

Promotion of the concept of Traceability in Latin America

Lothar Siekmann



**Medical Faculty
University of Bonn**

Institute of Clinical Chemistry
and Pharmacology



Reference-Institute of Bioanalytics

German Society of Clinical Chemistry and
Laboratory Medicine

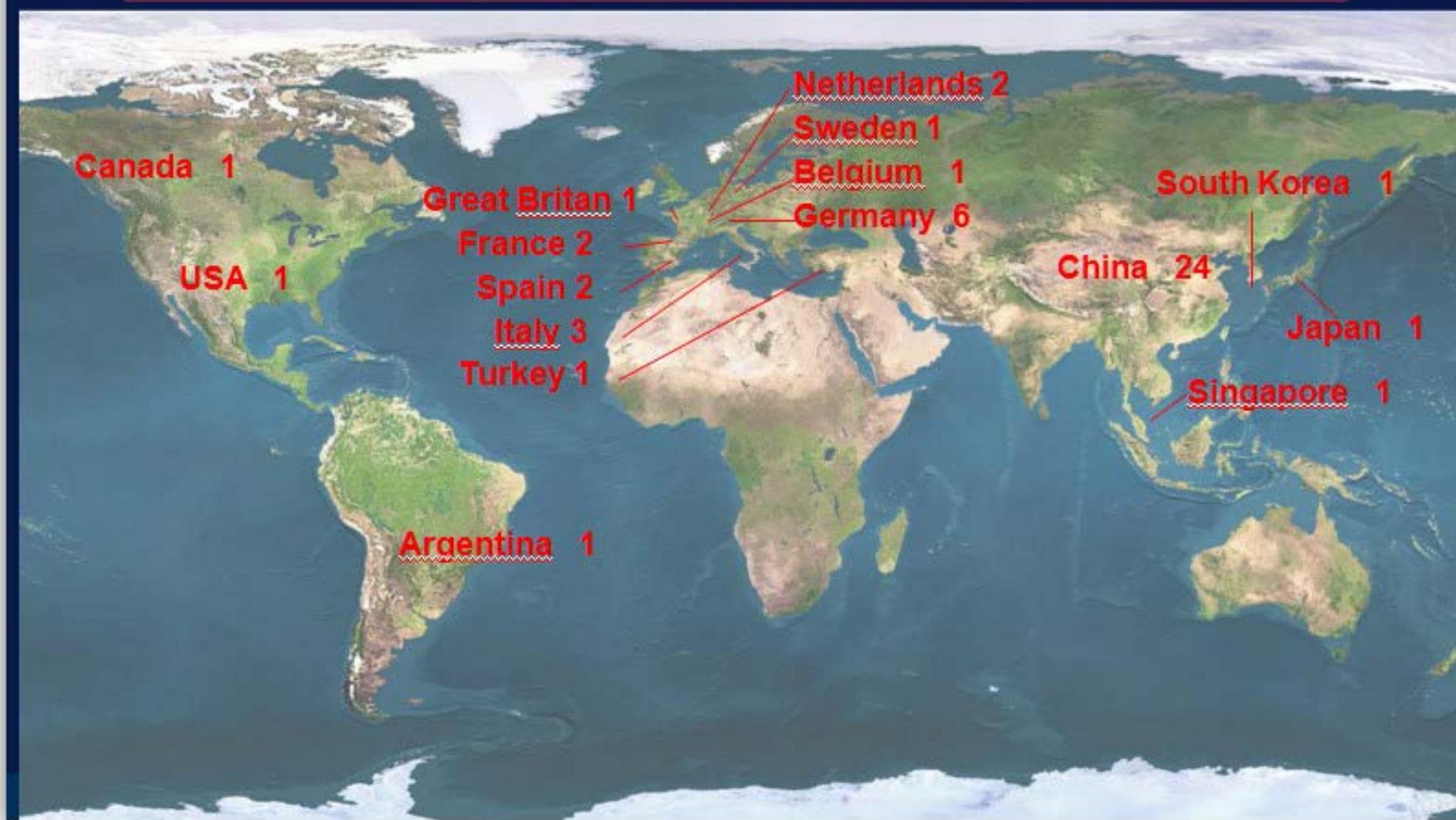
Global Implementation of the Concept of Traceability

becomes visible

- from the number of JCTLM-listed reference measurement services (Reference/Calibration laboratories),
- from the number of laboratories participating in EQAS for Reference/Calibration Laboratories (RELA).

Global Implementation of the Concept of Traceability

RELA – Participants





Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin



COLABIOCLI Symposium and Workshop

Implementation of the Concept of Traceability in Clinical Laboratories in Latin America

September 25th-26th, 2015 - Quito, Ecuador

1. Objectives:

- **Cooperation between the**
 - **Societies of Clinical Laboratories** and the actors of the Quality Infrastructure (QI), mainly focused to the
 - **National Metrology Institutes (NMIs)** and the
 - **National Accreditation Bodies (NABs);**
- **Overview of activities in which these actors could work together .**

2. Target Groups:

- Representatives from Societies of Clinical Laboratories from Latin America
- Representatives from National Metrology Institutes (NMIs) of the region
- Representatives from National Accreditation Bodies (NABs)

•Workshop “Implementation of the Concept of Traceability in Clinical Laboratories in Latin America” September 25th - 26th , 2015 - Quito, Ecuador List of participants

Surname	Name	Country	Institution	E-Mail
Acuña	Maria Amelia	Argentina	OAA	macuna@oaa.org.ar
Adams	Paula	Jamaica	JANAAC	paula.adams@janaac.gov.jm
Aguirre	Leonardo	Chile	Sociedad Chilena de Química Clínica	leonardoaguirre@mt@gmail.com
Anetor	John	Nigeria	C-TLM - IFCC	johnanetor@gmail.com
Barrantes	Mauro	Costa Rica	UCR	mauro.barrantes@ucr.ac.cr
Chavarro Medina	Luis Alf redo	Colombia	IN M de Colombia	lchavarro@inm.gov.co
Espinosa Ortiz	Edgar Antonio	Ecuador	INSPI	eespinoza@inspi.gob.ec
Gatti	Patricia Alejandra	Argentina	INTI	pagatti@inti.gob.ar
Girardi	Raul	Argentina	FBA	raul.girardi@fba.org.ar
Gomez	René	Chile	ISPCH	rgomez@ispch.cl
Gómez	Jeremias	Colombia	ONAC	jeremias.gomez@onac.org.com
Herrera	Cristina	Chile	INN	cristina.herrera@inn.cl
Jaramillo	Elena	Ecuador	Comité técnico SAE ASEDIM	ejaramillo@simedcorp.com
Kessler	Anja	Germany	RFB - IFCC	akessler@uni-bonn.de
Kruip	Anna	Germany	PTB	anna.kruip@ptb.de
Ormaza	Guadalupe	Ecuador	Comité técnico SAE	gormazaz@hotmail.com
Ortellado- Canese	Juana	Paraguay	Asociación de Bioquímicos del Paraguay	juanaortelladopy@gmail.com
Perez Urquiza	Melina	Mexico	CENAM	meperez@cenam.mx
Piana Ciurlanti	Ana Maria	Uruguay	ABU	anapiana23@gmail.com
Quintana	Sandra	Mexico	ema	bioclin@icloud.com
Regalado de Solano	Wendy Xiomara	El Salvador	OSA	wregalado@osa.gob.sv
Rodriguez	Cristina	Ecuador	Comité técnico SAE	crodriguez@acreditacion.gob.ec
Sáenz	Kléver	Ecuador	Comité técnico SAE	kleber.saenz@netlab.com.ec
Salas	Yolanda	Ecuador	INEN	ysalas@normalizacion.gob.ec
Schumann	Gerhard	Germany	MHH - IFCC	gerhard.schumann@geord.net
Siekmann	Lothar	Germany	UKB - IFCC	lotha.r.siekma@nbn.u-kb.uni-bonn.de
Sierra Amor	Rosa	Mexico	CMCLC - IFCC	rosa.sierra.amor@prodigy.net.mx
Silva Terra	Ana Inés	Uruguay	LATU	asilva@latu.org.uy
Ureña	Marietta	Costa Rica	ECA	m.urena@eca.or.cr
Vasco	Evelyn	Ecuador	INEN	evasco@normalizacion.gob.ec
Vivanco Díaz	Fernando	Ecuador	SAE	jvivanco@acreditacion.gob.ec
Weykamp	Cas	Netherlands	Queen Beatrix Hospital-IFCC	c.w.weykamp@skbwinterswijk.nl
Wollinger	Wagner	Brazil	IN METRO	wwollinger@inmetro.gov.br
Zuta Chong	Imilce	Peru	PTB	imilcezuta@gmail.com

Countries from Latin America

- represented at the Symposium and Workshop -

Argentina
Brasil
Chile
Costa Rica
Columbia
Ecuador

El Salvador
Jamaica
Mexico
Paraguay
Peru
Uruguay

Friday, 25th September 2015

Time	Activity	Experts / Facilitator
SIMPOSIUM: Traceability		
<i>Hotel Marriott Quito, Salón Amazonas- A Chair: Raúl Girardi</i>		
10h45 - 11h15	The Concept of Traceability in laboratory medicine El concepto de trazabilidad en la medicina de laboratorio,	Lothar Siekmann Germany
11:00 - 11:45	Reference methodology for catalytic concentration measurements Metodología de referencia para las mediciones de concentración catalíticos	Gerhard Schumann, Germany
11:45 - 12:15	Traceability of HbA1c Trazabilidad de HbA1c	Cas Weykamp, The Netherlands
12:15 - 12:45	Proficiency testing of Reference Laboratories in Laboratory Medicine Pruebas de competencia de Laboratorios de Referencia en Medicina de Laboratorio	Anja Kessler, Germany

Friday, 25th September 2015

Time	Activity	Experts / Facilitator
Workshop: Implementation of the Concept of Traceability in Clinical Laboratories in Latin America		
14:00 – 14:50	Introduction Short initial Presentations	Imilce Zuta, Chile Representatives of Clinical Societies from LA
14:50 -16:00	The Concept of Traceability - Discussion Traceability in External Quality Assessment	Lothar Siekmann, Germany Lothar Siekmann, Germany
16:20 - 17:30	IFCC Reference Procedures for Enzymes Useful advice and calculation of measurement uncertainties	Gerhard Schumann, Germany
17:30 - 18:45	Requirements for Calibration/Reference Laboratories – Accreditation according to ISO 15195 & ISO 17025	Anja Kessler, Germany

Saturday, 26th September 2015

Time	Activity	Experts / Facilitator
Workshop: Implementation of the Concept of Traceability in Clinical Laboratories in Latin America		
09:00 – 09:10	Comments, questions with respect to the first day	
09:10 – 11:00	Potential and Planned joint activities between the NMI and the National Society of Clinical Laboratories in Argentina How the traceability concept for clinical laboratories is currently faced in the country ? Mexico Costa Rica Chile	Raoul Girardi Patricia Gatti Sandra Quintana Mauro Barrantes Leonardo Aguire
11:30 – 13:00	Role of NMIs: A general overview of the dissemination of traceability for the calibration laboratories INTI – Argentina INMETRO – Brazil CENAM – Mexico LATU – Uruguay	Patricia Gatti Wagner Wollinger Melina Perez Ana Ines Silva Terra

Saturday, 26th September 2015

Time	Activity	Experts / Facilitator
Workshop: Implementation of the Concept of Traceability in Clinical Laboratories in Latin America		

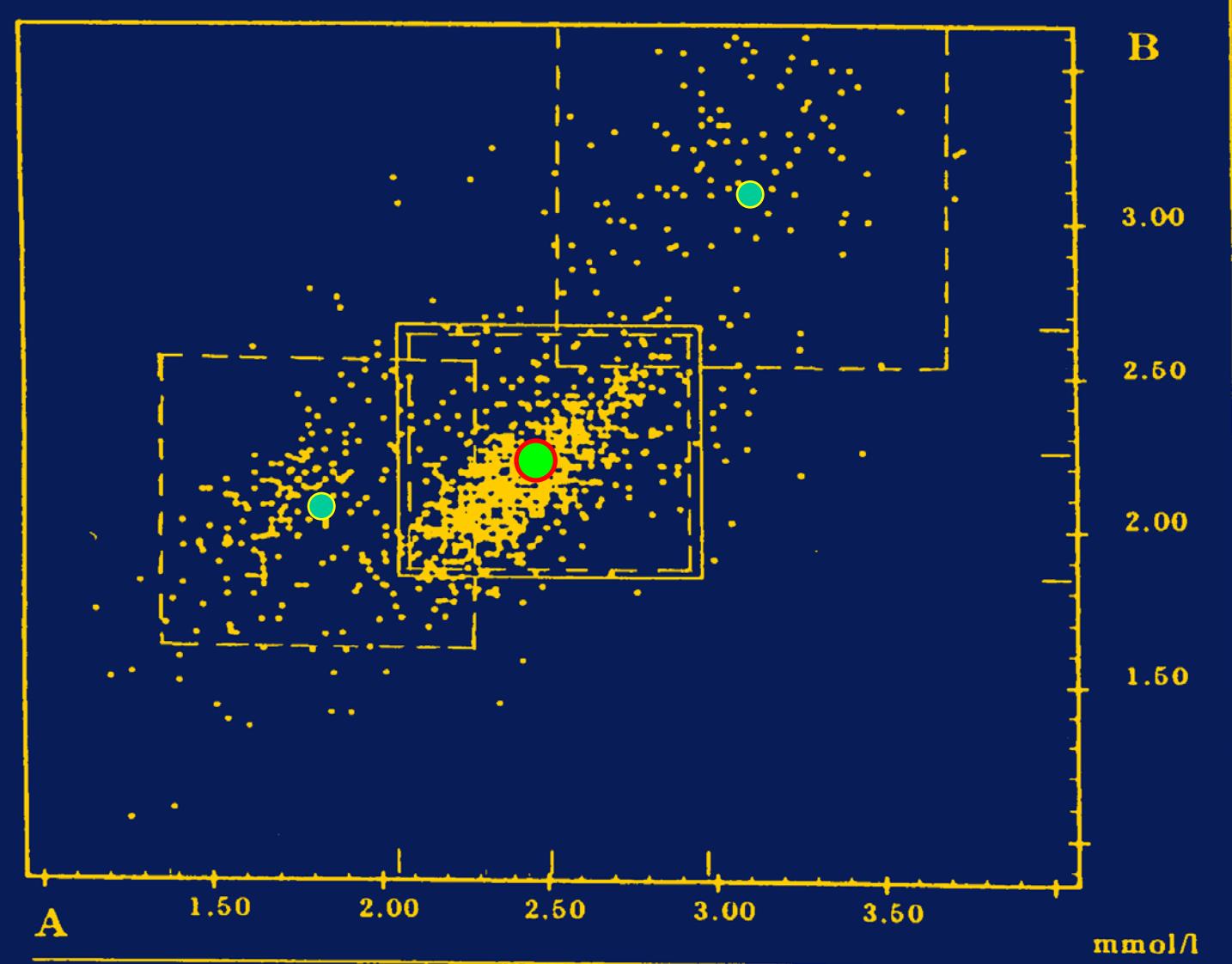
14:15 – 15:30	Role of the Reference Laboratory (Calibration Laboratory) Argentina Uruguay Chile	Raoul Girardi Ana Piana Rene Gomez
15:30 – 16:05	ISO 17511 - category classification – Experience of Columbia	Jeremiaz Gomez
16:35 – 17:45	Discussion – Next Steps	Imilce Zuta

EQA Survey 1987

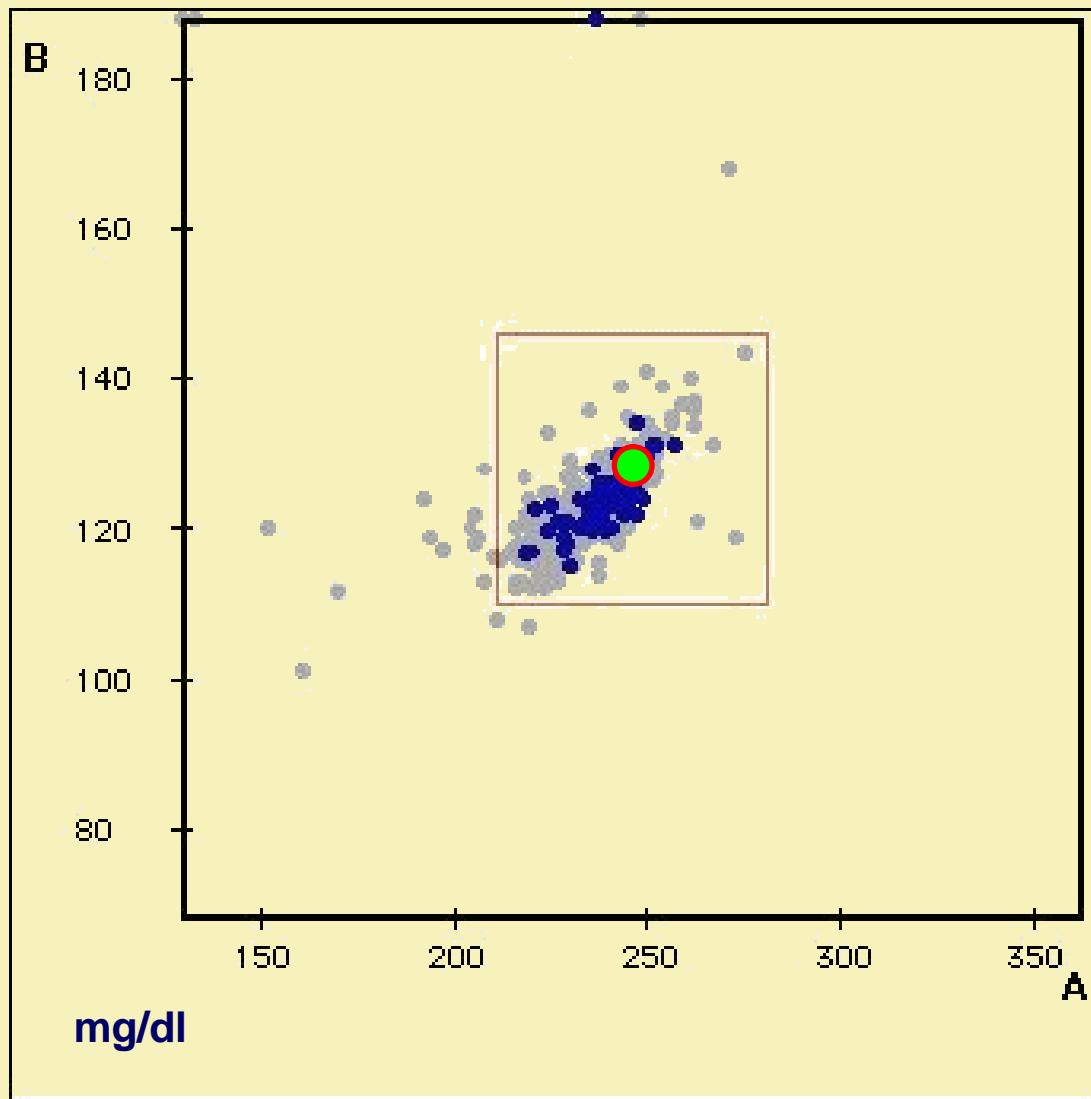
Analyt
Cholesterin

Methode
Alle Methoden

Erfolgsquote 68.6%



Cholesterol in Human Serum - DGKL-EQAS 03 - 07



Method: CHOD-PAP

Manufacturer: Kit - 38
Participants: 99 (680)

Recommendations

- based on experiences in Germany -
- Each clinical chemistry laboratory must participate in External Quality Assessment regularly (at least four times per year).
- Whenever available traceable target values assigned by accredited (ISO 17025 & 15195) reference / calibration laboratories shall be used for evaluation of participant's results.
- NMIs should influence legal authorities in their countries to establish appropriate EQA systems.