JCTLM
Accurate results for patient care

The commutability assessment of EQA materials and certified reference materials for HbA_{1c}

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2019/12/02 Sèvres, France

Disclosures

- Two analytical systems evaluated in this study, Mindray H50、Runda MQ-6000 were kindly provided by the manufacturers and temporarily equipped in NCCL. They were returned to the Manufacturers after the study was done. The manufacturers have no influence on the study.

- All reagents, calibrators and QA materials evaluated in this study were purchased from official agents by NCCL independently.

- No other relevant financial or nonfinancial relationships to disclose.

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About NCCL

" **NCCL** is a bit like CLIA, CAP, and CLSI rolled into one. They regulate. They conduct the National EQA/PT surveys. They also publish guidelines and recommendations for laboratory best practices."

—— The Westgard Rules blog, October 23, 2019

The Westgard Rules

October 23, 2019

Thanks, NCCL!

Posted by Sten Westgard, MS

Thrilled to visit NCCL in Beijing today, especially Dr Zhiguo Wang (pictured with book), who has been a tireless champion of quality for decades. NCCL is a bit like CLIA, CAP, and CLSI rolled into one. They regulate. They conduct the National EQA / PT surveys. They also publish guidelines and recommendations for laboratory best practices. NCCL recently recommended that labs adopt the Westgard sigma metric tools for QC optimization. The NCCL EQA / PT survey is also presenting results back to participants with method decision charts. It's an act of leadership we're happy to see and support.

https://james.westgard.com/the_westgard_rules/2019/10/thanks-nccl.htmlOctober 23, 2019

国家卫生健康委临床检验中心
National Center for Clinical laboratories

About NCCL

- **History**

  Established by the Ministry of Health (National Health commission, now), P.R. China on January 20th, 1982.

- **Mission**

  to control and improve the quality of clinical laboratory testing through evaluation, investigation and management.

- **Function**

  National Center for Laboratory Medicine Quality Management and Control

  National Center for Newborn Screening Quality Management and Control

  Chinese Hospital Association, branch of Clinical Laboratory (secretariat)

  Clinical Laboratory Standards Committee (secretariat)

  Beijing Engineering Research Center of Laboratory Medicine

NCCL's Activities

- **National external quality assessment programs in Laboratory Medicine**

121 programs , over 6000 participating laboratories throughout China

Total number of participating laboratories×programs in 2019: 85,176

国家卫生健康委临床检验中心
National Center for Clinical laboratories

NCCL's Activities

- **Reference system development and implementation**

  developing reference measurement procedure and reference material

  organizing the External Quality Assessment for Reference Laboratories "EQARL"

  promoting standardization and harmonization programs in China

- **Researches and investigations on quality issues in Laboratory Medicine**

RMP performed in NCCL

Lipids and lipoproteins

Cholesterol: CDC cholesterol Abell-Kendall method
Cholesterol: HPLC
Cholesterol: ID GC-MS, ID LC-MS/MS
Triglyceride: HPLC
Triglyceride: ID GC-MS, ID LC-MS/MS
HDLC, LDLC: CDC ultracentrifugation method
HDLC, LDLC: Ultracentrifugation-HPLC

Metabolites

Glucose: ID GC-MS, ID LC-MS/MS
Creatinine: ID LC-MS/MS
Uric acid: ID LC-MS/MS
Urea: ID GC-MS
Bilirubin: spectrophotometry

Electrolytes

Sodium: ICP/MS
Potassium: ICP/MS
Magnesium: ICP/MS
Calcium: ICP/MS

Non-peptide Hormone

Progesterone: ID GC-MS, ID LC-MS/MS
Testosterone: ID GC-MS, ID LC-MS/MS
T4: ID LC-MS/MS
Cortisol: ID LC-MS/MS
17β-Estradiol: ID LC-MS/MS

Enzymes, IFCC 37℃ RMP

AST
ALT
AP
AMY
CK
LDH
GGT

Protein

Total protein : spectrophotometry
HbA1c: IFCC HPLC/LC-MS/MS

NCCL's Certified reference materials

- **Legal Background**

  Approved by General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ)

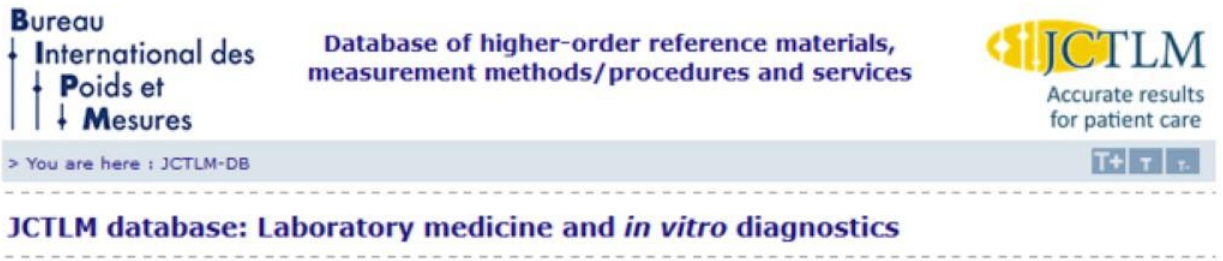
  Executive committee: National administrative committee for CRM

- **Technical specification**

  ISO Guide 35:2006 Reference materials -- General and statistical principles for certification

  JJG1006-1994 Technical regulation of Certified reference materials, China

JCTLM-listed RMPs, CRMs and services nominated by NCCL



- **RMP**

  Sodium: ICP/MS

  Potassium: ICP/MS

  Magnesium: ICP/MS

  Calcium: ICP/MS

  Cholesterol: HPLC, ID LC-MS/MS

  Glucose: ID GC-MS, ID LC-MS/MS

- **CRM**

  Glycated Hemoglobin in Human Hemolysate Buffer: GBW 09181a, 09182a and 09183a

- **Services**

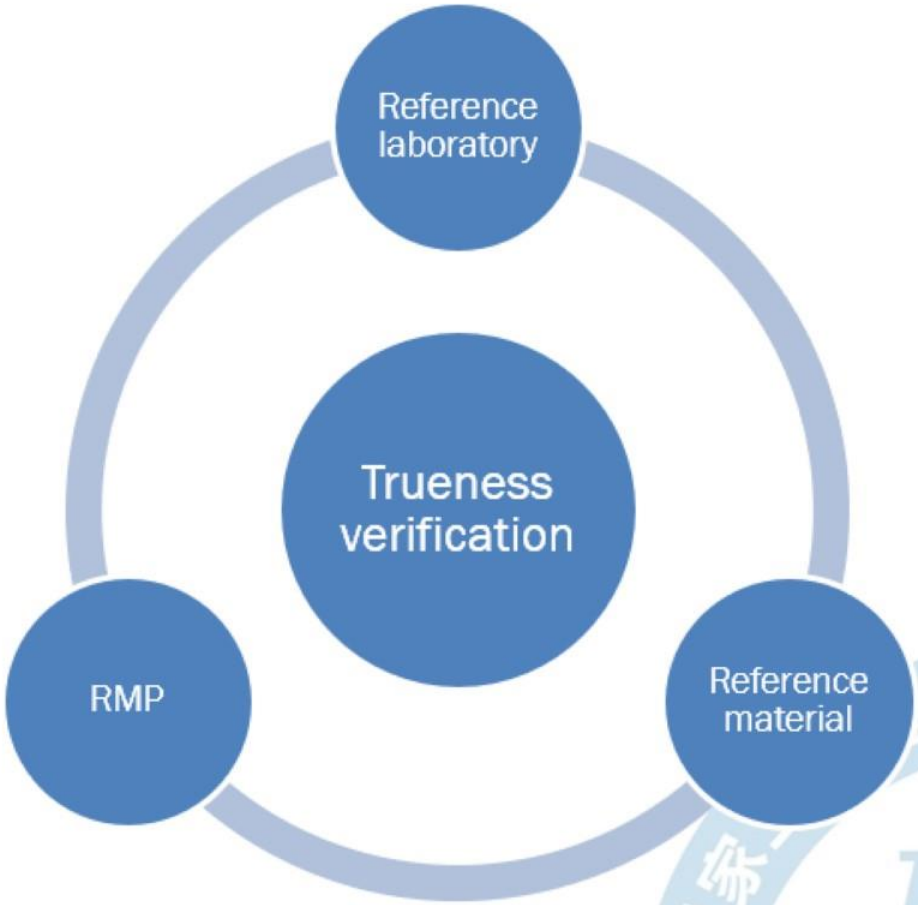
  Metabolites: Urea, Uric acid, Creatinine, cholesterol

  Protein: HbA1c

  Non-peptide hormone: Progesterone

  Enzyme: ALT, CK

The base of National Trueness verification pr



NCCL's Activities

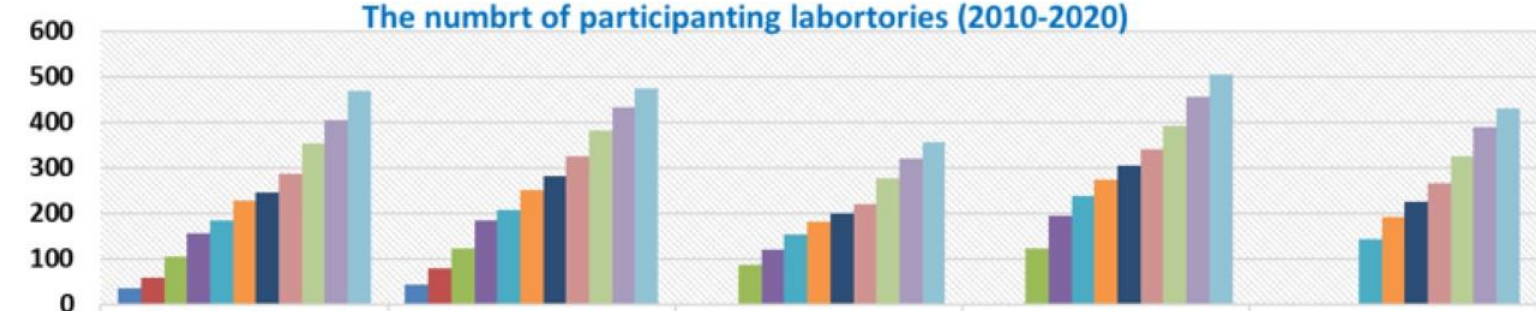
- **NCCL initiated the first accuracy-based EQA survey for laboratory medicine in China in 2010.**

"National trueness verification programs"

"Category I" EQA

Currently available for 30 analytes

The total number of participating laboratories: 2331 in 2020



	Metabolites and proteins	Lipdis	HbA1c	Enzyme	Electrolytes
2010	36	43			
2011	59	78			
2012	104	122	87	123	
2013	156	183	120	195	
2014	184	208	152	237	142
2015	228	250	182	273	192
2016	245	281	200	304	224
2017	286	324	221	340	267
2018	354	381	276	393	324
2019	404	432	321	455	389
2020	468	473	357	504	429

The importance of commutability

[1] Ying Yan, Yungang Pu, Qichen Long, Jiangtao Zhang, Tianjiao Zhang, Weiyan Zhou, Jie Zeng, Chao Zhang, Wenxiang Chen, Chuanbao Zhang*, Commutability of external quality assessment materials for serum magnesium and calcium measurements., Scand J Clin Lab Invest, 2019,: 1-8

[2] Ying Yan, Bingqing Han, Haijian Zhao, Rong Ma, Jing Wang, Donghuan Wang, Cuihua Hu, Wenxiang Chen and Chuanbao Zhang*, Commutability of external quality assessment materials for serum sodium and potassium measurements., Clin Chem Lab Med, 2019, 57(4): 465-475

[3] Jie zeng, Tianqi Qi, Shu Wang,Tianjiao Zhang, Weiyan Zhou, Haijian Zhao, Rong Ma, Jiangtao Zhang, Ying Yan, Jun Dong, Chuanbao Zhang, Wenxiang Chen*, Commutability of control materials for external quality assessment of serum apolipoprotein A-I measurement., Clin Chem Lab Med, 2018, 56(5): 789-795

[4] Menglei Ge, Haijian Zhao, Ying Yan, Tianjiao Zhang, Jie Zeng, Yufei Wang, Qinghui Meng, Chuanbao Zhang*, Evaluation of the Bias of Serum Magnesium Measurements and the Commutability of Processed Materials., Clin Lab, 2016, 62(5): 921-930

[5]. Qinghui Meng, Weiyan Zhou, Chuanbao Zhang, Jie Zeng, Haijian Zhao, Tianjiao Zhang, Donghuan Wang, Jiangtao Zhang, Ying Yan, Wenxiang Chen*, Serum triglyceride measurements: the commutability of reference materials and the accuracy of results., Clin Chem Lab Med, 2017, 55(9): 1284-1290

[6] Shunli Zhang, Jie Zeng, Chuanbao Zhang, Yilong Li, Haijian Zhao , Fei Cheng, Songlin Yu, Mo Wang, Wenxiang Chen*, Commutability of possible external quality assessment materials for cardiac troponin measurement., PLoS One, 2014, 9(7): e102046

[7]Zhang J, Zeng J, Ma R, et al. Matrix effect on serum uric acid determination. Laboratory Medicine, 2016,31(08):635-639[in Chinese]

[8] Zhang T, Zeng J, Wang M, et al. The commutability of reference materials for serum glucose measurements. Chinese Journal of Laboratory Medicine, 2015,38(5):296-300[in Chinese]

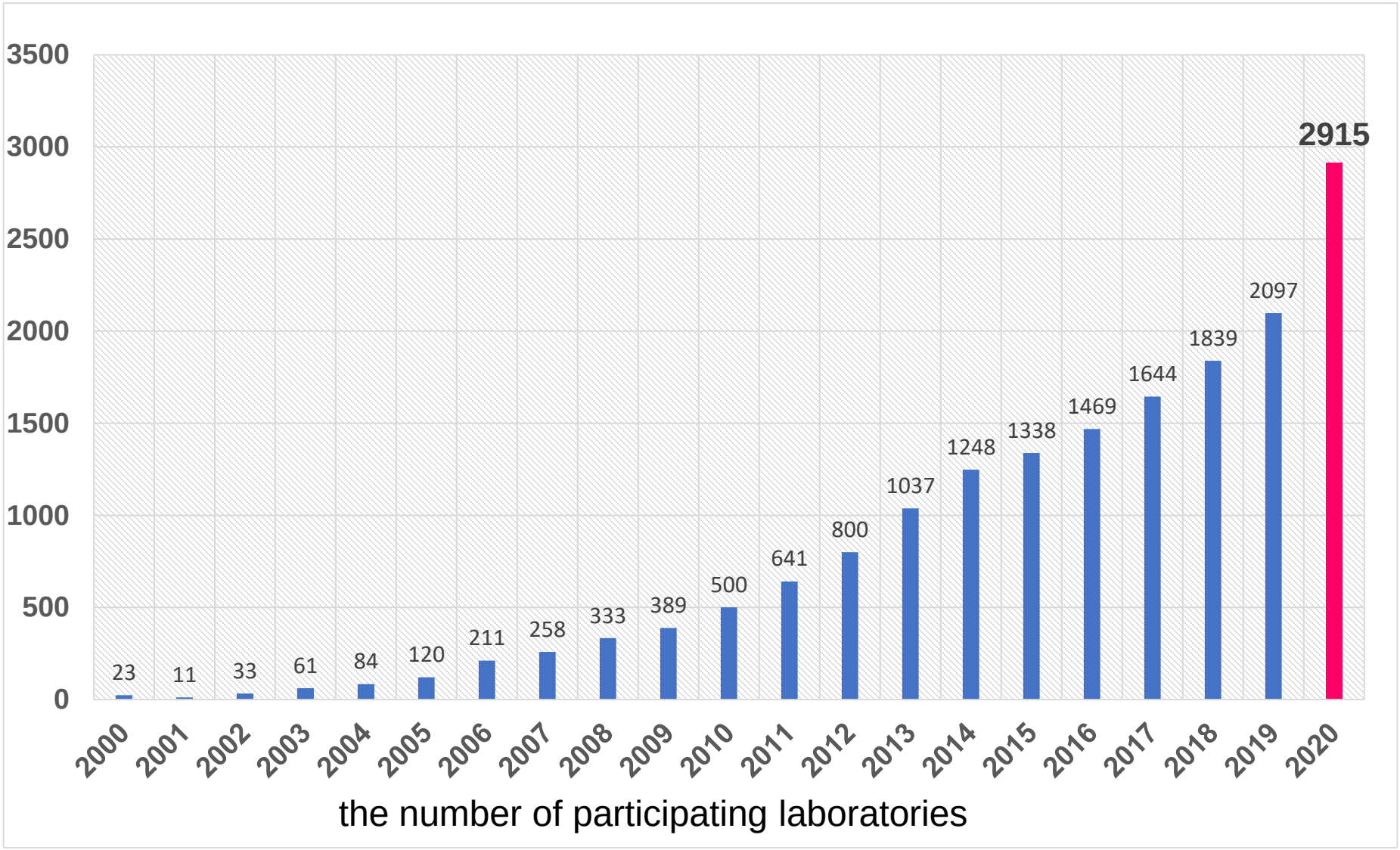
[9] Zhang C, Zhao H, Zeng J, et al. Commutability of certified reference material ERM-DA 471/IFCC for cystatin C measurement, Chinese Journal of Laboratory Medicine, 2015(5):306-309[in Chinese]

[10] Zhang L, Zeng J, Wang S, et al. Matrix effects of the processed materials in high-density lipoprotein cholesterol measurement. Chinese Journal of Laboratory Medicine, 2015,38(11):737-741[in Chinese]

[11] Qi T, Wang J, Zhang T, et al. The commutability study of processed materials for serum alanine aminotransferase measurements. Chinese Journal of Laboratory Medicine, 2018,41(3):227-231[in Chinese]

Characterization of commutability of EQA materials and certified reference materials for HbA1c

National EQA programs for HbA_{1c}



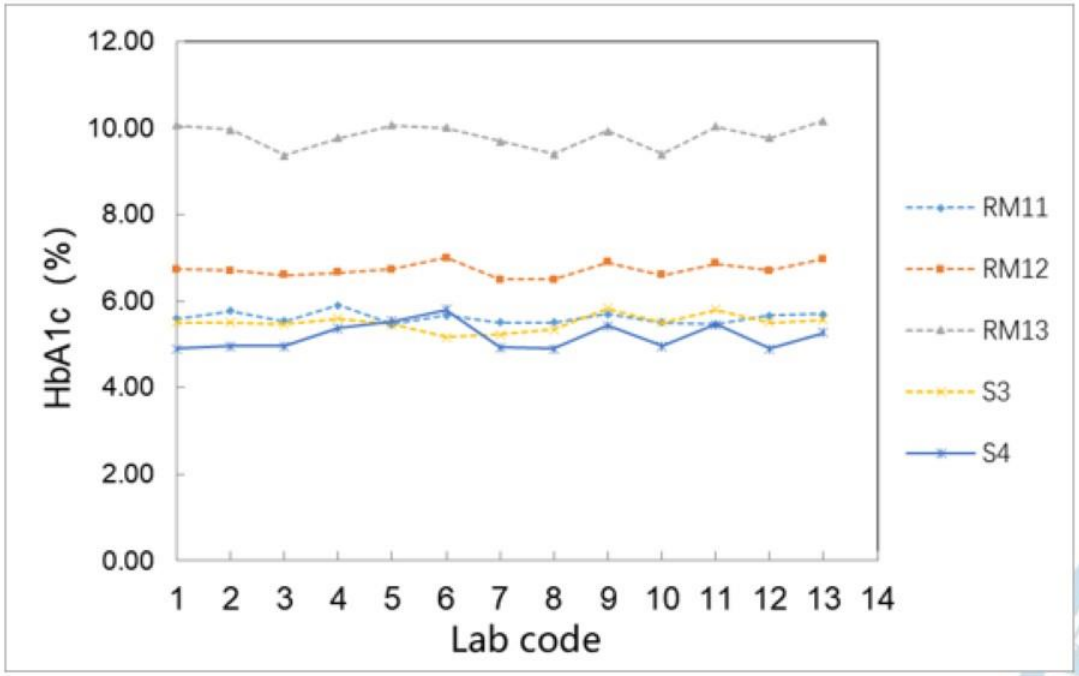
A Pilot commutability study

- **Experiment design**

— 3 frozen hemolysate buffer samples (RM11~13)， which were prepared in the same manner with the NCCL CRM GBW 09181a, 09182a and 09183a,

— 2 fresh blood samples (S3 and S4)

—13 clinical laboratories.



Code	Routin methods
1	TOSOH G7
2	Bio-Rad D-10
3	Bio-Rad Variant II
4	Roche
5	Tosoh G7
6	Bio-Rad Variant II
7	Roche
8	Tosoh G7
9	Primus
10	Tosoh G7
11	Primus
12	TOSOH G7
13	Primus

Experiment design

- **Individual native clinical samples**

50 of fresh EDTA whole blood samples (0 to 150 mmol/mol)

- Anonymized left-over blood samples collected from healthy or diabetic patients who had underwent HbA_{1c} testing at Beijing Hospital (Beijing, China) or Peking Union Medical College Hospital (Beijing, China)

- excluding the blood with obvious hemolysis or lipaemia

- free of common hemoglobin variants based on the results by Sebia Capillarys 2 FP

- all the collected blood samples were shipped to NCCL and stored at 4℃ no longer than 36 hours before use.

- The study was reviewed and approved by the Ethics Committee of Beijing Hospital and Peking Union Medical College Hospital, respectively

Experiment design

- **Reference Materials**

ID	RM	Description	IFCC value (mmol/mol)
H372923	EQA 201711	NCCL EQA materials - from pooled whole blood	31.86
H372924	EQA 201712		38.94
H372928	EQA 201713		49.46
H372929	EQA 201714		57.31
H372933	EQA 201715		71.05
H372908	GBW 09181a	Pooled Human Hemolysate (CRMs，according to the IFCC network' s document)	31.40
H372909	GBW 09182a		51.49
H372910	GBW 09183a		78.60
H372915	I360505	Human Hemolysate Panel (made from the individual donor's whole blood，according to the IFCC network' s document)	72.50
H372916	I360608		87.20
H372917	I360828		32.41
H372918	I360931		47.06
H372919	I361240		58.20
H373171	EQA 2015 A	Lyophilized EQA materials (from a EQA provider，but the detail was unknown)	32.13
H373186	EQA 2015 B		58.83
H373045	EQA 2016 A		71.43
H373046	EQA 2016 B		45.15

Experiment design

- **Evaluated methods**

  - covering about 70% systems used in national EQA programs for HbA1c in China

Platform	Reagents	Reagents Lot	Method principle	Code
Bio-Rad D-10	Bio-Rad	AA60506/7	Ion Exchange HPLC	Bio-Rad D-10
Bio-Rad Varient II Turbo	Bio-Rad	442722995	Ion Exchange HPLC	Bio-Rad V II Turbo
Mindray H50	Mindray	2017020901	Ion Exchange HPLC	Mindray H50
Runda MQ-6000	Runda	20170705D	Ion Exchange HPLC	MQ-6000
Tosoh G8	Tosoh	K8-101C	Ion Exchange HPLC	Tosoh G8
Hitachi 7180	Mindray	44617002	Enzymatic Assay	Mindray
Hitachi 7180	Sekisui	825RDO	Enzymatic Assay	Sekisui
Premier Hb 9210	Primus	6864/9626	Boronate affinity	Hb 9210
Roche Cobas 501	Roche	851332155	Immunoassay	Roche Cobas 501
Sebia Capillarys 2 FP	Sebia	24016/01	Capillary electrophoresis	Sebia

Experiment design

- **A specialized central laboratory**
- Considering
  - limitation in the volume of Individual native clinical samples (~2ml)
  - most of systems involved already equipped in NCCL

Platform	Provider	Platform	Provider
		Tosoh G8	NCCL
Bio-Rad D-10	NCCL	Hitachi 7180	NCCL
Bio-Rad Varient II Turbo	NCCL	Premier Hb 9210	NCCL
Mindray H50	Manufacturer	Roche Cobas 501	NCCL
Runda MQ-6000	Manufacturer	Sebia Capillarys 2 FP	NCCL

Experiment design

- **Procedure for sample measurements (routine methods)**

— all sample were pre-diluted manually according to the manufacturer instructions.

— all sample were measured in quadruplicate (two pre-dilution and two measurements for each diluted sample)

— 67 samples (50 clinical samples, 17 RMs) were analyzed in 3 working days with independently calibration on each day

— 2 control sample were measured at the beginning and at the end of each working day

— all sample were measured repeatedly as following order. The RMs were randomly interspersed between the blood samples for measurements.

Smaple1- dilution 1, Smaple2- dilution 1……. Smaple66- dilution 1, Smaple67- dilution 1

Smaple67- dilution 1, Smaple66- dilution 1……. Smaple2- dilution 1, Smaple1- dilution 1

Smaple1- dilution 2, Smaple2- dilution 2……. Smaple66- dilution 2, Smaple67- dilution 2

Smaple67- dilution 2, Smaple66- dilution 2 ……. Smaple2- dilution 2, Smaple1- dilution 2

— results were report in IFCC unit and/or NGSP unit based on the parameters of the systems

Experiment design

- **Procedure for sample measurements (Comparative method, RMP)**

  - performed in NCCL, a member of the IFCC reference network for HbA_{1c} , accredited according to ISO 17025 and ISO 15195 standards for HbA_{1c} measurement.

  - using the modified IFCC reference measurement procedure based on LC-MS/MS

  - 67 samples (50 CS, 17 RM) analyzed in duplicate, two digestion, two injection

  - 6 batches in total, using calibrators and 3 QC materials obtained from the IFCC network

DE GRUYTER

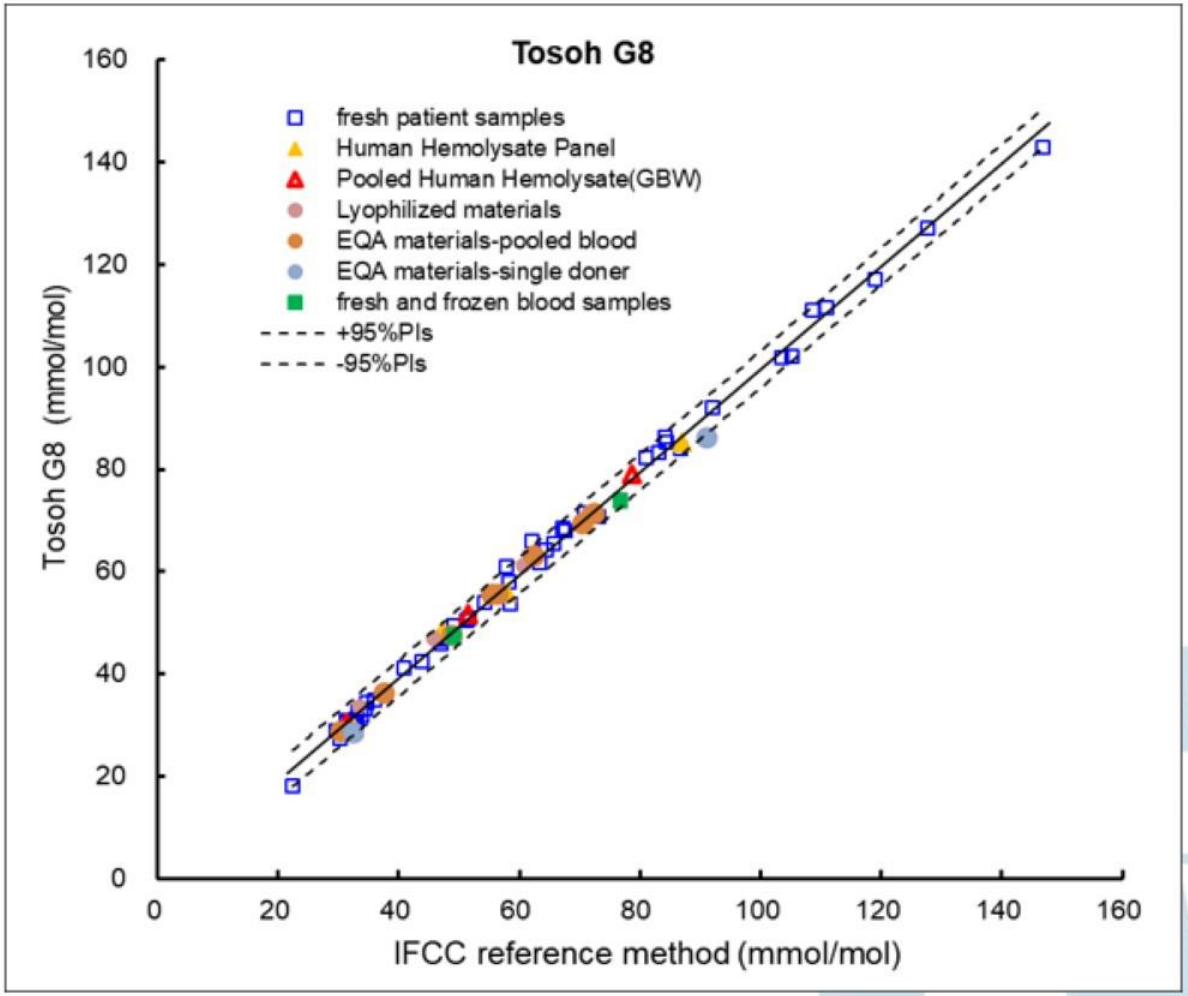
Clin Chem Lab Med 2016; 54(4): 569–576

Tianjiao Zhang, Chuanbao Zhang, Wenxiang Chen, Haijian Zhao, Jiangtao Zhang, Weiyan Zhou, Jie Zeng, Jing Wang and Donghuan Wang*

Quantification of hemoglobin A_{1c} by off-line HPLC separation and liquid chromatography-tandem mass spectrometry: a modification of the IFCC reference measurement procedure

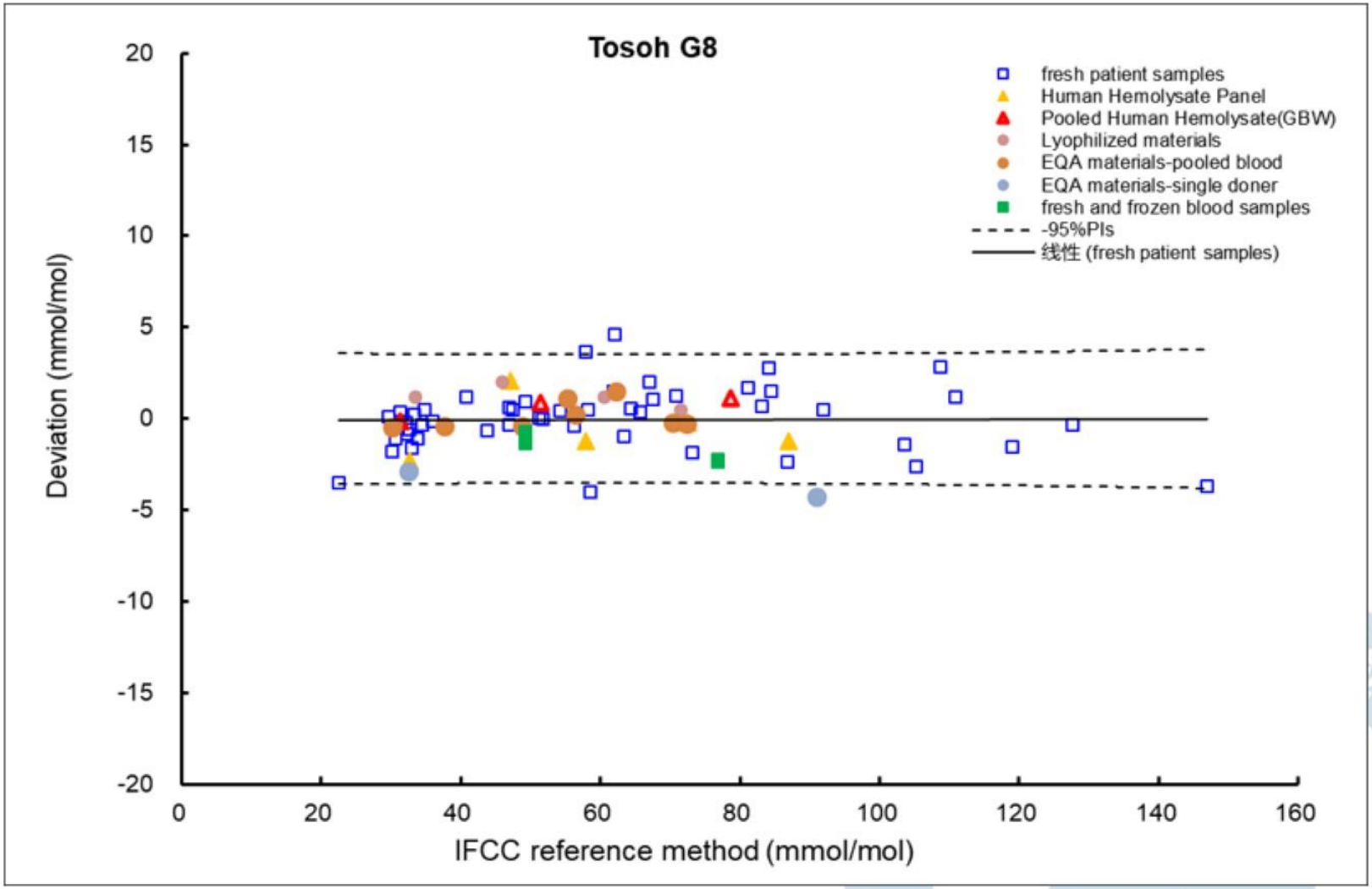
Commutability assessment - CLSI EP-14A3

- linear regression using ordinary least squares (OLS) with the 95% prediction intervals (PIs).



Commutability assessment - CLSI EP-14A3

- linear regression using ordinary least squares (OLS) with the 95% prediction intervals (PIs).

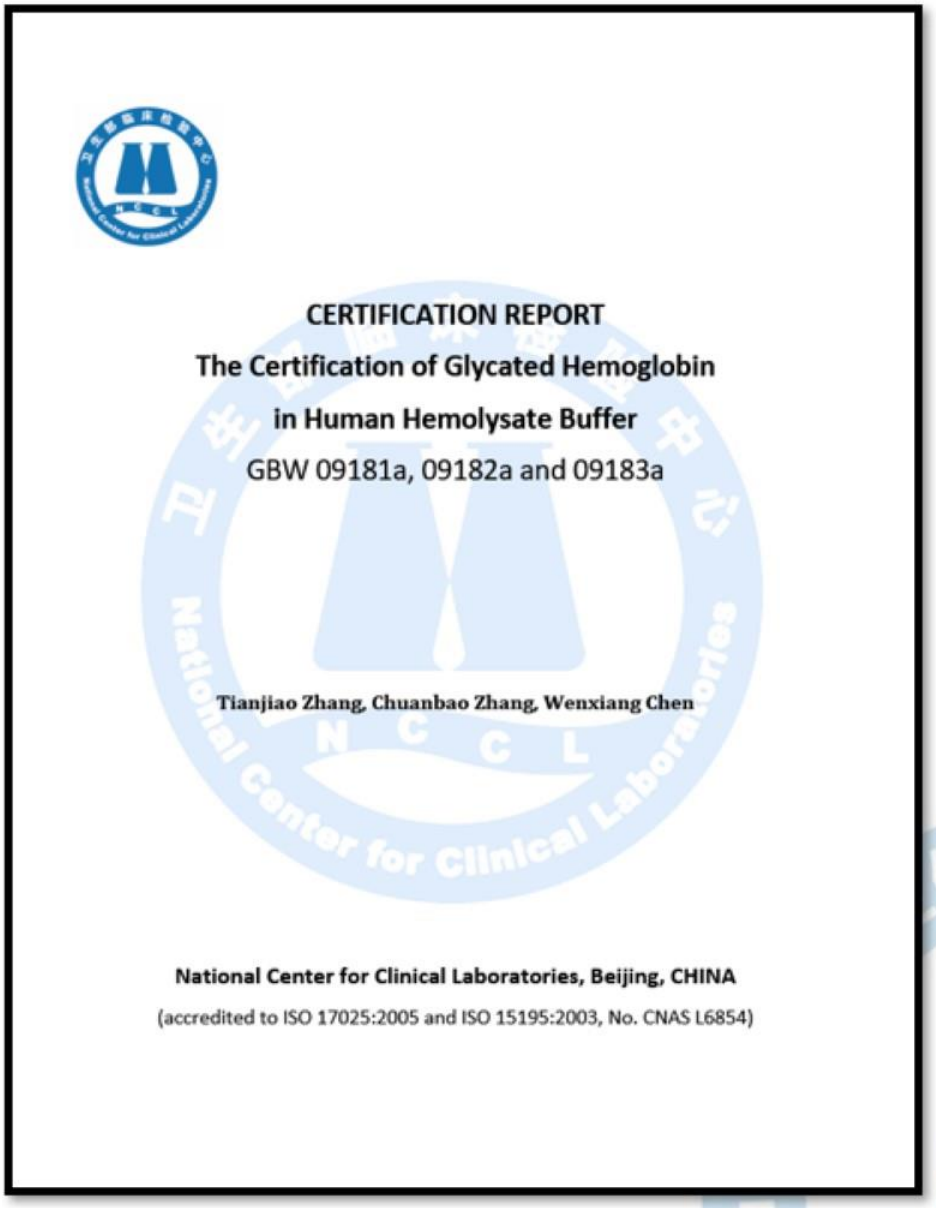


Commutability assessment - CLSI EP-14A3

- EQA materials were commutable for all methods.
- Glycated Hemoglobin in Human Hemolysate Buffer (pooled or individual), which were prepared according to the IFCC network' s document, were commutable for all analytical systems based on ion exchange HPLC and Premier Hb 9210 as well as Sebia Capillarys 2 Flex Piercing, Roche Cobas 501 according the CLSI EP-14A3; it showed noncommutability for two Enzymatic Assay, Mindray and Sekisui systems
- Lyophilized EQA materials showed considerable lack of commutability on Primus HB9210, Sebia Capillarys 2 FP, Roche Cobas 501 and Mindray and Sekisui systems

RM	Description	IFCC value(mmol/mol)	Bio-Rad D-10	Bio-Rad VII Turbo	Mindray H50	MQ-6000	Tosoh G8	Primus	Sebia	Roche cobas 501	Mindray	Sekisui
EQA 201711	NCCL EQA materials - from pooled whole blood	30.24	C	C	C	C	C	C	C	C	C	C
EQA 201712		37.55	C	C	C	C	C	C	C	C	C	C
EQA 201713		48.83	C	C	C	C	C	C	C	C	C	C
EQA 201714		56.34	C	C	C	C	C	C	C	C	C	C
EQA 201715		70.34	C	C	C	C	C	C	C	C	C	C
GBW 09181a	Pooled Human Hemolysate	31.36	C	C	C	C	C	C	C	C	C	NC
GBW 09182a		51.49	C	C	C	C	C	C	C	C	NC	C
GBW 09183a		78.60	C	C	C	C	C	C	C	C	NC	NC
I360505	Human Hemolysate Panel	32.58	C	C	C	C	C	C	C	C	C	C
I360608		47.14	C	C	C	C	C	C	C	C	NC	C
I360828		57.93	C	C	C	C	C	C	C	C	NC	C
I360931		72.47	C	C	C	C	C	C	C	C	NC	C
I361240		87.00	C	C	C	C	C	C	C	C	NC	NC
EQA 2015 A	Lyophilized EQA materials	33.41	C	C	C	C	C	C	C	C	C	C
EQA 2015 B		60.62	C	C	C	C	C	C	NC	C	NC	NC
EQA 2016 A		71.54	C	C	C	C	C	C	C	NC	NC	NC
EQA 2016 B		45.85	C	NC	C	C	C	NC	C	C	C	C

Commutability assessment - CLSI EP-14A3



CERTIFICATION REPORT

The Certification of Glycated Hemoglobin

in Human Hemolysate Buffer

GBW 09181a, 09182a and 09183a

Tianjiao Zhang, Chuanbao Zhang, Wenxiang Chen

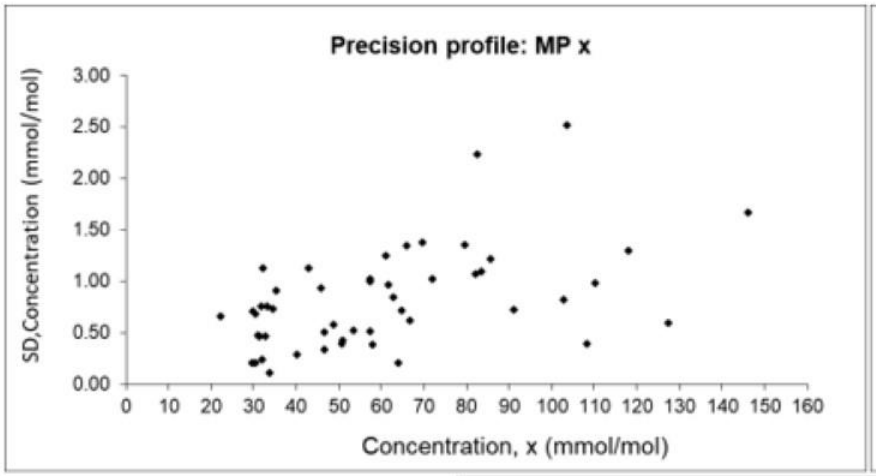
National Center for Clinical Laboratories, Beijing, CHINA

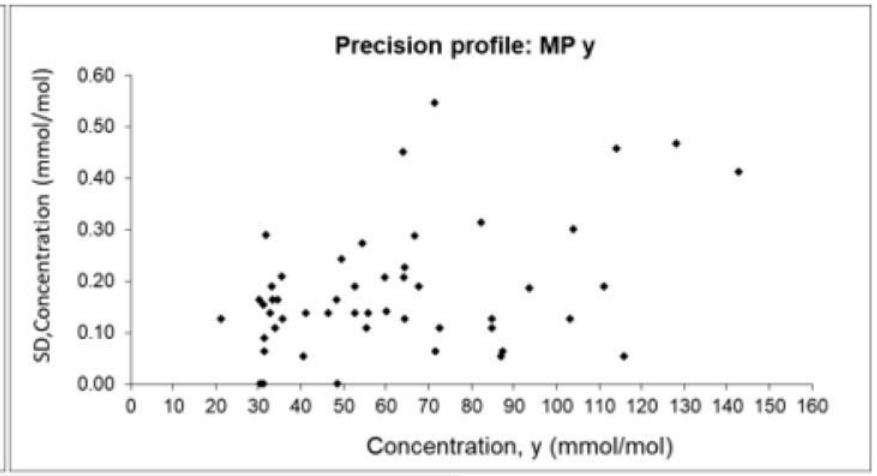
(accredited to ISO 17025:2005 and ISO 15195:2003, No. CNAS L6854)

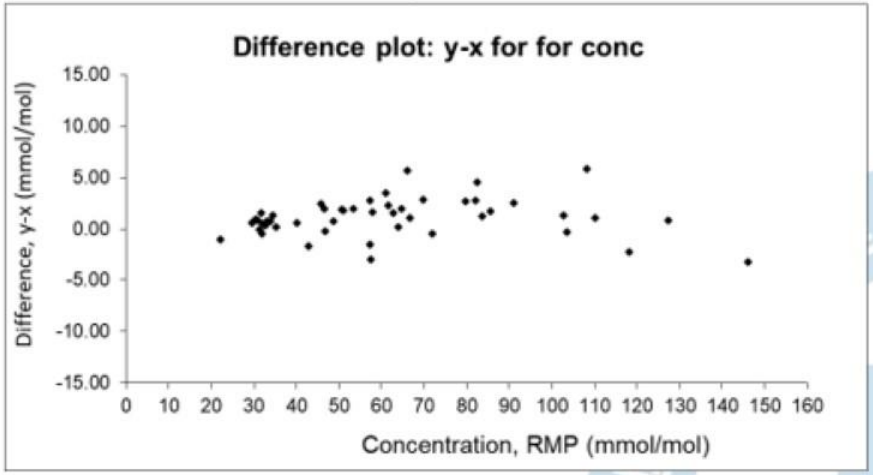
Commutability assessment - the IFCC approach

- **Precision plots for the routine methods (y) and the RMP (x)**

  — the commutability assessment was based on the nontransformed data in this study.







Commutability assessment - the IFCC approach

- **Component of variation**
  - — The position effects were not estimated with this study design.
  - — Random error from sample preparation for RMs were estimated
    RMP: 2 digestions, 2 injection (LC-MS/MS)
    Routine methods: two pre-dilution and two measurements for each diluted sample
  - — random error between batches for QCs
    RMP: 6 batches with 3 QC samples
    Routine methods: 3 working days with 2 QC samples

	MP x	MP y	Difference	Explanation of terms
$s_{e(CS)}$	0.947	0.217		SD for random error from triplicate measurements of CSs
Bias y vs x			1.073	Average bias between methods y and x
s_d			1.587	SD for sample specific differences
$s_{e(RM)}$	0.412	0.139		SD for random error from multiple measurements of RMs
$s_{Preparation(RM)}$	0.016	0.190		SD for random error from sample preparation for RMs
$s_{Batch(QC)}$	0.416	0.127		SD for random error between batches for QCs
$s_{d(corr)}$			1.576	SD for sample specific differences corrected for sample preparation on effects

Commutability assessment - the IFCC approach

- **The appropriate estimate of b(μ)**

— The bias function b(μ) is a common bias between the runs with the 2 MPs (the bias can be expressed by a continuous function of μor a constant). The appropriate estimate of the bias function at the concentration of the RM depends on the outcome of the experiment.

A: The bias function b(μ) is approximately constant in the whole concentration interval, and the CSs bracket the concentration of the RM

Arkray HA-8180, Bio-Rad D-10, MQ-6000, Primus Hb9210, Roche Cobas 501, SEKISUI (Enzymatic Assay)

B: The bias function b(μ) is approximately constant in a concentration interval enclosing the RM

Mindray H50, Tosoh G8, Mindray(Enzymatic Assay),

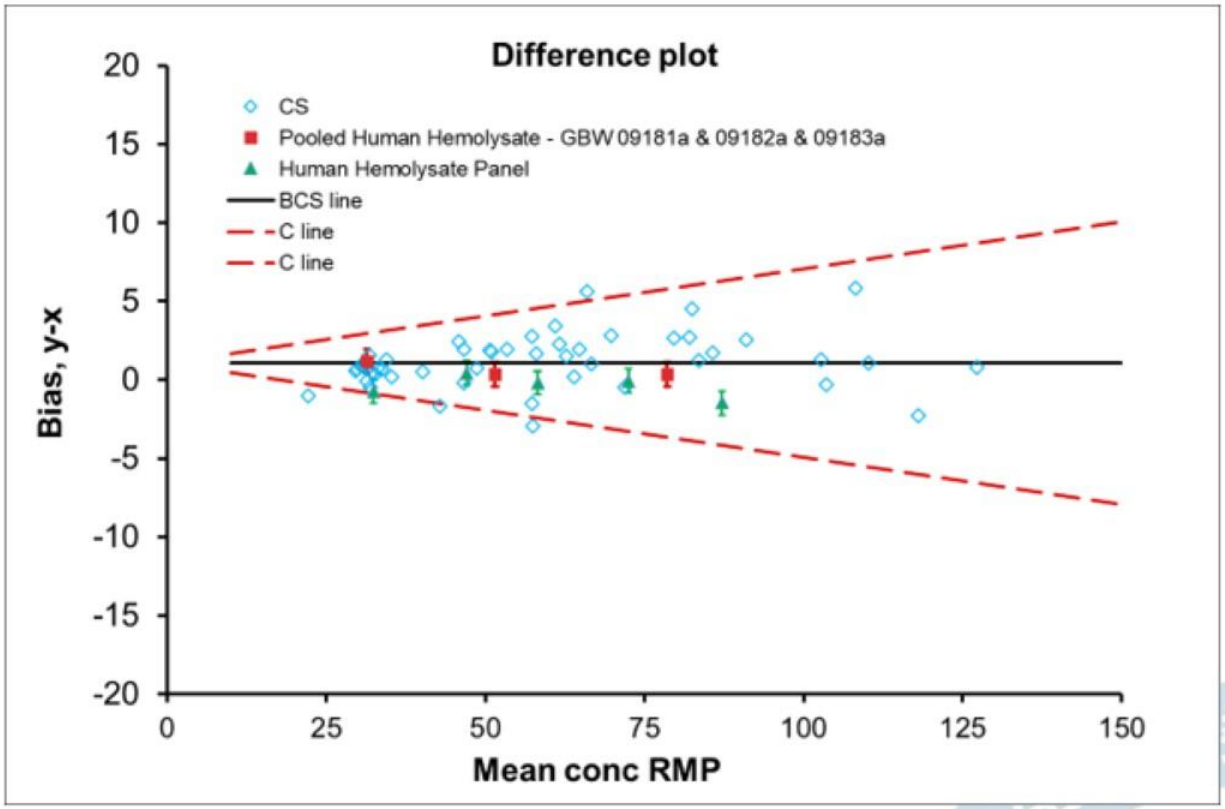
C: The bias function b(μ) has an approximately linear trend in an interval where there are q/2 CSs on each side of the RM

— the moving average was used as an estimate of the bias of the corresponding RMs

Bio-Rad VII Turbo, Sebia capillary S2 FP

Commutability assessment - the IFCC approach

- the criterion was set as 6% (current NCCL's trueness verification program acceptance limit)



Commutability assessment - Results and discussion

RM	IFCC value (mmol/mol)	Ion Exchange HPLC										Boronate affinity		Capillary electrophoresis		Immuno-assay		Enzymatic Assay			
		Bio-Rad D-10		Bio-Rad VII Turbo		Mindray H50		MQ-6000		Tosoh G8		Primus		Sebia		Roche		Mindray		Sekisui	
		IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI
EQA 201711	31.86	NC	C	I	C	I	C	I	C	NC	C	I	C	I	C	I	C	I	C	I	C
EQA 201712	38.94	NC	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
EQA 201713	49.46	I	C	I	C	C	C	C	C	C	C	I	C	I	C	I	C	I	C	C	C
EQA 201714	57.31	NC	C	I	C	C	C	C	C	C	C	I	C	I	C	I	C	C	C	I	C
EQA 201715	71.05	I	C	C	C	C	C	C	C	C	C	I	C	C	C	C	C	C	C	C	C
GBW 09181a	31.40	I	C	I	C	I	C	C	C	I	C	I	C	I	C	I	C	I	C	NC	NC
GBW 09182a	51.49	C	C	C	C	C	C	C	C	C	C	C	C	C	C	I	C	I	NC	I	C
GBW 09183a	78.60	C	C	C	C	C	C	C	C	C	C	C	C	C	C	I	C	I	NC	I	NC
I360505	32.41	I	C	I	C	NC	C	I	C	NC	C	I	C	I	C	I	C	I	NC	I	C
I360608	47.06	C	C	I	C	C	C	C	C	C	C	I	C	I	C	I	C	I	NC	I	C
I360828	58.20	I	C	C	C	I	C	C	C	C	C	C	C	C	C	I	C	I	NC	I	NC
I360931	72.50	C	C	C	C	C	C	C	C	C	C	C	C	C	C	I	C	NC	C	I	C
I361240	87.20	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	NC	NC	I	C
EQA 2015 A	32.13	I	C	I	C	I	C	I	C	I	C	NC	C	I	C	I	C	I	C	I	C
EQA 2015 B	58.83	I	C	I	C	C	C	C	C	C	C	C	C	I	NC	I	C	NC	NC	I	NC
EQA 2016 A	71.43	C	C	C	C	C	C	C	C	C	C	C	C	I	NC	NC	NC	NC	NC	NC	NC
EQA 2016 B	45.15	I	C	I	NC	C	C	I	C	I	C	NC	NC	C	C	NC	NC	I	C	I	C

Commutability assessment - Results and discussion

- The IFCC approach gave the inconclusive results for GBW 09181a, 09182 and 09183a on different systems.

- The IFCC approach gave the difference results for a individual human hemolysate at low concentrations on Mindray H50 and Tosoh G8 system.

- Mindray and Sekisui systems showed a complicated results of commutability evaluation with two methods.

RM	IFCC value (mmol/mol)	Ion Exchange HPLC										Boronate affinity		Capillary electrophoresis		Immuno-assay		Enzymatic Assay			
		Bio-Rad D-10		Bio-Rad VII Turbo		Mindray H50		MQ-6000		Tosoh G8		Primus		Sebia		Roche		Mindray		Sekisui	
		IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI
GBW 09181a	31.40	I	C	I	C	I	C	C	C	I	C	I	C	I	C	I	C	I	C	NC	NC
GBW 09182a	51.49	C	C	C	C	C	C	C	C	C	C	C	C	C	C	I	C	I	NC	I	C
GBW 09183a	78.60	C	C	C	C	C	C	C	C	C	C	C	C	C	C	I	C	I	NC	I	NC
I360505	32.41	I	C	I	C	NC	C	I	C	NC	C	I	C	I	C	I	C	I	NC	I	C
I360608	47.06	C	C	I	C	C	C	C	C	C	C	I	C	I	C	I	C	I	NC	I	C
I360828	58.20	I	C	C	C	I	C	C	C	C	C	C	C	C	C	I	C	I	NC	I	NC
I360931	72.50	C	C	C	C	C	C	C	C	C	C	C	C	C	C	I	C	NC	C	I	C
I361240	87.20	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	NC	NC	I	C

Commutability assessment - Results and discussion

- The IFCC approach gave the difference results for EQA materials on Bio-Rad D-10 system
- Lyophilized EQA materials showed a complicated results of commutability evaluation with two methods.

RM	IFCC value (mmol/mol)	Ion Exchange HPLC										Boronate affinity		Capillary electrophoresis		Immuno-assay		Enzymatic Assay			
		Bio-Rad D-10		Bio-Rad VII Turbo		Mindray H50		MQ-6000		Tosoh G8		Primus		Sebia		Roche		Mindray		Sekisui	
		IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI	IFCC	CLSI
EQA 201711	31.86	NC	C	I	C	I	C	I	C	NC	C	I	C	I	C	I	C	I	C	I	C
EQA 201712	38.94	NC	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
EQA 201713	49.46	I	C	I	C	C	C	C	C	C	C	I	C	I	C	I	C	I	C	C	C
EQA 201714	57.31	NC	C	I	C	C	C	C	C	C	C	I	C	I	C	I	C	C	C	I	C
EQA 201715	71.05	I	C	C	C	C	C	C	C	C	C	I	C	C	C	C	C	C	C	C	C
EQA 2015 A	32.13	I	C	I	C	I	C	I	C	I	C	NC	C	I	C	I	C	I	C	I	C
EQA 2015 B	58.83	I	C	I	C	C	C	C	C	C	C	C	C	I	NC	I	C	NC	NC	I	NC
EQA 2016 A	71.43	C	C	C	C	C	C	C	C	C	C	C	C	I	NC	NC	NC	NC	NC	NC	NC
EQA 2016 B	45.15	I	C	I	NC	C	C	I	C	I	C	NC	NC	C	C	NC	NC	I	C	I	C

Summary

- The commutability of 5 EQA materials (from pooled whole blood), 3 CRMs (Pooled Human Hemolysate), 5 human hemolysate panel (the individual donor's hemolysate), 3 lyophilized EQA materials were evaluated according to the CLSI EP-14A3 and IFCC approach.

- The EQA materials and CRMs showed commutability on most of analytical systems, therefore, they might be used in the validation of methods or as quality control materials for the measurement of HbA1c

- The commutability evaluation based on IFCC Working Group Recommendations highly depends on the experiment design, more attention should be paid before the study is started.

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Thank for your attention !

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