



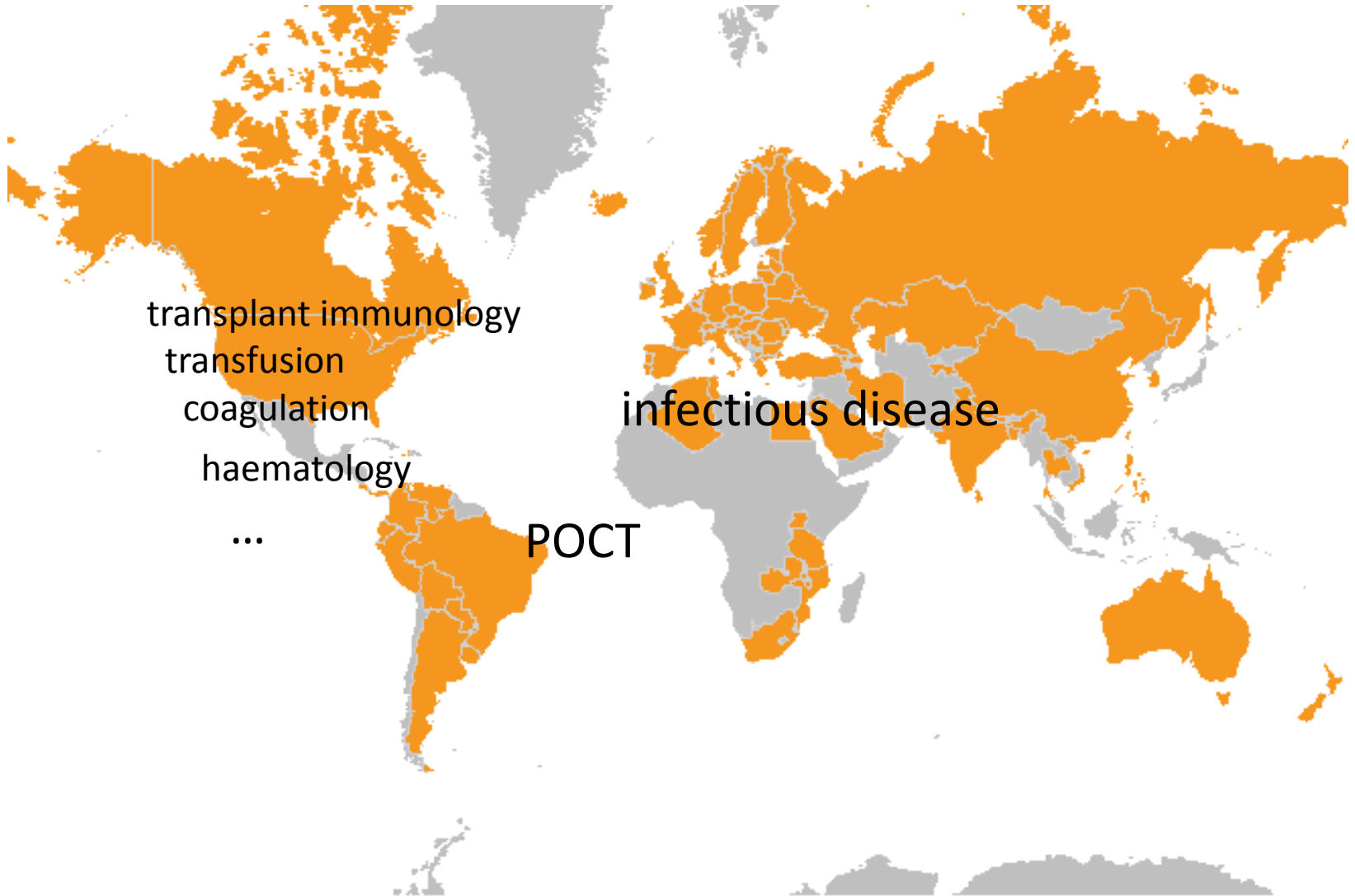
**INSTAND**<sub>e.V.</sub>

# JCTLM Member activities

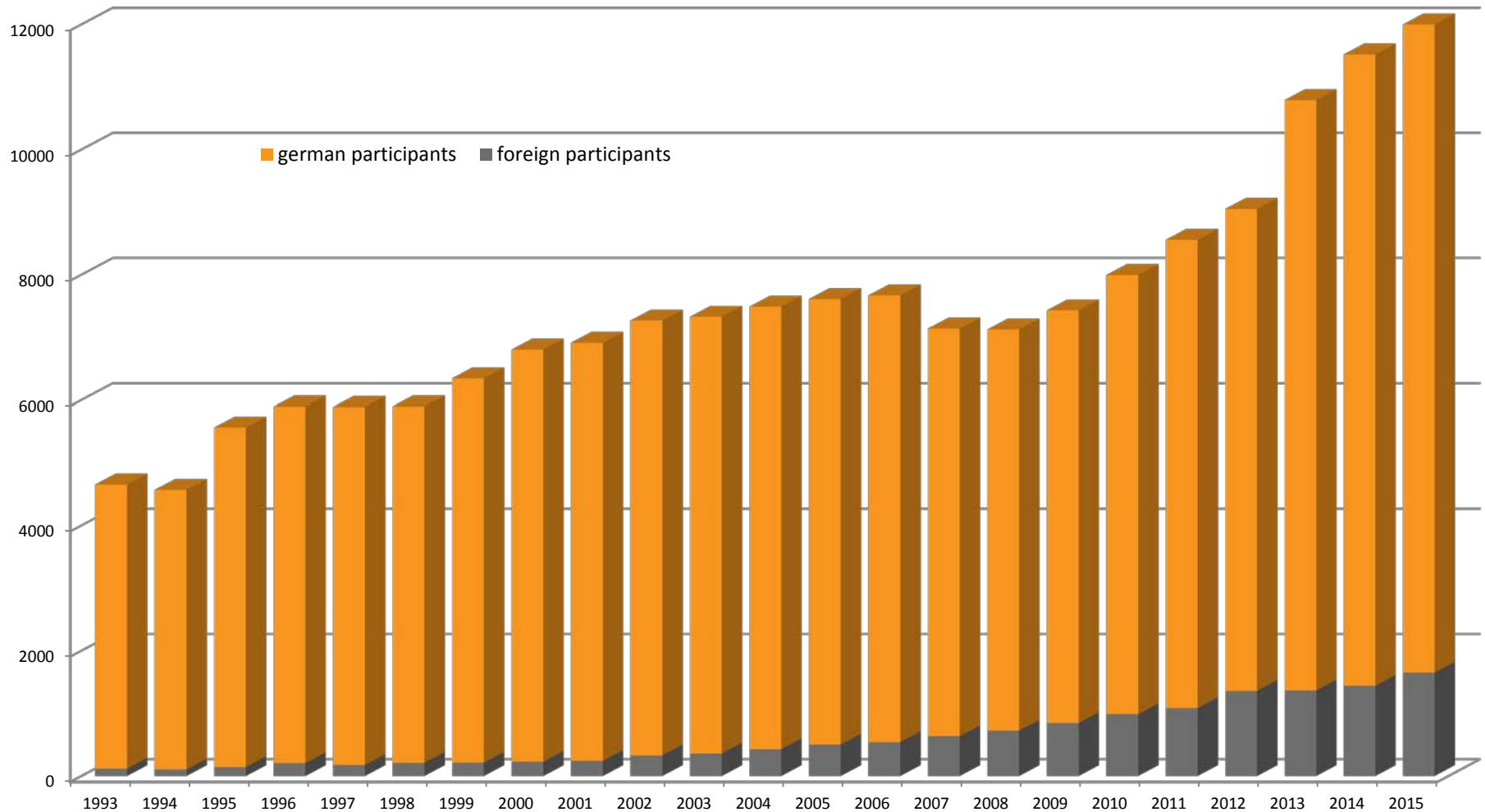
Prof. Dr. Michael Spannagl

Dr. Patricia Kaiser

# EQAS organizer worldwide



# Number of participants from 1993-2015



# RiliBÄK - Guideline of the German Medical Association on Quality Assurance in Medical Laboratory Testing



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# New Guideline for Quality Assurance of the German Medical Association (RiliBÄK)

-> mandatory for all medical laboratories in Germany

<b>Section A</b> <b>Fundamental requirements</b> for quality assurance	Effective since 1 April 2008 Update 2011
<b>Specific Section B 1</b> Quantitative analyses in laboratory medicine <i>- internal QA</i> <i>- external QA</i>	Effective since 1 April 2008
<b>Specific Section B 2</b> Qualitative analyses in laboratory medicine <i>- internal QA</i> <i>- external QA</i>	Effective since 1 July 2011
<b>Specific Section B 3</b> Direct detection and characterization of pathogens <i>- internal QA</i> <i>- external QA</i>	Effective: 1 June 2015
<b>Specific Section B 4</b> Analyses of ejaculate <i>- internal QA</i> <i>- external QA</i>	Effective since 1 July 2011
<b>Specific Section B 5</b> Molecular- and cytogenetic analyses <i>- internal QA</i> <i>- external QA</i>	Effective since 1 October 2011

reimbursement

# New Guideline for Quality Assurance of the German Medical Association (RiliBÄK)

-> mandatory for all medical laboratories in Germany

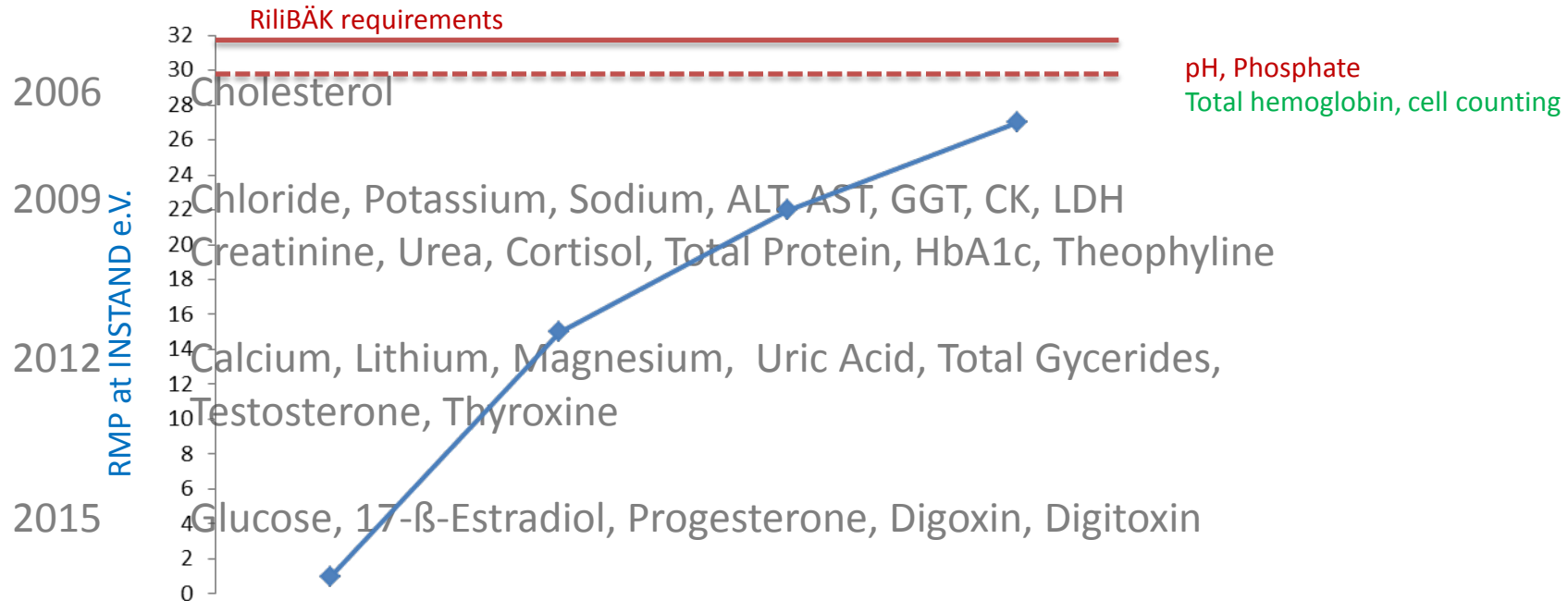
(extract from annex B1)

1 No.	2 Analyte	3 Acceptable relative deviation of the single value or the relative root mean square	4 Range of validity of columns 3 to 5			5 Acceptable relative deviation in a round robin test	6 Type of target value in a round robin test
			From	To	Unit		
19	Digoxin	14.0% 17.5%	> 1 0.5	5 ≤ 1	µg/l µg/l	30.0%	RMV
20	Erythrocytes	4.0%	1.5	7	10 <sup>12</sup> /l	8.0%	RMV
21	Estradiol 17-beta	22.0%	10 37	500 1835	ng/l pmol/l	35.0%	RMV
22	Ethanol (clinical toxicology)	9.0%	> 0.6	5	g/l	12.0%	SV
		15.0%	0.2	≤ 0.6	g/l	21.0%	
23	Ferritin	13.5%	10	600	µg/l	25.0%	SV
24	FSH	14%	4	70	U/l	21.0%	SV
25	Gamma glutamyl transferase (γ-GT) EC 2.3.2.2	11.5%	20 0.33	300 5	U/l µkat/l	21.0%	RMV
26	Glucose	11.0%	40 2.2	400 22	mg/dl mmol/l	15.0%	RMV
27	Haematocrit	5.0%	10 0.1	60 0.6	% l/l	9.0%	SV
28	Haemoglobin	4.0%	2 1.2	20 12.4	g/dl mmol/l	6.0%	RMV
29	Haemoglobin A 1 c (HbA1 c)	10.0%	30	140	mmol/mol Hb	18.0%	RMV
30	Uric acid	7.0%	2	13	mg/dl	13.0%	RMV

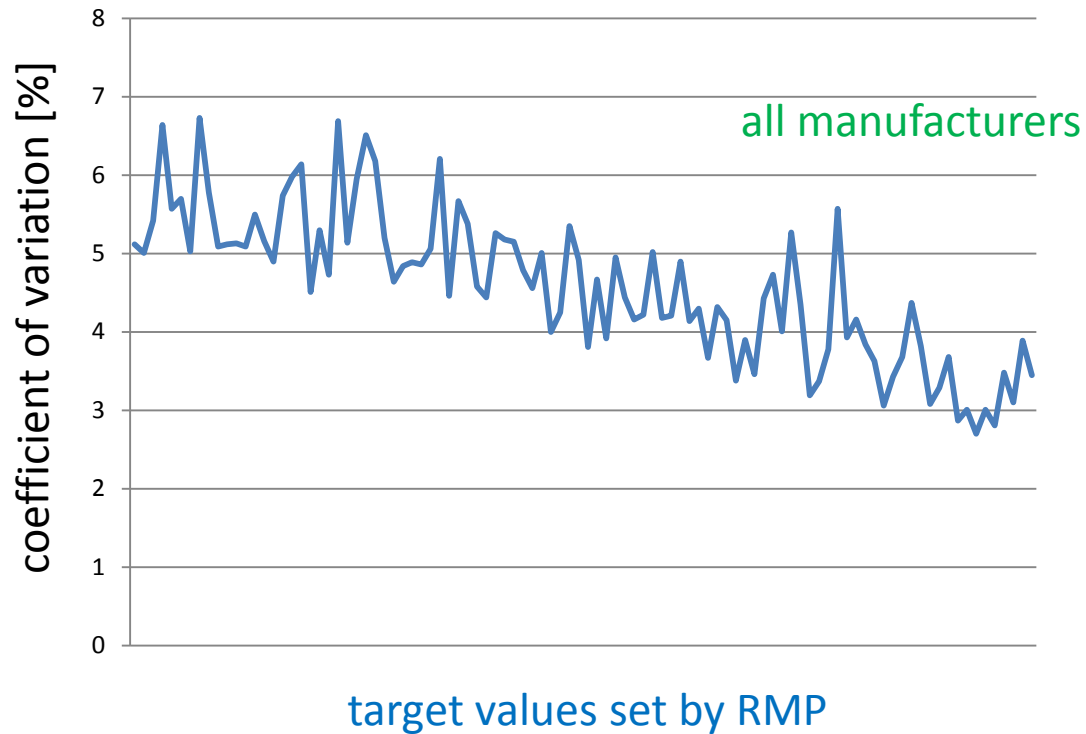


# Reference laboratory

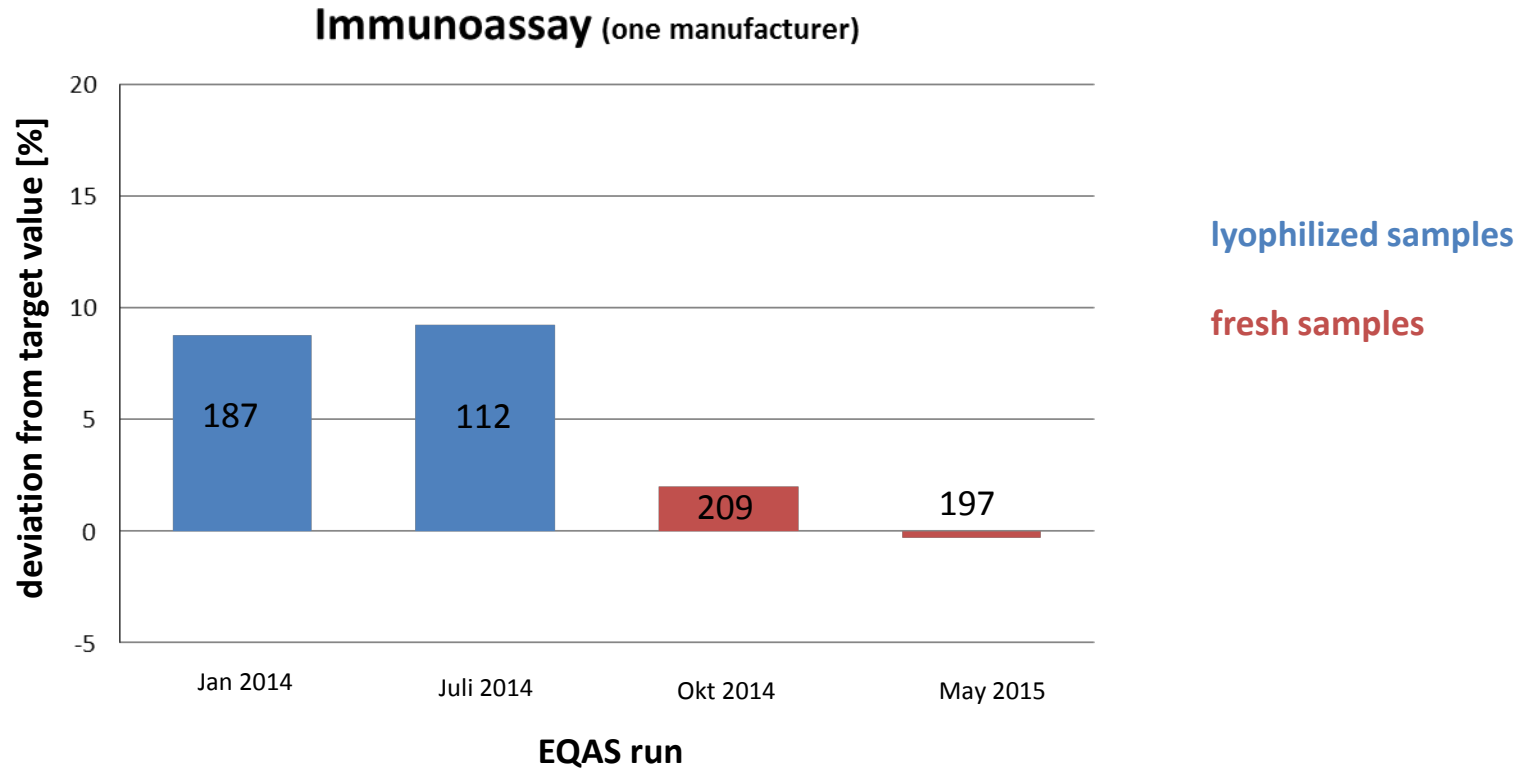
Accredited as calibration laboratory according to ISO 17025 and ISO 15195



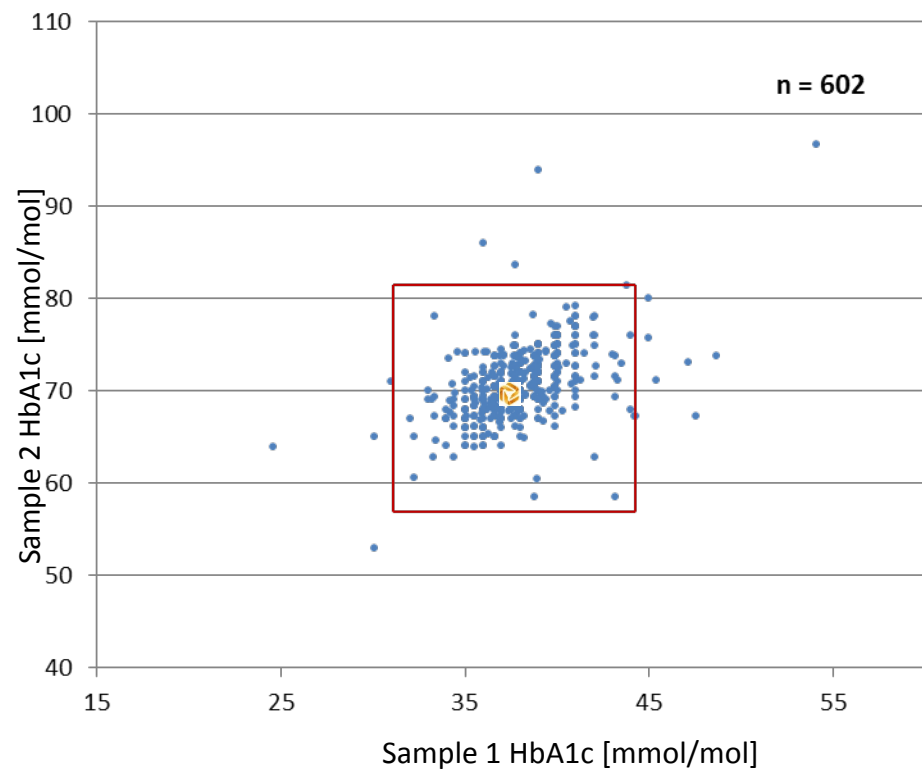
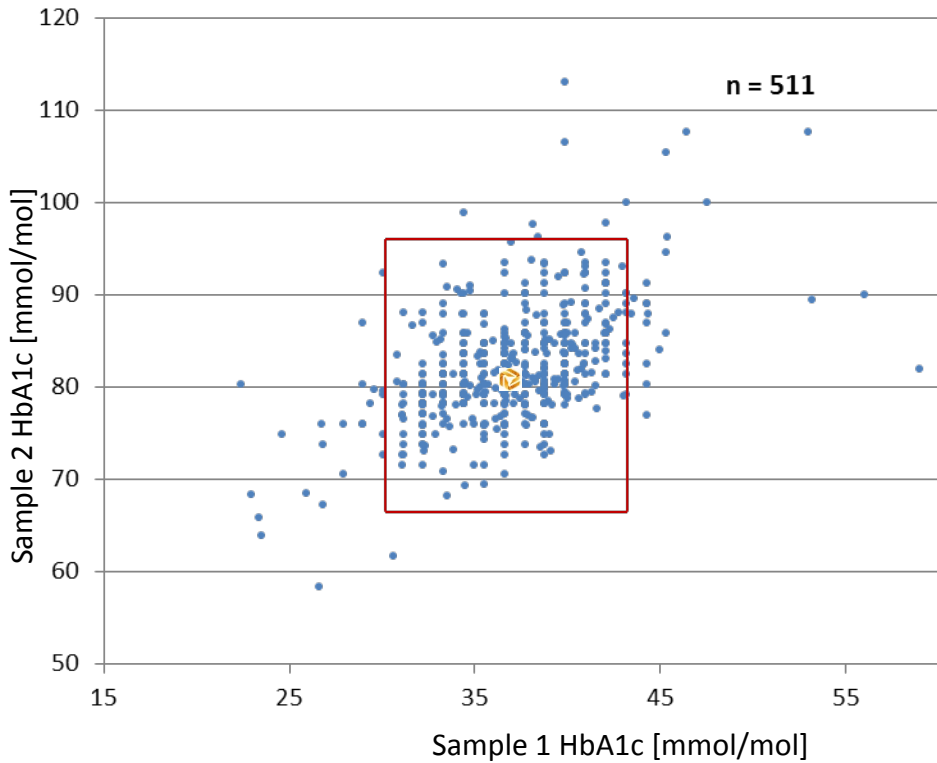
# Interlaboratory CV Glucose EQAS results 2002 - 2015



# Deviation from target value EQAS for HbA1c with lyophilized and fresh whole blood samples



# HbA1c EQAS results



acceptability range  $\pm 18\%$  from target value

January 2009  
lyophilized samples

May 2015  
fresh blood samples

## Participation in intercomparison studies

**RELA – IFCC  
ring trials**

**IFCC HbA<sub>1c</sub>  
Network Laboratories  
campaigns**

## Further activities

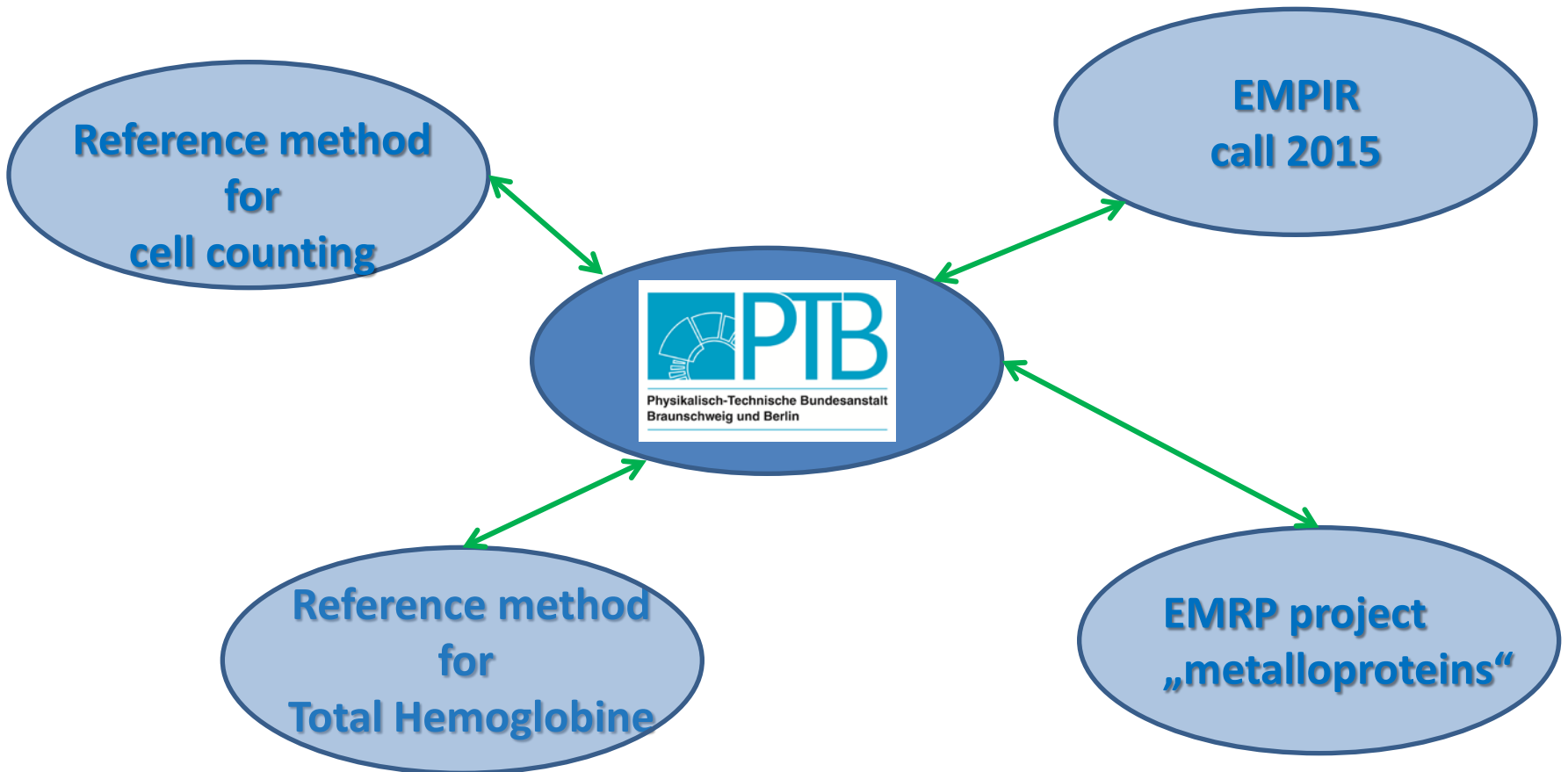
**IFCC Working Groups**

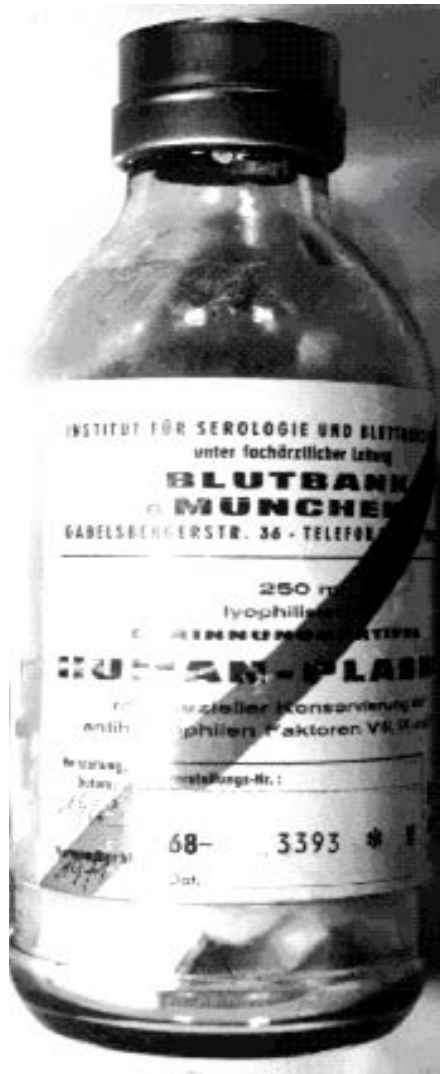
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graph TD; A[IFCC Working Groups] --> B(WG on HbA2 standardisation); A --> C(Communtability)
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**WG on HbA<sub>2</sub> standardisation**

**Communtability**

## Further activities





## Coagulation factor VIII Replacement therapy 1950 - 2015



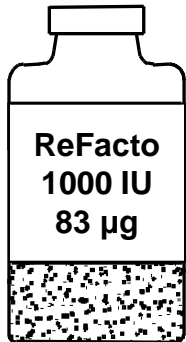


# ReFacto AF vs. Xyntha

previous ReFacto

Worldwide

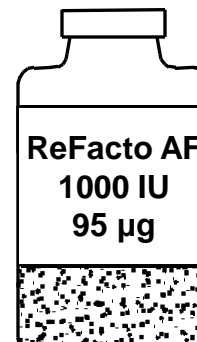
CS Assay WHO 6. IS



Xyntha/ReFacto AF

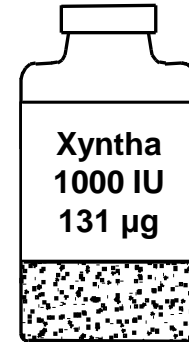
Europe

CS Assay WHO 7. IS



USA/Canada

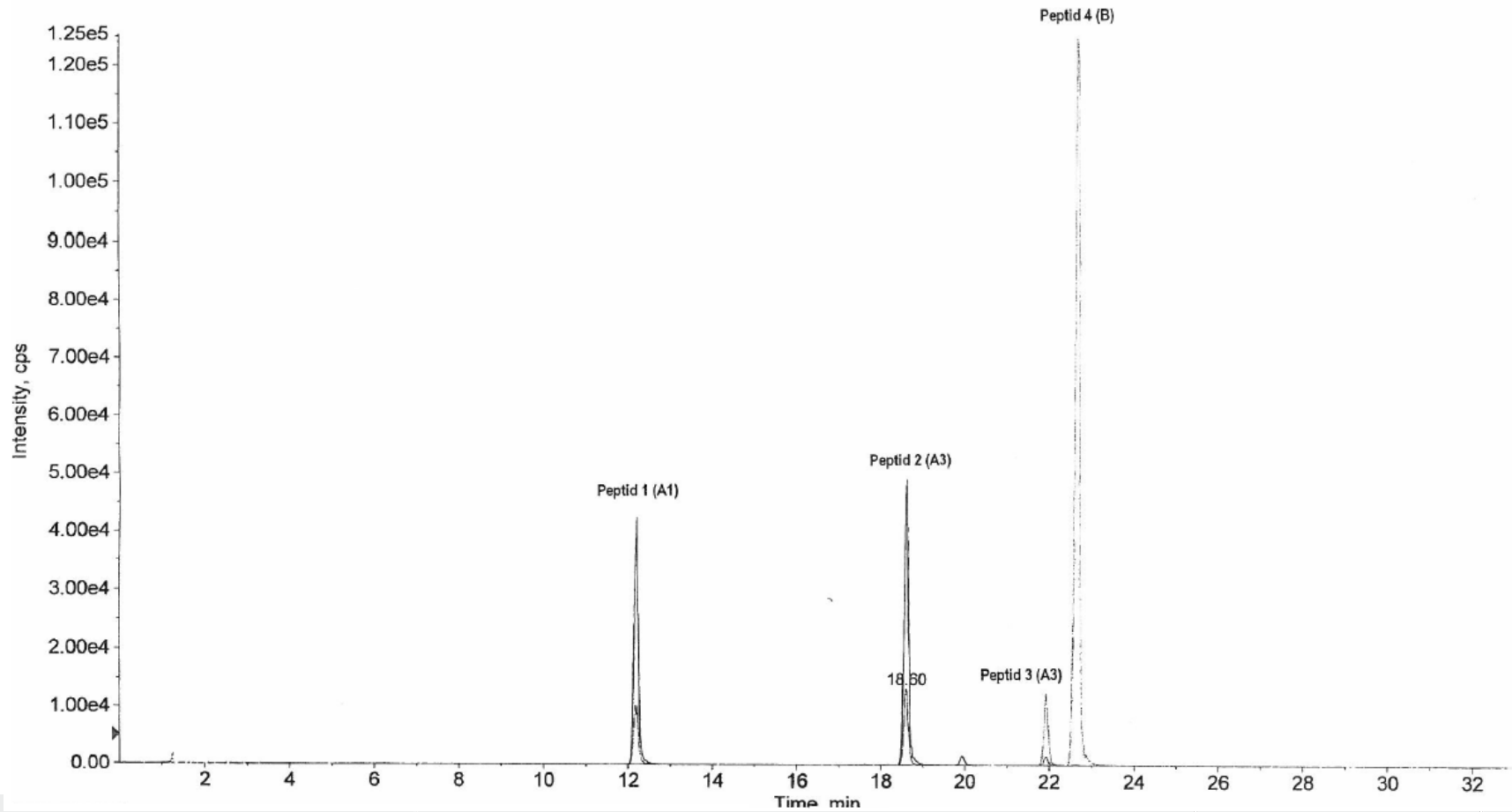
OS Assay WHO 7. IS



## LC-MS/MS chromatogram of recomb. FVIII after tryptic digestion

XIC of +MKM (8 pairs): 372.1/333.2 amu from Sample B

Max. 1.3e4 cps.



# Perspectives

- High quality reference materials
- Commutability
- To convince the „real world“ of the traceability concept

**Thank you for your attention**