

## Draft template for biennial activity report from JCTLM Member organizations

All JCTLM Members are invited to attend the Members' and Stakeholders' Meeting, which is held once every two years, and submit a report of their activities in support of traceability in laboratory medicine over the preceding period.

For that purpose this template document provides guidance to JCTLM Members for drafting their biennial activity report. Organizations are invited to provide the information below for submission to the Executive Committee.

<b>Organization:</b>	<b>Instand e.V.</b>
<b>JCTLM Member status:</b>	<b>stakeholder</b>
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<b>Period covered:</b>	<b>2015 – 2017</b>

### 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 the 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 has been extended to 27 measurands.

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

Analyte	Matrix	Reference	JCTLM database identification no.
<b>Electrolytes</b>			
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
Sodium	Plasma/Serum	Clin. Lab., 2013, 59, 1017-1029	C11RMP7
<b>Enzymes</b>			
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

<b>Metabolites and substrates</b>			
Creatinine	Serum	Clin. Chem., 1993, 39, 1001-1006	NRMeth 1
		Clin. Chem., 1993, 39, 993-1000	
Glucose	Serum	Clin. Chem., 1993, 39, 1001-1006	NRMeth 4
		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
Uric acid	Serum	Clin. Chem., 1993, 39, 1001-1006	NRMeth 3
		Clin. Chem., 1993, 39, 993-1000	
<b>Non-peptide hormones</b>			
Cortisol	Serum	Eur. J. Clin. Chem. Clin. Biochem., 1996, 34, 853-860	NRMeth 8
17 $\beta$ -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
<b>Drugs</b>			
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
<b>Proteines</b>			
HbA1c	Whole blood	Clin. Chem., 2008, 54, 1018-22	C1RMP_P16_MS
total Protein	Serum	Clin. Chem., 1981, 27, 1642-1654	NRMeth 30

The calibration laboratory of Instand e.V. is active in Working Groups of the IFCC for HbA2 and HbA1c Standardization. In addition it cooperates with the Physikalisch-Technische Bundesanstalt (PTB) for the development of reference measurement procedures for HbA2 and hemoglobin. To further promote the concept of metrological traceability the calibration laboratory of Instand e.V. is involved in the EMPIR project 15HLT02 on biomarkers in the field of Alzheimer's disease.

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

As a further extension of our accreditation scope we plan to implement the reference measurement procedure for total hemoglobin based on the National Standard DIN 58931. For HbA2 we will be involved in the value assignment of a newly developed certified reference material.

## 3. Promoting traceability in laboratory medicine

Palermi R, Caruso D, Kaiser P, Arsene CG, Schaeffer-Reiss C, Van Dorsselaer A, Bissé E, Ospina M, De Jesús VR, Wild B, Mosca A on behalf of the IFCC Working Group on Standardisation of Hemoglobin A2 (WG-HbA2)

Developing a reference system for the IFCC standardization of HbA2  
Clin Chim Acta 467 (2017) 21–26

Kaiser P, Spannagl M, van Campenhout C, Lenga Y, Siebelder C, Weykamp C  
HbA1c: EQA in Germany, Belgium and the Netherlands using fresh whole blood samples with target values assigned with the IFCC reference system.  
Clin Lab Med 2016;54:1769-75

Brauckmann C, Frank C, Schulze D, Kaiser P, Stoscha R and Swart C  
Preparation and characterisation of an <sup>57</sup>Fe enriched haemoglobin spike material for species-specific isotope dilution mass spectrometry  
J. Anal. At. Spectrom., 2016,31, 1846-1857

Kaiser P, Peetz D, Spannagl M  
Qualitätssicherung in der Diabetologie  
Der Diabetologe 2016;12:1-4

#### **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

Note: The information of this report will be accessible publicly on the relevant JCTLM Members webpage, unless the author of the report states otherwise. In the case the organization does not authorize the publication of the report in part or full, the author will add a statement to clarify which part(s) of the report will /will not be rendered public.