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RESEARCH ARTICLE

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EQA/PT scheme to improve the equivalence of enzymatic results between mutual recognition laboratories in Beijing

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Abstract

Background: To utilize the external quality assessment (EQA)/proficiency testing (PT) scheme to evaluate the equivalence of different clinical enzymatic measuring systems in Beijing.

Methods: The Beijing Center for Clinical Laboratory (BCCL) distributed three investigation samples to mutual recognition clinical laboratories in Beijing including alanine aminotransferase (ALT), aspartate aminotransferase (AST), γ-glutamyltransferase (GGT), creatine kinase (CK), and lactate dehydrogenase (LDH). These samples were derived from serum pools with values assigned by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) enzymatic reference measurement procedures (RMPs). Each laboratory performed duplicate tests of the samples. Then, the samples at level 1 were used to recalibrate individual measuring systems for repeating the tests. BCCL collected data for evaluation of their analytical quality.

Results: Before recalibration, the biases of ALT and AST tests were not traceable to the IFCC RMPs, and the bias pass rates of GGT, CK, and LDH tests were only 51.2%, 55.7%, and 48.6% respectively. After recalibration, the pass rates of ALT, AST, GGT, CK, and LDH increased to 95.1%, 82.9%, 95.1%, 97.1%, and 70.0% respectively. The EQA/PT also showed that after recalibration, more than 95% of laboratories met the optimum level specifications of the biological variation for ALT, AST, GGT, and CK tests and the desirable for LDH tests.

Conclusion: The enzymatic tests in Beijing need to be further standardized by category 1 or 2 EQA/PT scheme for mutual recognition between clinical laboratories. The criteria of biological variation are more relevant for determining the equivalence of clinical enzymatic tests.

KEYWORDS
biological variation, enzymatic assay, external quality assessment, proficiency testing, standardization

1 | INTRODUCTION

In modern medical practice, patients always choose multiple medical institutions for medical care services. Therefore, the equivalence of results obtained from different measuring systems between and within laboratories is especially important. The General Office of the Ministry of Health of China has issued a notification requesting that same level medical institutions mutually recognize the examination results. Standardization is necessary to achieve interchangeable test results among institutions regardless of measuring principles, methods, and systems.[1,2] At present, standardization has become the goal of global efforts in laboratory medicine.[3,4] The external quality assessment (EQA)/proficiency testing (PT), as a management tool to monitor and verify the performance of participating laboratories, plays an important role in promoting clinical laboratory standardization.[5–9]

Improving the traceability and comparability of tests is essential to achieve this goal. Metrological comparability is obtained through tracing to internationally recognized reference materials (RMs) and reference measurement procedures (RMPs) on the traceability chain.[10] To transfer accurate quantity value from RMPs to the routine measuring system, Braga F concluded the following six pillars: certified reference materials, reference methods, reference measurement services, reference intervals and decision points, which are traceable to higher-order references, internal and external quality control and targets for uncertainty and error of measurement.[11] As an indispensable aspect, the EQA/PT scheme is the fifth pillar in this theory, and only the EQA/PT scheme based on trueness can satisfy the need for standardization.

The Beijing Center for Clinical Laboratories (BCCL) is the agency responsible for implementing the EQA/PT in Beijing. By using the RMPs recommended by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), we initiated and organized six domestic laboratories to establish a reference measurement system for alanine aminotransferase (ALT), aspartate aminotransferase (AST), γ-glutamyltransferase (GGT), creatine kinase (CK), and lactate dehydrogenase (LDH). At first, we assigned values to fresh frozen human serum pools with reference materials to prepared enzyme calibrators. Subsequently, we carried out a quantity transfer from the enzymatic reference measurement system to routine measuring systems using these homemade enzyme calibrators as medium. In this study, we designed and applied the category 1 EQA/PT scheme to validate the accuracy-based standardization and mutual recognition of clinical enzymology tests.

2 | MATERIALS AND METHODS

2.1 | Composition of measuring systems

This survey involved 70 clinical laboratories from different hospitals in Beijing for mutual recognition. Routine measuring systems from all 70 laboratories participated in the CK and LDH survey, whereas 41 participated in the ALT, AST, and GGT survey. For the ALT, AST, and GGT tests, 18–20 laboratories used the homogeneous system,

TABLE 1 The composition of routine measuring systems

Enzyme	Laboratory	Homogeneous systems	Groups by instruments					Heterogeneous systems	Numbers		
			Beckman Coulter Olympus	Hitachi	Roche	Mindray			Instruments	Reagents	Calibrators
ALT	41	18	10	4	3	1		23	3	12	5
AST	41	19	11	4	3	1		22	3	12	4
GGT	41	20	12	4	3	1		21	3	13	5
CK	70	20	12	4	3	1		50	5	20	6
LDH	70	18	11	3	3	1		52	5	21	5

Abbreviations: ALT, Alanine aminotransferase; AST, Aspartate aminotransferase; CK, Creatine kinase; GGT, Gamma-glutamyltransferase; LDH, Lactate dehydrogenase.

which means reagents and calibrators were recommended by the instrument suppliers.[12] The other 21–23 laboratories obtained at least one component of the measuring system, reagents or calibrators from sources other than the instrument suppliers, referred to hereafter as heterogeneous systems.[13] In the analysis of CK and LDH, 20 and 18 laboratories used homogeneous systems, while the other 50 and 52 used heterogeneous systems. As shown in Table 1, the homogeneous system for each enzyme was grouped according to the instrument's manufacturer, including Beckman Coulter Olympus, Hitachi, Roche, and Mindray. In the participating laboratories employing heterogeneous systems, 3–5 different instruments, 12–21 different reagents, and 4–6 calibrators were used.

2.2 | Investigation samples

Fresh sera without chyle and hemolysis was collected and stored at −80℃. Pooled serum samples were prepared at the three levels of enzyme activity concentration following the national standard of the production of reference materials for clinical enzymology of China by the Enzymology Reference Measurement Laboratory of Beijing Aerospace General Hospital, which has ISO 17025 and ISO 15195 accreditations (Registration No. L5536). The process of sample preparation and value assignment has been previously described.[14] Samples are assigned values by enzyme reference procedures or measuring systems which compared to the reference methods. As shown in Table 2, the assigned values of five enzymes for ALT, AST, GGT, CK, and LDH at three different levels were expressed as the assigned value ± extended uncertainty (U/L, U), when the coverage factor (k) equaled 2. The three serum samples are numbered as sample 1, sample 2, and sample 3.

TABLE 2 The target values of investigation samples

Enzyme	Sample No	Target value (U/l), k = 2
ALT	1	112.2 ± 1.1
	2	183.3 ± 2.7
	3	82.0 ± 2.2
AST	1	101.4 ± 0.2
	2	296.0 ± 5.4
	3	79.7 ± 2.7
GGT	1	175.7 ± 0.9
	2	158.4 ± 3.7
	3	85.4 ± 2.1
CK	1	370.9 ± 2.9
	2	205.7 ± 4.4
	3	660.6 ± 5.9
LDH	1	309.7 ± 4.0
	2	203.0 ± 3.7
	3	441.9 ± 5.6

Abbreviations: ALT, Alanine aminotransferase; AST, Aspartate aminotransferase; CK, Creatine kinase; GGT, Gamma-glutamyltransferase; LDH, Lactate dehydrogenase.

2.3 | Enzymatic assay in individual laboratories

BCCL distributed the three investigation samples to the individual laboratories in dry ice for storage at −80°C. Before use, the samples were gently reversed five times after thawing completely at room temperature, and the tests were completed within 4 h. After the calibration in each measuring system with their routine calibrators, three investigation samples were tested in duplicate under internal quality control. Then, the routine measuring systems in 70 clinical laboratories were recalibrated using investigation sample 1. For ALT and AST, the Roche Diagnostic reagent of pyridoxal-5'-phosphatemonohydrate was used. Then, the three investigation samples were tested in duplicate after recalibration. The test results before and after recalibration, as well as the information of the individual measuring systems, were recorded and reported to BCCL within the specified time.

2.4 | Quality evaluation

Trueness verification: In this study, the bias percentages of ALT, AST, GGT, CK, and LDH were calculated based on the difference between the mean of replicates for each sample and the target value assigned by IFCC RMPs. Then, the biases were evaluated according to the quality specifications formulated in the Analytical Quality Specifications for Routine Analytes in Clinical Biochemistry of China Ministry of Health Industry Standards (WS/T 403–2012). The bias pass rate of a single sample refers to the percentage of the number of measuring systems that produced the qualified bias. The bias pass rate of an individual laboratory was judged by the biases at two different levels that meet the bias quality specifications. Youden plots of the results at two different concentration levels were generated, and the equivalent limits shown on the plots represent the corresponding concentration range required by quality specification. If the results of two samples fell within the equivalent limit, the laboratory bias would be considered to meet the requirements.

Quality grades: In this study, the intra-individual biological variation (CV_I) and inter-individual biological variation (CV_G) were derived from the database on biological variations in global healthy populations provided by Dr Ricos and colleagues.[15] The three grades of quality specifications were calculated using the following formulas decided by international experts: Optimum $<1.65 \times 0.25 CV_I + 0.125(CV_I^2 + CV_G^2)^{0.5}$;Desirable $<1.65 \times 0.50CV_I + 0.250(CV_I^2 + CV_G^2)^{0.5}$;Minimum $<1.65 \times 0.75CV_I + 0.375(CV_I^2 + CV_G^2)^{0.5}$. The evaluation criteria based on biological variation for enzymatic analytes are shown in Table 3.

Quality evaluation: For each analysis, “acceptable” means one test result of individual sample falls within the criteria range, and “satisfactory” refers to the test results of the three samples of analysis are all within the range of criteria.

TABLE 3 Evaluation criteria based on the biological variation for enzymatic analytes

Enzyme	Concentration range, U/l	*n*	Biological variation, %		Total allowable error, %		
			CV_I	CV_G	Optimum	Desirable	Minimum
ALT	82.0–183.3	41	19.4	41.6	13.7	27.5	41.2
AST	79.7–296.0	41	12.3	23.1	8.4	16.7	25.0
GGT	85.4–175.7	41	13.4	42.1	11.0	22.1	33.2
CK	205.7–660.6	70	22.8	40.0	15.2	30.3	45.5
LDH	203.0–441.9	70	8.6	14.7	5.7	11.4	17.1

Abbreviations: ALT, Alanine aminotransferase; AST, Aspartate aminotransferase; CK, Creatine kinase; CV_G, between-subject variation; CV_I, within-subject variation; GGT, Gamma-glutamyltransferase; LDH, Lactate dehydrogenase.

TABLE 4 System grouping statistical results of five enzymes

Enzyme	Target value, U/l	Homogeneous systems			Heterogeneous systems			*P*
		n	Mean, U/l	Bias,%	*n*	Mean, U/l	Bias,%	
ALT	112.2	18	91.5	−18.4	23	91.0	−18.9	0.835>0.05
	183.3		146.2	−20.2		144.3	−21.3	0.634>0.05
	82.0		65.3	−20.4		65.6	−20.0	0.860>0.05
AST	101.4	19	89.0	−12.2	22	89.1	−11.8	0.986>0.05
	296.0		238.4	−19.4		223.0	−24.7	0.019<0.05
	79.7		61.0	−23.5		63.2	−20.7	0.621>0.05
GGT	175.7	20	168.7	−4.0	21	168.3	−4.2	0.909>0.05
	158.4		153.2	−3.3		155.1	−2.1	0.653>0.05
	85.4		82.4	−3.5		81.4	−4.7	0.595>0.05
CK	370.9	20	390.4	5.3	50	374.8	1.05	0.002<0.05
	205.7		217.6	5.8		209.6	1.9	0.004<0.05
	660.6		710.7	7.6		670.6	1.5	0.000<0.05
LDH	309.7	18	308.1	−0.52	52	310.0	0.10	0.734>0.05
	203.0		200.8	−1.08		202.1	−0.44	0.717>0.05
	441.9		441.3	−0.14		444.7	0.63	0.631>0.05

Abbreviations: ALT, Alanine aminotransferase; AST, Aspartate aminotransferase; CK, Creatine kinase; GGT, Gamma-glutamyltransferase; LDH, Lactate dehydrogenase.

2.5 | Statistical methods

All data were collected and processed with Microsoft Excel (2007) by BCCL, including the statistical average (x), bias (%), and pass rate (%). SPSS17.0 Statistical software was used to perform grouping statistics of the independent sample's *t*-test. $p < 0.05$ was considered statistically significant. Minitab 17 software was used to generate Youden plots for the trueness analysis.

3 | RESULTS

3.1 | Statistical results of system grouping

The enzymatic results of each investigation sample were divided into two groups according to the classification of homogeneous or heterogeneous systems. As shown in Table 4, there was no statistically significant difference between the two groups for ALT, GGT, and LDH tests. In contrast, three samples of CK and one sample of high level AST showed statistical significance between the two groups.

3.2 | Bias pass rate of individual enzymatic test before and after recalibration

To verify the trueness of measuring systems, the pass rates of individual samples and each enzyme were calculated both before and after recalibration. As shown in Table 5, prior to recalibration, the bias passing rates of GGT, CK, and LDH tests were only 51.2%, 55.7%, and 48.6% respectively. The values of ALT and AST were even unable to be traced to the IFCC reference measurement procedures to meet the quality specifications. By contrast, after recalibration, the bias passing rate of ALT, AST, GGT, CK, and LDH assays increased to 95.1%, 82.9%, 95.1%, 97.1%, and 70.0% respectively, although the LDH tests displayed a

slightly lower passing rate at a high level. By using sample 1 for recalibration, the Youden plots of ALT, AST, GGT, CK and LDH tests before and after recalibration were also generated using the results of sample 2 and sample 3. As shown in Figure 1A–J, recalibration resulted in much more test bias falling within the equivalent limits, which were tagged by the rectangular box and apparently improved the compliance with quality specifications.

3.3 | Quality assessment based on the criteria of biological variation

The three quality grading optimum, desirable, and minimum based on biological variation were evaluated for ALT, AST, GGT, CK, and LDH before and after recalibration. As shown in Table 6, before recalibration, 95.7% of CK tests met the optimum level criteria, 97.6% of GGT and 92.8% of LDH tests met the desirable level criteria, and 100% of ALT tests met the minimum level criteria. However, only 63.6% of AST tests met the minimum level criteria. After recalibration, all ALT, AST, GGT and CK tests met the optimal level criteria and all LDH met the desirable level criteria.

3.4 | Quality assessment based on total allowable error (TEa) of Clinical Laboratory Improvement Amendment of 1988 (CLIA'88)

According to TEa of CLIA'88, the enzymatic test results of each measuring system were assessed before and after recalibration. As shown in Table 7, for GGT, CK and LDH, before calibration, more than 97.6% of tests met the TEa of CLIA'88; however, for ALT and AST, more than half of the tests did not meet the criteria. After recalibration, 100% of tests for these five enzymes met the TEa of CLIA'88.

4 | DISCUSSION

The results of the enzymatic assay varied significantly between different laboratories and measuring systems.[16] A survey in five European countries showed that 80% of laboratories were still unable to confirm that their enzymatic tests were in full compliance with standard procedures and the remaining 20% of the laboratory could not trace their results toward IFCC RMPs. The inter-laboratory coefficient of variation (CV%) is twice in countries with insufficient enzymatic standardization than in countries with strict standardization.[17] Heterogeneous enzymatic systems also account for a large proportion of clinical laboratories in China. For example, there are as many as 12–21 reagent manufacturers of five enzymes in Beijing (Table 1), making the situation of enzymatic standardization more complicated. Therefore, commutable reference material is needed for pursuing equivalent results of clinical samples.[18–20]

Our study showed that for GGT, CK and LDH, about 50% of the laboratory biases did not meet the specified quality specifications when assigned investigation samples were used to verify the trueness. In addition, the results of ALT and AST were not traceable to IFCC RMPs. We found that the aminotransferase

TABLE 5 Passing rate before and after recalibration of enzymatic analytes based on AQS of China

				Before calibration		After calibration	
Enzyme	Target value U/l	*n*	AQS (China),%	Pass rate, % Sample	Pass rate, % lab	Pass rate, % Sample	Pass rate, % lab
ALT	112.2	41	6.0	0	0	97.6	95.1
	183.3			0		97.6	
	82.0			0		97.6	
AST	101.4	41	5.0	7.3	0	95.1	82.9
	296.0			0		95.1	
	79.7			2.4		85.4	
GGT	175.7	41	5.5	61.0	51.2	100.0	95.1
	158.4			61.0		97.6	
	85.4			53.6		97.6	
CK	370.9	70	5.5	67.1	55.7	100.0	97.1
	205.7			64.3		97.1	
	660.6			58.6		97.1	
LDH	309.7	70	4.0	44.3	48.6	94.3	70.0
	203.0			54.3		81.4	
	441.9			57.1		74.3	

Abbreviations: ALT, Alanine aminotransferase; AQS (China), Analytical Quality Specifications for Routine Analytes in Clinical Biochemistry; AST, Aspartate aminotransferase; CK, Creatine kinase; GGT, Gamma-glutamyltransferase; LDH, Lactate dehydrogenase.

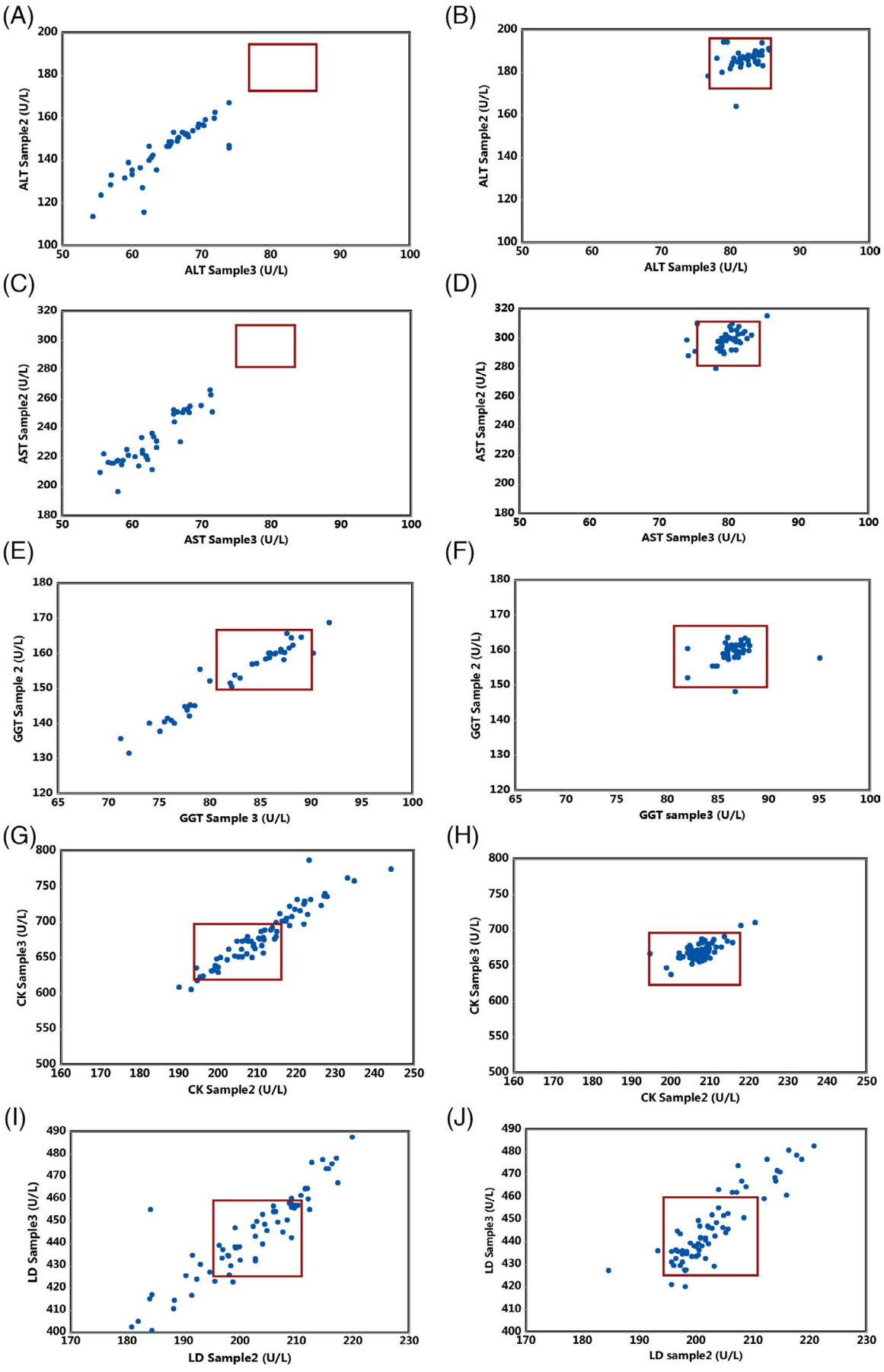
(A)
ALT Sample2 (U/L)
ALT Sample3 (U/L)
(B)
ALT Sample2 (U/L)
ALT Sample3 (U/L)
(C)
AST Sample2 (U/L)
AST Sample3 (U/L)
(D)
AST Sample2 (U/L)
AST Sample3 (U/L)
(E)
GGT Sample 2 (U/L)
GGT Sample 3 (U/L)
(F)
GGT Sample 2 (U/L)
GGT sample3 (U/L)
(G)
CK Sample3 (U/L)
CK Sample2 (U/L)
(H)
CK Sample3 (U/L)
CK Sample2 (U/L)
(I)
LD Sample3 (U/L)
LD Sample2 (U/L)
(J)
LD Sample3 (U/L)
LD sample2 (U/L)

FIGURE 1 The results of five enzymes of routing measuring systems before and after calibration. The results for sample 2 and sample 3 (x-axis and y-axis) obtained from measuring systems by all participant laboratories before recalibration (A,C,E,G,I) and after recalibration (B,D,F,H,J) are shown in Youden plot format. The square in the plots is equivalent limit, which represent the corresponding concentration range required by quality specification of China

commercial reagents without 5'-pyridoxal phosphate (pp) transferase were used in clinical laboratories, which were different from IFCC methods with pp transferase. So, the test results had about −20% bias from the assigned value by IFCC (Table 3), resulting in the failure to meet the specified analytical specifications. After traceability recalibration using the value assigned investigation samples, we improved the accuracy and comparability of the five enzymatic tests. However, the passing rate of AST and LDH was slightly lower, which in line with early studies.[21,22] Further investigations are needed on this topic.

Aloisio et al.[23] suggested that laboratory professionals should independently verify the correct implementation of metrological traceability of measuring systems. The EQA/PT scheme not only plays an important role in evaluating the performance of each laboratory but also has unique efficacy in monitoring the equivalence of measurement results and the success of standardization.[24] Miller et al.[25] divided EQA/PT scheme into six categories according to their ability to evaluate measurement procedure standardization or harmonization including the nature of the material, the target assignment procedure, the presence of replicate samples, and performance evaluation criteria. Category 1 EQA/PT schemes are ideal, with commutable samples, value assignment by reference measurement systems, replicated samples, and criteria based on biological variation. It can assess the reproducibility, calibration traceability as well as the harmonization among individual laboratories, and measurement procedures. Category 2 EQA/PT schemes have the same characteristics as category 1, but without using replicate samples, the reproducibility in the laboratory cannot be evaluated. The category 3 and 4 schemes, which target value is not reference systems assignment, are limited to evaluating the consistency of the results. The category 5 and 6 schemes, which use non-commutable samples and non-reference system to establish the target value, are limited in evaluating the comparability of the same group and not provide the bias of different measurement procedures. In the past, due to the lack of enzyme reference measurement system, BCCL implemented category 6 EQA/PT schemes of enzyme, which were only used to evaluate the peer group comparability of participating laboratories. At the initial stage of mutual recognition, category 4 EQA/PT schemes were implemented using commutable human sera to evaluate the comparability of the results. But it cannot verify the trueness of the laboratory results. Early studies showed that the EQA/PT based on consensus values, such as peer group means and quality specifications derived from non-objective models may fail to highlight analytical problems.[26,27] At present, the establishment of the reference measurement system of enzyme in Beijing has provided three classical pillars of Braga for the accuracy of the results. The investigation and design of the category 1 or 2 EQA/PT schemes laid the foundation for the establishment of the fifth pillar of Braga and provided data support for the mutual recognition of enzyme test results based on accuracy.

There are currently no data available on the quality standards used in EQA/PT schemes, and the criteria of EQA/PT scheme in different countries also vary from each other.[28] At present, the evaluation criteria of clinical enzyme EQA/PT in Beijing adopt the TEa of CLIA'88, which is at level four of the hierarchical model. However, the TEa of CLIA'88 is derived from experience and not objective enough. Its main purpose is simply to allow most laboratories to pass and only to filter out a small number of unqualified laboratories. Therefore, as a minimum specification, the TEa of CLIA'88 affects a laboratory to perform test in accordance with its U.S. legislative requirements. In the present study, we found before recalibration, more than 97.6% of laboratories could meet the EQA/PT criteria for GGT, CK, and LDH, except for the low satisfactory rates of ALT and AST due to the non-traceability to IFCC RMPs. After recalibration, 100% laboratories meet these criteria for all enzymatic tests. Obviously, the quality evaluation criteria of CLIA'88 are too permissive for the mutual recognition between laboratories. The laboratory is required to meet the criteria and expected to reach optimal specifications to share the common reference interval and the decision point. Thus, the criteria should be more restrictive than the TEa of CLIA'88.

The criteria based on biological variation are at the second level of the hierarchical model and thus have an objective theoretical foundation. It also incorporates the biological variation of healthy people with clinical needs, making it suitable for all laboratories, regardless of laboratory size, type, and environmental factors. Therefore, criteria based on biological variation or clinical needs are more effective than statistical data and it is considered to be the most scientific and practical method for medical requirements.[21] Dr Ricos and colleagues created a global database of biological variation in healthy people and further divided it into three levels of quality: optimal, desirable, and minimum, which has been widely used by laboratories and EQA/PT organizers to set quality specifications.[29,30] The consensus statement of the 1st strategic conference of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) defined biological variation as one of the three models setting analytical performance specifications and recommended strongly for grading.[21] EFLM also proposed a theoretical rationale for selecting the best model.[31] The criteria based on biological variation provide more comprehensive and objective evaluation for evidence-based assay at the detection level of each laboratory. Our survey results revealed that only CK tests were satisfactorily standardized prior to recalibration. After recalibration, the ALT, AST, GGT, and CK tests have all met the optimal level of biological variation and the defined clinical needs, and LDH tests met desirable level. Therefore, these criteria

TABLE 6 Evaluation results of enzyme analytes based on the criteria of biological variation

Enzyme	Target value U/l	*n*	Acceptable rate of sample,% Before calibration			Satisfactory rate of enzyme,% Before calibration			Acceptable rate of sample,% After calibration		Satisfactory rate of enzyme,% After calibration	
			Optimum	Desirable	Minimum	Optimum	Desirable	Minimum	Optimum	Desirable	Optimum	Desirable
ALT	112.2	41	21.9	85.3	100.0	7.3	82.9	100	100	100	100	100
	183.3		7.3	82.9	100.0				100	100		
	82.0		9.7	87.8	100.0				100	100		
AST	101.4	41	26.8	56.0	97.6	0	26.8	53.6	100	100	100	100
	296.0		0	31.7	58.5				100	100		
	79.7		2.4	34.1	70.7				100	100		
GGT	175.7	41	85.4	100	100	78.0	97.6	97.6	100	100	100	100
	158.4		80.5	97.6	97.6				100	100		
	85.4		82.9	97.6	100				100	100		
CK	370.9	70	97.1	100	100	95.7	100	100	100	100	100	100
	205.7		98.6	100	100				100	100		
	660.6		95.7	100	100				100	100		
LDH	309.7	70	61.4	92.8	97.1	54.3	92.8	97.1	98.5	100	81.4	100
	203.0		68.6	94.3	97.1				90.0	100		
	441.9		71.4	94.3	98.6				84.2	100		

Abbreviations: ALT, Alanine aminotransferase; AST, Aspartate aminotransferase; CK, Creatine kinase; CV_G, between-subject variation; CV_I, within-subject variation; GGT, Gamma-glutamyltransferase; LDH, Lactate dehydrogenase.

TABLE 7 Evaluation results of enzyme analytes based on TEa of CLIA'88

Enzyme	Target value U/l	*n*	CLIA'88, TEa,%	Before calibration		After calibration	
				Acceptable rate of sample,%	Satisfactory rate of enzyme,%	Acceptable rate of sample,%	Satisfactory rate of enzyme,%
ALT	112.2	41	20	61.0	48.8	100	100
	183.3			53.7		100	
	82.0			51.2		100	
AST	101.4	41	20	80.5	34.1	100	100
	296.0			34.1		100	
	79.7			39.0		100	
GGT	175.7	41	20	100	97.6	100	100
	158.4			97.6		100	
	85.4			97.6		100	
CK	370.9	70	30	100	100	100	100
	205.7			100		100	
	660.6			100		100	
LDH	309.7	70	20	98.6	98.6	100	100
	203.0			100		100	
	441.9			100		100	

Abbreviations: ALT, Alanine aminotransferase; AQS (China), Analytical Quality Specifications for Routine Analytes in Clinical Biochemistry; AST, Aspartate aminotransferase; CK, Creatine kinase; CLIA'88, Clinical Laboratory Improvement Amendment of 1988; GGT, Gamma-glutamyltransferase; LDH, Lactate dehydrogenase; TEa, total allowable error.

are expected to use to assess the quality for mutual recognition laboratories.

5 | CONCLUSIONS

The enzymatic tests in Beijing need to be further standardized for mutual recognition between clinical laboratories. It is also necessary to implement trueness EQA/PT schemes to monitor the equivalence of measurement results and the success of standardization. Using evaluation criteria and quality grading based on biological variation, we can evaluate the detection level of enzymatic test results in mutual recognition laboratories more comprehensively and objectively, and provide a guarantee based on accuracy.

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CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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