

Biennial activity report from JCTLM Member organizations

Organization:	Instand e.V.
JCTLM Member status:	stakeholder
Author(s):	Dr. Patricia Kaiser and Prof. Dr. Spannagl
Author(s) email(s):	Kaiser@instand-ev.de; spannagl@instand-ev.de
Period covered:	2022 – 2023

1. Major achievement(s) in support of standardization in laboratory medicine

Instand e.V is a worldwide active EQA scheme organizer. It has been appointed to be a reference institution for quality control in medical laboratories by the German Medical Association. In its own calibration laboratory Instand e.V. has established reference measurement procedures to set target values for EQA scheme evaluation fulfilling the requirements of the *Guideline of the German Medical Association on Quality Assurance in Medical Laboratory Testing*. The calibration laboratory is accredited according to DIN EN ISO/IEC 17025 and DIN EN ISO 15195, operating according to DIN EN ISO 15193. The scope of our accreditation covers 35 measurands (28 analytes) in the field of laboratory medicine.

Reference measurement services provided by the calibration laboratory of INSTAND e.V.

Analyte	Matrix	Reference	JCTLM database identification no.
Electrolytes			
Calcium	Plasma/Serum	Clin. Lab., 2013, 59, 1017-1029	C11RMP2
Chloride	Plasma/Serum	Clin. Lab., 2013, 59, 1017-1029	C11RMP3
Lithium	Plasma/Serum	Clin. Lab., 2013, 59, 1017-1029	C11RMP4
Magnesium	Plasma/Serum	Clin. Lab., 2013, 59, 1017-1029	C11RMP5
Potassium	Plasma/Serum	Clin. Lab., 2013, 59, 1017-1029	C11RMP6
Potassium	Urine	Clin. Lab., 2013, 59, 1017-1029	
Sodium	Plasma/Serum	Clin. Lab., 2013, 59, 1017-1029	C11RMP7
Sodium	Urine	Clin. Lab., 2013, 59, 1017-1029	
Enzymes			
ALT	Serum	Clin. Chem. Lab. Med., 2002, 40, 718-724	NRMeth 67
AST	Serum	Clin. Chem. Lab. Med., 2002, 40, 725-733	NRMeth 68
CK	Serum	Clin. Chem. Lab. Med., 2002, 40, 635-642	NRMeth 65
GGT	Serum	Clin. Chem. Lab. Med., 2002, 40, 734-738	NRMeth 69
LDH	Serum	Clin. Chem. Lab. Med., 2002, 40, 643-648	NRMeth 66

Metabolites and substrates			
Creatinine	Serum	Clin. Chem., 1993, 39, 1001-1006	NRMeth 1
		Clin. Chem., 1993, 39, 993-1000	
Creatinine	Urine	Clin. Chem., 1993, 39, 1001-1006	
		Clin. Chem., 1993, 39, 993-1000	
Glucose	Serum	Clin. Chem., 1993, 39, 1001-1006	NRMeth 4
		Clin. Chem., 1993, 39, 993-1000	
Glucose	Urine, CSF	Clin. Chem., 1993, 39, 1001-1006	
		Clin. Chem., 1993, 39, 993-1000	
total Cholesterol	Serum	Clin. Chem., 1993, 39, 1001-1006	NRMeth 2
		Clin. Chem., 1993, 39, 993-1000	
total Glycerol	Serum	Eur. J. Clin. Chem. Clin. Biochem., 1996, 34, 853-860	NRMeth 5
Urea	Serum	Clin. Chem., 1999, 45, 1523-1529	NRMeth 52
Urea	Urine	Clin. Chem., 1999, 45, 1523-1529	
Uric acid	Serum	Clin. Chem., 1993, 39, 1001-1006	NRMeth 3
		Clin. Chem., 1993, 39, 993-1000	
Uric acid	Urine	Clin. Chem., 1993, 39, 1001-1006 Clin. Chem., 1993, 39, 993-1000	
Non-peptide hormones			
Cortisol	Serum	Eur. J. Clin. Chem. Clin. Biochem., 1996, 34, 853-860	NRMeth 8
17 β -Estradiol	Serum	Clin. Chem., 1988, 34, 2066-2069	NRMeth 10
Progesterone	Serum	Anal. Chem., 1994, 66, 4116-4119	NRMeth 6
Testosterone	Serum	Anal. Chem., 1994, 66, 4116-4119	NRMeth 7
Thyroxine	Serum	Biol. Mass Spectrom., 1994, 23, 475-482	NRMeth 11
Drugs			
Digitoxin	Serum	Clin. Lab., 2006, 52, 37-42	C4RMP4
Digoxin	Serum	Clin. Lab., 2006, 52, 37-42	C4RMP5
Theophylline	Serum	Clin. Lab., 2002, 48, 535-540	C4RMP6
Proteines			
HbA1c	Whole blood	Clin. Chem., 2008, 54, 1018-22	C1RMP_P16_MS
total Protein	Serum	Clin. Chem., 1981, 27, 1642-1654	NRMeth 30
Hemoglobin	Whole blood	DIN 58931:2021-09	C17RMP1

2. Planned activity(ies) in support of standardization in laboratory medicine

For HbF we will be involved in the value assignment of newly developed certified reference material. In addition, we will take part in the EurA1c Trial for HbA1c.

3. Promoting traceability in laboratory medicine

The calibration laboratory of Instand e.V. is active in Working Groups of the IFCC for HbA2 (WG-HbA2), procalcitonin (WG-PCT), Commutability (WG-C) and HbF (WG-HbF). In addition, we are active member for many years in the IFCC Network on Standardisation of HbA1c. To further promote the concept of metrological traceability the calibration laboratory of Instand e.V. is involved in the EURAMET Project European Partnership on Metrology “COMET”.

Relevant publications from Instand e.V. on this topic:

Huynh HH, Bœuf A, Pfannkuche J, Schuetz P, Thelen M, Nordin G, van der Hagen E, Kaiser P, Kessler D, Badrick T, Poggi B, Tiikkainen U, Davies GJ, Kessler A, Plebani M, Vinh J, Delatour V; The IFCC WG-PCT members. (2021)

Harmonization status of procalcitonin measurements: what do comparison studies and EQA schemes tell us? *Clin Chem Lab Med.* 2021 Jun 21. doi: 10.1515/cclm-2021-0566.

Delatour V, Clouet-Foraison N, Jaisson S, Kaiser P, Gillery P (2020)

Beware of Noncommutability of External Quality Assessment Materials for Hemoglobin A 1c *Clin Chem* 2020;66(2):390-391 DOI: doi.org/10.1093/clinchem/hvz024

Denis Grote-Koska*, Rainer Klauke, Patricia Kaiser, Udo Kramer, Rainer Macdonald, Dietmar Lerche, Antje Staaden, Korbinian Brand and Gerhard Schumann (2020)

Total haemoglobin – a reference measuring system for improvement of standardization *Clinical Chem Lab Med* 2020;aop. DOI: doi.org/10.1515/cclm-2019-1177

Vincent Delatour, Noemie Clouet-Foraisona, Stephane Jaisson, Patricia Kaiser and Philippe Gillery

Trueness assessment of HbA1c routine assays: are processed EQA materials up to the job? *Clin Chem Lab Med* 2019;57:1623-31

The EurA1c Trial Group

EurA1c: the European HbA1c Trial to Investigate the Performance of HbA1c Assays in 2166 Laboratories across 17 Countries and 24 Manufacturers by Use of the IFCC Model For Quality Targets *Clinical Chemistry* 2018;64:1183-92

Cristian Gabriel Arsene, Patricia Kaiser, Renata Paleari, André Henrion, Michael Spannagl, Andrea Mosca, on behalf of the IFCC Working Group on Standardisation of Hemoglobin A2 (WG-HbA2)

Determination of HbA2 by quantitative bottom-up proteomics and isotope dilution mass spectrometry *Clinica Chimica Acta* 2018; 487:318-24

4. Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems

As calibration laboratory Instand e.V. participates annually in the international intercomparison studies of the RELA-IFCC surveys and the IFCC network campaigns for HbA1c. For further promotion of the standardization process in medical laboratory Instand e.V. is active in expert committees of the German Medical Association (BÄK), DIN, CEN and ISO.

5. Open questions and suggestions to be addressed by JCTLM

none