Commutability of external quality assessment materials for point-of-care glucose testing using the Clinical and Laboratory Standards Institute and International Federation of Clinical Chemistry approaches

Yan Wang¹ | Mario Plebani² | Laura Sciacovelli² | Shunli Zhang¹ | Qingtao Wang¹,³ | Rui Zhou¹

¹Department of Laboratory Medicine, Beijing Chao-Yang Hospital, Capital Medical University, Beijing, China
²Department of Laboratory Medicine, Padova University Hospital, Padova, Italy
³Beijing Center for Clinical Laboratories, Beijing, China

Correspondence
Rui Zhou, Department of Laboratory Medicine, Beijing Chao-Yang Hospital, Capital Medical University, Beijing, China. Email: zr-molly@163.com
Qingtao Wang, Department of Laboratory Medicine, Beijing Chao-Yang Hospital, Capital Medical University, Beijing, China. Email: wqt36@163.com

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Abstract
Objectives: The aim of this study was to assess the commutability of three external quality assessment (EQA) materials for point-of-care (POC) glucose testing using two approaches, to identify suitable EQA materials to evaluate and monitor the quality of POC testing.

Methods: Commercial control materials (CCMs), pooled human serum samples (PHSs), and homemade human whole-blood samples (HWBs) were measured along with 33 individual clinical samples using five POC instruments and a Hitachi 7600 analyzer. Data were analyzed by Deming regression analysis with a 95% prediction interval as described in Clinical and Laboratory Standards Institute (CLSI) EP30-A, and by difference in bias analysis as described by the International Federation of Clinical Chemistry (IFCC) Working Group on Commutability.

Results: Using the CLSI approach, HWBs, CCMs, and PHSs were commutable with five, one, and two instruments, respectively. With the IFCC approach, HWBs were commutable with two instruments, while CCMs and PHSs were largely inconclusive or non-commutable on five instruments.

Conclusions: HWBs were commutable on all instruments by the CLSI approach and may be a suitable EQA material for POC testing. Although some results differed between the IFCC and CLSI approaches, both indicated that HWBs were far superior to CCMs and PHSs in commutability.

KEYWORDS
blood glucose, commutability, external quality assessment, point-of-care testing, whole blood
1 | INTRODUCTION

Point-of-care testing (POCT) is a popular means of providing laboratory testing at or near the site of patient care. It has become an important component of laboratory medicine by virtue of its portability and ease of operation by non-laboratory personnel or patients themselves.1-3 Point-of-care (POC) glucose testing plays an important role in the treatment and management of diabetes mellitus, enabling strict glycemic control and creating opportunities to increase the efficiency of clinical services to improve patient outcomes.6,7 Most analytical methods use one of three enzymatic reactions to quantify glucose: glucose oxidase (GOD), glucose dehydrogenase (GDH), or hexokinase/glucose-6-phosphate dehydrogenase (HK). In these systems, enzymatic activity produces an electrical current or color change proportional to the glucose concentration. Isotope dilution gas chromatography-mass spectrometry (ID-GC/MS) serves as a higher-order procedure in reference laboratories, while the HK method is widely accepted for routine calibration and accuracy evaluation.8

Stringent accuracy assessment criteria for both self- and hospital-based blood glucose monitoring have been proposed by many international organizations, including the International Standardization Organization (ISO) and the Clinical Laboratory and Standards Institute (CLSI).9-12 However, in clinical application, the accuracy of POC glucose testing remains unsatisfactory. Several studies have described variability in measurements made by different POC glucose instruments or between these instruments and central laboratory analyzers,13-16 mainly due to the lower specificity of the enzymes used (GOD and GDH), which make them susceptible to interference.17,18

External quality assessment (EQA) is crucial to ensure the continuous high quality of medical laboratories. Commutability is required to be able to use EQA results to evaluate the performance of participating laboratories, as it enables measurement standardization. The International Vocabulary of Metrology defines the commutability of a reference material (RM) as close agreement between the measurements of a stated quantity of the material obtained by two different measurement procedures (MPs), as well as agreement between patient sample (PS) measurements. Miller et al have suggested an EQA scoring system with six categories, based on the ability of an EQA to evaluate participant and instrument performance.19 Category I is the most desirable, as programs in this category use commutable samples with target values established by a reference system, and can evaluate both individual laboratories and MPs for reproducibility, calibration traceability, and uniformity between laboratories and between MPs. Particularly for EQAs, the lack of commutability of applied samples is internationally recognized as one of the major hurdles in achieving a Category I POC glucose testing.5,19 as it often impedes interpretation.20,21

Because evaluating the commutability of EQA materials requires consistent sample typology (capillary samples) and stringent requirements that are difficult to apply, a pragmatic evaluation approach is required to ensure the correct interpretation of results provided in POC EQA reports. The aim of this study was to assess the commutability of three types of EQA materials by two different approaches, and to define suitable EQA materials to evaluate and monitor the quality of POC glucose testing.

2 | MATERIALS AND METHODS

2.1 | Study design

As EQA materials, we evaluated commercial control material (CCM), pooled human serum (PHS), and homemade human whole blood (HWB), all at three concentrations (denoted 1-3), using five POC instruments and a laboratory-based analyzer. The commutability of EQA materials was assessed by Deming regression analysis with a 95% prediction interval (PI), as described in CLSI EP30-A22 and by bias difference analysis, as recommended by the International Federation of Clinical Chemistry (IFCC) Working Group (WG) on Commutability.23,24

2.2 | Experimental instruments

2.2.1 | Comparative instrument

A Hitachi 7600 Automatic Biochemical Analyzer (Hitachi Coro, Tokyo, Japan) was used as a comparative instrument, which uses the HK method (L-Type Glu2, YZB/JAP 0915-2003, Wako Pure Chemical Industries, Ltd.). This method is traceable to NIST standard material (SRM917) and is the generally accepted reference method for glucose measurement in central laboratories.25 The Hitachi 7600 analyzer is regularly involved in EQAs organized by the National Center for Clinical Laboratories (NCCL) in China, and its EQA results were satisfactory. Before experimentation, the analyzer was calibrated.

| Instrument       | Manufacturer         | Principle       | Reportable range, mmol/dL | Blood sample | Hematocrit, % | Lot           |
|------------------|----------------------|-----------------|---------------------------|--------------|---------------|---------------|
| ACCU-CHEK Performa | Roche Diagnostics   | GDH             | 0.6-33.3                  | C, V, A, N   | 10.0-65.0     | 474910        |
| ACCU-CHEK Active  | Roche Diagnostics   | GDH             | 0.6-33.3                  | C, V, A, N   | 20.0-70.0     | 23472431      |
| StatStrip Xpress  | Nova Biomedical      | GOD             | 0.6-33.3                  | C, V, A, N   | No interference | 0317248249   |
| CONTOUR TS        | Bayer Vital GmbH     | GDH             | 0.6-33.3                  | C, V, A, N   | 0.0-70.0      | DW6BM3E05B    |
| HORIBA LP-150C    | HORIBA STEC, Co.     | GOD             | 0.6-55.5                  | C, V, A, N   | 20.0-60.0     | 657021        |

Abbreviations: A, arterial; C, capillary; GDH, glucose dehydrogenase; GOD, glucose oxidase; N, neonate; V, venous.
with a matched chemical calibrator (Batch No 999-21401, Wako Pure Chemical Industries, Ltd.).

### 2.2.2 | POC glucose instruments

Five different mainstream-brand POC glucose instruments were evaluated in this study (Table 1). Each POC instrument was operated and performed according to the specifications of its manufacturer. We performed one run with each instrument using one lot of strips and internal control materials, and these measurements were within the specified limits, indicating that all instruments were stable throughout the analysis period.

### 2.3 | Samples

#### 2.3.1 | Individual PSs

The 33 venous blood samples (K$_2$-ethylenediaminetetraacetic acid [EDTA] anticoagulated) were obtained from residual clinical samples in the Laboratory Department of Beijing Chao-Yang Hospital, the Third Clinical Medical College of Capital Medical University (Beijing, China), and included individuals with and without diabetes mellitus. Plasma glucose concentrations ranged from 3.19 to 21.94 mmol/L. Samples from patients with anemia, sepsis, and shock, and samples that were turbid, icteric, and hemolytic were excluded. Each PS was split into two aliquots and stored no longer than 2 hours at 2-8°C prior to measurement. One aliquot was analyzed with the five POC instruments, as all five manufacturers state that their instruments are suitable for use with venous whole-blood samples. The other aliquot was immediately centrifuged at 1600 g for 5 minutes to separate the blood cells from the plasma. A 50% glucose solution was added to the separated plasma pools to produce final concentrations of 6.0, 16.0, or 28.0 mmol/L. The separated cells were fixed in a 4.0% formaldehyde and 4.0% glutaraldehyde solution for 24-48 hours at 25°C, followed by three washes with 0.9% sodium chloride, filtering, and a final centrifugation at 1600 g for 5 minutes to pellet the fixed cells. Finally, the fixed cells and the plasma pools were recombined at 1:1 ratio to generate 3.0, 8.0, and 14.0 mmol/L HWBs. The samples were aliquoted (0.3 mL/tube) and stored at 2-8°C for 2 weeks. The homogeneity and stability of the materials were evaluated according to ISO 13528.

#### 2.3.2 | CCM

Low-, medium-, and high-concentration CCMs (2.0-4.0, 5.0-12.0, and 13.0-20.0 mmol/L, respectively) were prepared and provided by Guangzhou WONDFO Biotech Co., China. The aqueous CCMs were composed of water, glucose, and human hemoglobin, and were aliquoted (0.3 mL/tube) and stabilized at 2-8°C for 2 weeks prior to experimentation. The homogeneity and stability of the materials were evaluated according to ISO 13528.

#### 2.3.3 | PHS

The PHSs were prepared by pooling serum samples collected from residual clinical serum samples in the Laboratory Department of Beijing Chao-Yang Hospital. The inclusion and exclusion criteria for individual serum samples were the same as those for PSs. PHSs of low-, medium-, and high glucose concentration (<3.5, 4.0-6.0, and 10.0 mmol/L, respectively) were collected into 50 mL test tubes. The serum pools were thoroughly mixed by inverting, aliquoted (0.3 mL/tube), and stored at 2-8°C for 2 weeks. Exposure to freeze-thaw cycles was limited to one cycle after serum collection and one cycle after pooling the sera. The homogeneity and stability of the materials were evaluated according to ISO 13528.

### 2.4 | Measurements

PSs and the three EQA materials were measured with five POC instruments and the Hitachi 7600 analyzer on the same day. All samples were adequately mixed at room temperature before analysis and measured in triplicate; for the EQA materials, three replicates were performed on each instrument. Samples were evaluated by the instruments in a set order, and the elapsed time between the first and last measurements was <30 minutes. All measurements were performed in a laboratory setting with controlled room temperature (23 ± 5°C) and humidity, according to the manufacturers’ specifications.

### 2.5 | Data analysis

Microsoft Excel 2013 (Microsoft) was used to process the data, using formulas provided in the CLSI EP30-A and IFCC WG on Commutability...
documents. Outlier values were excluded based on CLSI EP30-A section 6.3.5: exclusion of data and handling of outliers in Part 2 of the IFCC document.\textsuperscript{22,24} Of the 33 PSs, 30 were suitable for statistical analysis.

### 2.5.1 | Precision and comparability of different instruments

To evaluate the precision of each POC instrument, within-run coefficients of variation (CVs) were calculated using triplicate measurements of PSs. Passing-Bablok regression analysis was used to estimate the slopes and intercepts of each of the POC instruments vs the Hitachi 7600 analyzer, and the Spearman rank correlation coefficient was also calculated.

### 2.5.2 | Commutability assessment

Two different approaches were used for commutability evaluation. Difference plots were generated separately for comparisons between each POC instrument and the Hitachi 7600, and logarithm-transformations were determined if scattering increased with concentration.

1. According to CLSI EP30-A, the $\log_{10}$-transformed results of PSs were analyzed by Deming regression analysis. A 95% PI around the regression line was calculated using the formulas described in CLSI EP30-A Appendix C and was plotted along with the $\log_{10}$-transformed results of the three EQA materials. When the result of each EQA material fell within the 95% PI it was regarded as commutable; otherwise, it was considered non-commutable.\textsuperscript{22} As the materials in this study are used as EQAs, we have defined results touching the PI as commutable.

2. According to the recommendations of the IFCC WG on Commutability, a difference in bias approach was used. In this approach, the bias of each PS, $B_{\ln(PS)}$, was calculated as the difference between the ln-transformed mean results obtained with each POC instrument vs the Hitachi 7600 analyzer \[ \ln_{\text{POC}} - \ln_{\text{Hitachi 7600}} \]. The mean bias of all PSs, $\bar{B}_{\ln(PS)}$, was used as an estimate of the bias for the PSs. The associated uncertainty, $\bar{u}(\bar{B}_{\ln(PS)})$, was calculated as the SD of the $\ln_{\text{POC}}$ values divided by the square root of the number of PSs ($n = 30$).

The bias of each EQA material, $B_{\ln[M]}$, was calculated as the difference between the ln-transformed mean results obtained with each of the POC instruments vs the Hitachi 7600 analyzer \[ \ln_{\text{POC}} - \ln_{\text{Hitachi 7600}} \]. To estimate the associated uncertainty of $B_{\ln[M]}$, the SDs between the replicate results of the EQA materials were pooled by calculating the mean variance for each POC instrument, $\overline{\text{SD}}^2(\ln_{\text{POC}})$, and for the Hitachi 7600, $\overline{\text{SD}}^2(\ln_{\text{Hitachi 7600}})$. $\bar{u}(\bar{B}_{\ln[M]})$ was calculated using the equation:

\[
\overline{\text{SD}}^2(\ln(M)_{\text{POC}}) + \overline{\text{SD}}^2(\ln(M)_{\text{Hitachi 7600}})/p,
\]

in which $p$ is the number of replicate measurements for each EQA material. The pooled SDs of the EQA materials assumed equal SDs, which were evaluated using a precision profile as described in Part 2 of the IFCC document.\textsuperscript{24}

The difference in bias, $D_{M_i}$, was estimated as $\ln_{\text{POC}} - \ln_{\text{Hitachi 7600}}$. The associated expanded uncertainty $U(D_{M_i})$ was calculated using the equation $1.96 \times \sqrt{u^2(B_{\ln(M)}) + u^2(\bar{B}_{\ln(PS)})}$. The coverage factor 1.9 was used to obtain at least 90% coverage. To evaluate the commutability of an individual EQA material, the $D_{M_i}$ and $U(D_{M_i})$ were compared with criterion C, which was set at 10.0% (1/2 of the desirable goal for the bias) based on ISO15197.\textsuperscript{10}

In the comparability evaluation according to the IFCC WG approach, three outcomes were possible:\textsuperscript{27,28}

1. The uncertainty interval $D_{M_i} \pm U(D_{M_i})$ falls completely within $0 \pm C \rightarrow$ EQA $M_i$ is commutable.
2. The uncertainty interval $D_{M_i} \pm U(D_{M_i})$ falls completely outside $0 \pm C \rightarrow$ EQA $M_i$ is non-commutable.
3. The uncertainty interval $D_{M_i} \pm U(D_{M_i})$ falls partially overlaps with $0 \pm C \rightarrow$ EQA $M_i$ is inconclusive result.

Difference in bias ($D_{M_i}$) and associated uncertainty ($U(D_{M_i})$) values can be found in the supplementary file.

### 3 | RESULTS

#### 3.1 | Precision and comparability of different instruments

As shown in Table 2, the median within-run CVs of the five POC instruments varied from 1.36% (the HORIBA LP-150C) to 4.13% (the StatStrip Xpress). Passing-Bablok slopes and intercepts and Spearman rank correlation coefficients for each POC-Hitachi 7600 comparison are also shown in Table 2. The results from the five POC instruments showed good linear correlation, with Spearman coefficients ranging from 0.987 to 0.992. The slopes of the Passing-Bablok regression lines varied from 0.891 to 1.166, and the intercepts varied from −0.385 to 0.065.

#### 3.2 | Commutability of the EQA materials according to the CLSI approach

Commutability assessments of the three EQA materials according to the CLSI approach are shown in Figure 1. CCM-1, -2, and -3 were commutable on 3/5, 2/5, and 4/5 instruments, respectively. PHS-1 -2, and -3 were commutable on 4/5, 3/5, and 5/5 instruments, respectively. HWBs at three concentrations were commutable on all five POC instruments, exhibiting the best performance among the three EQA materials by this approach.
3.3 | Commutability of the EQA materials according to the IFCC approach

Commutability assessments of the three EQA materials according to the IFCC approach are shown in Figure 2. HWB-1, -2, and -3 were commutable on 3/5, 4/5, and 3/5 instruments, respectively, while CCMs and PHSs were inconclusive or non-commutable on all five POC instruments. All three HWB concentrations were commutable on the ACCU-CHEK Performa and HORIBA LP-150C.

3.4 | Comparative commutability of the EQA materials using the two different approaches

Table 3 summarizes the individual results for each EQA material and each POC instrument according to the CLSI and IFCC approaches. Approximately 47% of the results were consistent between the two approaches, while 47% were inconsistent (commutable vs inconclusive or non-commutable vs inconclusive). The CCM-3 results were particularly inconsistent, as they were commutable on three POC

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**TABLE 2** Precision of each POC instrument and their correlations with the Hitachi 7600 analyzer using mean PS results

| Instruments         | Within-run CV, % Median (Q1, Q3) | Intercept (95% CI)   | Slope (95% CI)   | Correlation coefficient |
|---------------------|----------------------------------|----------------------|------------------|-------------------------|
| ACCU-CHEK performa  | 2.91 (1.92, 4.05)                | -0.066 (-0.339 to 0.254) | 0.897 (0.841-0.942) | .992                    |
| ACCU-CHEK active    | 3.13 (1.34, 5.73)                | -0.385 (-0.882 to 0.056) | 1.166 (1.096-1.255) | .987                    |
| StatStrip Xpress    | 4.13 (2.03, 6.23)                | -0.227 (-0.462 to 0.074) | 0.904 (0.858-0.942) | .989                    |
| CONTOUR TS          | 3.82 (2.37, 5.08)                | -0.087 (-0.349 to 0.162) | 0.891 (0.850-0.935) | .990                    |
| HORIBA LP-150C      | 1.36 (0.49, 2.55)                | -0.065 (-0.231 to 0.146) | 1.002 (0.966-1.027) | .991                    |
| Hitachi 7600        | 0.64 (0.44, 0.87)                | N/A                  | N/A              | N/A                     |

*Note:* Regression parameters (slope and intercept) between each POC instrument and the Hitachi 7600 analyzer were calculated by Passing-Bablok regression analysis.

*Abbreviations:* CI, confidence interval; CV, coefficient of variation; N/A, not applicable.

**FIGURE 1** Commutability of the three EQA materials using the CLSI approach. Commutability assessment of the three external quality assessment (EQA) materials (commercial control materials (CCMs), pooled human serum samples (PHSs), and homemade human whole-blood samples (HWBs) according to Clinical and Laboratory Standards Institute (CLSI) EP30-A. The glucose levels of the EQA materials and patient samples (PSs) were measured with five point-of-care (POC) instruments and a Hitachi 7600 analyzer. The log-transformed results measured by the Hitachi 7600 and the POC instruments are plotted on the x- and y-axes, respectively. Solid and dashed lines represent the regression lines and the limits of the 95% PIs of Deming regressions, respectively. The black circles represent the log-transformed results of the PSs, and the blue squares, green triangles, and red circles represent the log-transformed results of the HWBs, CCMs, and PHSs, respectively.
instruments using the CLSI approach, but produced non-commutable results using the IFCC approach.

4 | DISCUSSION

The use of POCT in laboratory medicine is evolving at an increasing rate, with progressively more medical treatment decisions made based on it. Therefore, it is crucial to conduct EQAs to assess the accuracy and clinical reliability of POCT. If an EQA is category I, the consistency of results between different measuring systems can be assessed using a true value, which would improve the harmonization and standardization of POCT. However, a main issue for EQA organizers is the scarcity of commutable EQA materials that are compatible with different POC instruments.

This study aimed to assess the commutability of three EQA materials using five POC glucose instruments and a central laboratory platform through two different approaches, to identify EQA materials that are as similar to native PSs as possible.

Before assessing the commutability of the three EQA materials, we evaluated the precision and comparability of the different instruments with PSs. In terms of the allowable imprecision error of POC glucose testing, Skeie et al. stated that a within-run CV < 5.0% meets the clinical needs of 75.0% patients, with the exception of those with hypoglycemia. In this study, the HORIBA LP-150C had the best precision, and all five POC instruments were acceptable, with within-run CVs < 5.0%. The results also displayed good linear correlation in each comparison.

Commutability assessments of the three EQA materials were first performed using the CLSI EP30-A approach, which analyzes samples with the pair MPs and determines if the materials fall within the 95% PI. Bukve et al. recently demonstrated that whole-blood EQA material was commutable on three POC glucose instruments using this approach. Our study showed that HWBs were commutable on all five POC instruments at all three concentrations analyzed, while CCMs and PHSs were commutable on one and two instruments at all three levels, respectively. The CLSI approach is commonly used in RM commutability assessment; however, it has some limitations. First, the 95% PI is determined by how well correlated the analytical performances of the compared methods are, and more scatter in the relationship can easily make a material commutable. In other words, a RM can be commutable using a method with poor analytical performance but non-commutable using a method with good analytical performance. Second, this approach depends on visual inspection of where the FIGURE 2 Commutability of the three EQA materials using the IFCC approach. Commutability assessment of the three external quality assessment (EQA) materials (commercial control materials (CCMs), pooled human serum samples (PHSs), and homemade human whole-blood samples (HWBs) according to International Federation of Clinical Chemistry (IFCC) Working Group on Commutability. The glucose levels of the EQA materials and patient samples (PSs) were measured with five point-of-care (POC) instruments and a Hitachi 7600 analyzer. The mean concentrations of each POC and the Hitachi 7600 are plotted on the x-axis. The bias of the difference between the EQA materials and PSs is plotted on the y-axis. The black solid lines represent the mean bias lines of the PSs, and the red dashed lines represent the commutability criteria. The black circles represent the bias of the PSs. The blue squares, green triangles, and red circles represent the mean bias between each POC and the Hitachi 7600 for the HWBs, CCMs, and PHSs, respectively. The red bars are the expanded uncertainty in the difference in bias between the EQA materials and the mean bias of the PSs.
Consistently, our study revealed several inconclusive commutability assessment of EQA materials using these two approaches. The CCMs and PHSs were largely inconclusive or non-commutable on all five POC instruments. These results indicate that HWBs have higher commutability than CCMs and PHSs.

Recent studies have reported different conclusions for the commutability assessment of EQA materials using these two approaches. Therefore, the CLSI approach may not be ideal for assessing the commutability of EQA materials.

Difference in bias analysis to evaluate commutability was recently recommended by the IFCC WG to overcome the drawbacks of the CLSI approach. The IFCC approach determines whether the difference in bias between samples plus the uncertainty fulfills a fixed criterion to conclude whether a material is commutable, non-commutable, or indeterminate. It quantifies the closeness of agreement and the associated uncertainty between RMs and clinical samples. The fixed commutability criterion is based on clinical application requirements and the intended use of a RM. Generally, for a material used as a trueness control in calibration traceability, the criterion should be strict in commutability validation, whereas for an EQA program, the criterion might be less stringent. As currently, most glucose POC instruments have decreased precision and lower accuracy in the hypoglycemic range than central laboratory analyzers. The commutability criterion was set at 10.0%. Using this approach, HWBs were commutable with 2/5 POC instruments at all three concentrations, while the CCMs and PHSs were largely inconclusive or non-commutable on all five POC instruments. These results indicate that HWBs have higher commutability than CCMs and PHSs.

In conclusion, compared to CCMs and PHSs, HWBs had better commutability characteristics with mainstream POC glucose instruments by two different approaches, indicating that they are suitable EQA materials to evaluate and monitor the analytical quality of POC glucose testing. Furthermore, the results suggest that the IFCC approach for commutability evaluation should be used when selecting EQA materials for POCT.

CONFLICT OF INTEREST
The authors declare no conflict of interest.

ORCID
Qingtao Wang https://orcid.org/0000-0001-5291-585X
Rui Zhou https://orcid.org/0000-0003-2263-2159
REFERENCES

1. St-Louis P. Status of point-of-care testing: promise, realities, and possibilities. Clin Biochem. 2000;33:427-440.

2. Freedman DB. Clinical governance: implications for point of care testing. Ann Clin Biochem. 2002;39:421-423.

3. Lee-Lewandrowski E, Gregory K, Lewandrowski K. Point of care testing in a large urban academic medical center: evolving test menu and clinical applications. Clin Chim Acta. 2010;411:1799-1805.

4. Lewandrowski K, Gregory K, Macmillan D. Assurance quality in point-of-care testing: evolution of technologies, informatics, and program management. Arch Pathol Lab Med. 2011;135:1405-1414.

5. Pecoraro V, Germagnoli L, Banfi G. Point-of-care testing: where is the evidence? A systematic survey. Clin Chem Lab Med. 2014;52:313-324.

6. Kristensen GB, Sandberg S. Self-monitoring of blood glucose with focus on analytical quality: an overview. Clin Chem Lab Med. 2010;48:963-972.

7. Sacks DB, Arnold M, Bakris GL, et al. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chem. 2011;57:e1-e47.

8. Andreis E, Küllmer K, Appel M. Application of the reference method to standardize glucose monitoring: a focus on diabetes mellitus. Clin Chem Lab Med. 2010;48:508-515.

9. ISO 15197:2003. In vitro diagnostic test systems-requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus. Reference number ISO: 2003(E), Geneva: International Organization for Standardization; 2003.

10. ISO 15197: 2013. In vitro diagnostic test systems-requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus. Reference number ISO: 2013(E), Geneva: International Organization for Standardization; 2013.

11. ISO 22870: 2016. Point-of-care testing (POCT)—requirements for quality and competence. Geneva: International Organization for Standardization (ISO); 2016.

12. CLSI. Point-of-care blood glucose testing in acute and chronic care facilities; approved guideline. CLSI document POCT 12–A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

13. Chen ET, Nichols JH, Duh SH, Hortin G. Performance evaluation of blood glucose monitoring devices. Diabetes Technol Ther. 2003;5:749-768.

14. Khan AI, Vasquez Y, Gray J, Wians FH Jr, Kroll MH. The variability of results between point-of-care testing glucose meters and the central laboratory analyzer. Arch Pathol Lab Med. 2006;130:1527-1532.

15. Aslan B, Stemp J, Yip P, Gun-Munro J. Method precision and frequent causes of errors observed in point-of-care glucose testing. Am J Clin Pathol. 2014;142:857-863.

16. Ekhlaspour L, Mondesir D, Lautsch N, et al. Comparative accuracy of 17 point-of care glucose meters. J Diabetes Sci Technol. 2017;11:558-566.

17. Schles TG. Interference of maltose, icodextrin, galactose, or xylose with some blood glucose monitoring systems. Pharmacochemistry. 2007;27:1313-1321.

18. Erbach M, Freckmann G, Hinzmann R, et al. Interferences and limitations in blood glucose self-testing: an overview of the current knowledge. J Diabetes Sci Technol. 2016;10:1161-1168.

19. Miller WG, Jones GR, Horowitz GL, Weykamp C. Proficiency testing external quality assessment: current challenges and future directions. Clin Chem. 2011;57:1670-1680.

20. Jacobs J, Fokkert M, Slingerland R, De Schrijver P, Van Hoovels L. A further cautionary tale for interpretation of external quality assurance results (EQA): commutability of EQA materials for point-of-care glucose meters. Clin Chim Acta. 2016;462:146-147.

21. Wood WG. Problems and practical solutions in the external quality control of point of care devices with respect to the measurement of blood glucose. J Diabetes Sci Technol. 2007;1:158-163.

22. CLSI. Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine; Approved Guideline. CLSI document EP30-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

23. Miller WG, Schimmel H, Rej R, et al. IFCC working group recommendations for assessing commutability, part 1: general experimental design. Clin Chem. 2018;64:447-454.

24. Nilsson G, Budd JR, Greenberg N, et al. IFCC Working Group recommendations for assessing commutability part 2: using the difference in bias between a reference material and clinical samples. Clin Chem. 2018;64:455-464.

25. Department of Noncommunicable Disease Surveillance Geneva. World Health Organization. Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus. WHO/NCD/NCS/99.2; 1999.

26. ISO 13528: 2015. Statistical methods for use in proficiency testing by interlaboratory comparison. Geneva: International Organization for Standardization (ISO); 2015.

27. Deprez L, Toussaint B, Zegers I, et al. Commutability assessment of candidate reference materials for pancreatic amylase. Clin Chem. 2018;64:1193-1202.

28. Yan Y, Han B, Zhao H, et al. Commutability of external quality assessment materials for serum sodium and potassium measurements. Clin Chem Lab Med. 2019;57:465-475.

29. Bietenbeck A, Geilenkeuser WJ, Klawonn F, et al. External quality assessment schemes for glucose measurements in Germany: factors for successful participation, analytical performance and medical impact. Clin Chem Lab Med. 2018;56:1238-1250.

30. Skeie S, Thue G, Sandberg S. Patient-derived quality specifications for instruments used in self-monitoring of blood glucose. Clin Chem. 2001;14:67-73.

31. Bukve T, Sandberg S, Vie WS, et al. Commutability of a whole-blood external quality assessment material for Point-of-care c-reactive protein, glucose and hemoglobin testing. Clin Chem. 2019;65:791-797.

32. Yue Y, Zhang S, Xu Z, et al. Commutability of reference materials for α-fetoprotein in human serum. Arch Pathol Lab Med. 2017;141:1421-1427.

33. Zhang S, Zeng J, Zhang C, et al. Commutability of possible external quality assessment materials for cardiac troponin measurement. PLoS ONE. 2014;9:e102046.

34. Braga F, Paneghini M. Commutability of reference and control materials: an essential factor for assuring the validity of measurements in laboratory medicine. Clin Chem Lab Med. 2019;57:967-973.

35. Apple FS, Collinon PO: IFCC Task Force on Clinical Applications of Cardiac Biomarkers. Analytical characteristics of high-sensitivity cardiac troponin assays. Clin Chem. 2012;58:54-61.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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