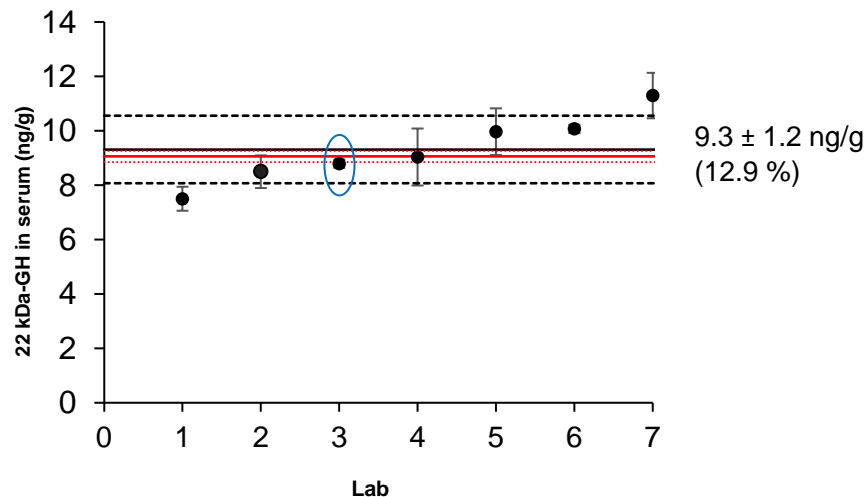
First CCQM comparison in matrix

Total hemoglobin in lyophilised blood
CCQM P201



median: (120.7 ± 2.1) mg/g

Human growth hormone in serum
CCQM P164



w_{grav} : 9.1 ± 0.2 ng/g

median: 8.92 ng/g

Thanks to

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WG Bioorganic Mass Spectrometry
Head of WG Bioorganic Mass Spectrometry

} Coordination of
P164

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