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Original Article

Biochemistry Section

Comparative Evaluation of Reagent Lot-to-Lot Variability using In-house, NABL 112 and CLSI EP26-A Protocols: A Cross-sectional Study in a Clinical Biochemistry Laboratory

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ABSTRACT

Introduction: Reagent lot-to-lot variation represents a subtle yet significant source of analytical uncertainty in clinical laboratories. Even minor shifts between reagent lots can alter assay calibration, bias, and precision, thereby compromising longitudinal comparability and, ultimately, patient safety. Despite explicit requirements in the International Organisation for Standardisation (ISO) 15189:2022 and the National Accreditation Board for Testing and Calibration Laboratories (NABL) 112, verification procedures remain heterogeneous across laboratories and often rely on limited empirical evaluation rather than statistically defined acceptance criteria.

Aim: To undertake a comparative assessment of reagent lot-to-lot variability across seven key biochemical analytes using three verification frameworks-an in-house laboratory protocol, NABL 112, and the Clinical and Laboratory Standards Institute (CLSI) EP26-A guideline-in a NABL-accredited clinical biochemistry laboratory.

Materials and Methods: The present cross-sectional study was conducted over a twelve-month period in a tertiary care, NABL-accredited laboratory in Gujarat, India. Paired patient samples and quality control materials were analysed across reagent lot transitions on Siemens analysers. Verification outcomes were evaluated using regression analysis, Total Allowable Error (TEa), Measurement Uncertainty (MU), and Critical Difference (CD) metrics, as prescribed by the respective protocols.

Results: All analytes met the acceptance criteria under the in-house and NABL 112 protocols. Under the CLSI EP26-A framework, Thyroid-Stimulating Hormone (TSH) failed acceptance (observed difference=2.3 mIU/L>rejection limit (RL)=0.88 mIU/L), while all other analytes conformed. The EP26-A protocol required larger sample sizes and narrower rejection limits, demonstrating greater sensitivity in detecting clinically meaningful differences between reagent lots.

Conclusion: While conventional verification protocols ensure operational efficiency, the CLSI EP26-A approach provides a statistically robust and clinically aligned framework for detecting reagent lot variability. Integrating its principles into routine practice could enhance analytical reliability, regulatory compliance, and long-term traceability of patient results within accredited laboratory systems.

Keywords: Clinical and laboratory standards institute, Clinical laboratory techniques, Measurement uncertainty, National accreditation board for testing and calibration laboratories accreditation, Quality control, reagent lots

INTRODUCTION

Accurate and reproducible laboratory measurements form the foundation of modern medical diagnostics, with nearly two-thirds of clinical decisions guided by laboratory data [1,2]. Ensuring the dependability of test results is therefore critical for effective patient management and optimal clinical outcomes. To achieve this, medical laboratories have progressively strengthened their internal quality systems, incorporating method validation, verification, and daily quality control processes to maintain analytical accuracy within defined limits [3].

In recent years, increasing emphasis has been placed on aligning analytical performance characteristics with clinically relevant performance specifications [3]. Internal Quality Control (IQC) continues to serve as a cornerstone of quality assurance by providing real-time monitoring of measurement uncertainty and within-laboratory variation. Innovations such as patient-based, real-time quality control systems have further enhanced analytical surveillance and error detection [4].

Despite these advances, variation between reagent lots remains a frequently underestimated source of analytical inconsistency [5]. Each batch of reagent or calibrator, identified by a manufacturer's lot number, is produced under nominally uniform conditions [6]. In practice, however, minor variations in raw material composition, production environment, or formulation may alter reagent properties [7]. These subtle changes can influence assay bias and precision, both of which contribute to overall measurement uncertainty [8,9]. When such deviations exceed acceptable limits, longitudinal comparability may be compromised, potentially leading to clinical misinterpretation and adverse impacts on patient safety.

Reagent Lot-To-Lot Verification (LTLV) serves as an essential quality safeguard, confirming that the performance of a new reagent batch remains consistent with that of the previous lot and that observed differences fall within predefined acceptance criteria [6]. Both international and national accreditation frameworks-ISO 15189:2022 and NABL 112-mandate verification of new reagent lots prior to their implementation in routine testing [10,11]. To support laboratories in this process, the CLSI published guideline EP26-A, which provides a statistically robust methodology for evaluating between-reagent lot variation [12].

Previous comparative studies on reagent lot verification have largely been limited to two approaches-CLSI EP26-A and laboratory-specific in-house protocols-resulting in a restricted understanding that does not fully account for verification requirements across different accreditation systems [13,14]. Moreover, in-house protocols described in earlier studies vary considerably between laboratories, limiting direct comparability. To address this gap, the present study incorporates a third approach based on the NABL 112 guideline and evaluates it alongside the other two methodologies [15].

The in-house protocol evaluated in the present study is of particular interest, as it has been refined over several years in one of India's earliest NABL-accredited medical college laboratories, shaped by extensive input from assessors and laboratory consultants. By examining multiple biochemical analytes under all three verification frameworks-the in-house protocol, the NABL 112-based method, and CLSI EP26-A-the present study provides a comprehensive evaluation of reagent LTLV and offers evidence-based guidance to laboratories in selecting verification strategies that enhance analytical quality and patient safety.

MATERIALS AND METHODS

The present cross-sectional study was conducted in a NABL-accredited Clinical Biochemistry Laboratory of a tertiary care teaching hospital in rural Gujarat, India. Laboratory data generated between July 2023 and June 2024 were included for analysis. Ethical approval was obtained from the Institutional Ethics Committee of Bhaikaka University (IEC/BU/2024/Ex.08/29/2024). Following approval, the present study was conducted and analysed between September 2024 and August 2025.

Patient test results and IQC data generated during reagent lot changeovers were included in the analysis. Samples were selected based on the availability of sufficient residual volume and representative analyte concentrations, either spanning the analytical measurement range or lying near established clinical decision limits.

Study Procedure

A total of seven analytes-glucose, creatinine, vitamin B12, albumin, sodium, Alanine aminotransferase (ALT), and TSH-were included for reagent lot-to-lot comparability.

Reagent lot verifications were performed on two Siemens autoanalysers: Dimension EXL 200 and ADVIA Centaur XPT. Reagents and calibrators were procured from Siemens, and Level 1 and Level 2 quality control materials were obtained from Bio-Rad (USA). Laboratory means and Standard Deviations (SDs) for Quality Control (QC) materials were established according to institutional protocols based on ISO 15189 and NABL 112 guidelines [10,11].

Reagent LTLV protocols: Three independent approaches were compared for reagent lot verification:

1. An in-house protocol routinely followed by the laboratory
2. A NABL 112 guideline-based approach
3. The CLSI EP26-A protocol

Each method employs specific acceptance criteria and statistical principles to determine whether a new reagent lot can be safely implemented for patient testing.

In-house protocol: The in-house approach evaluated the impact of reagent lot changes by comparing results from five patient samples along with two levels of quality control-one representing the normal range and the other the pathological range. The new reagent lot was accepted for routine use only when both patient sample results and QC results met the laboratory's predefined acceptance criteria.

For QC material, both QC levels were analysed using the old and new reagent lots. Results for each level were required to fall within ±2 SD of their established means, ensuring that the introduction of a new lot did not cause any shift in routine control performance [16].

For patient samples, five specimens covering the analytical measurement range were analysed in parallel using both the old and new reagent lots. TEa for each analyte was calculated and compared with the TEa limits defined by the CLIA [17]. Acceptance criteria included a regression slope between 0.90 and 1.10, an intercept less than 0.50, and Total Error (TE) not exceeding the defined TEa thresholds [18].

NABL protocol: According to the NABL 112 guideline, at least two patient samples or QC materials were tested concurrently using both the existing and new reagent lots [18]. The percentage difference between results obtained from the two lots was compared with acceptable limits defined by the Measurement Uncertainty (MU) associated with each analyte, ensuring consistency between reagent lots.

MU, defined as a parameter associated with a measurement result that characterises the dispersion of values that could reasonably be attributed to the measurand [11], was calculated using the laboratory's IQC data collected over the preceding six months. The calculation incorporated both repeatability and calibration uncertainty components. The maximum MU value for each analyte was used as the acceptance criterion for LTLV, providing an approach aligned with the laboratory's actual analytical performance.

CLSI EP26-A protocol [12]: LTLV was also performed in accordance with the CLSI EP26-A guideline [12]. Unlike the other two approaches, both the sample size and Rejection Limit (RL) in this protocol are calculated based on the analytical performance of each parameter at a single Medical Decision Concentration (MDC), rather than being predefined.

The Critical Difference (CD) represents the maximum acceptable change between reagent lots that would be considered clinically permissible. For each analyte, CD values were defined using TEa limits specified by CLIA regulations [17]. A single MDC was selected for each analyte to represent a clinically relevant comparison threshold.

Analytical precision parameters were derived from internal QC data. Within-run precision (Sr) was determined from repeated IQC measurements within a single analytical run, while within-reagent-lot precision (SWRL) was calculated from cumulative IQC data across multiple runs using a single reagent lot. The QC level used for this purpose closely approximated the analyte's MDC.

Statistical power was set at 90%, with a Type I error rate (α) of 5%, to ensure adequate sensitivity for detecting clinically meaningful differences. Two key ratios were calculated for each analyte: CD/SWRL, representing the ratio of critical difference to within-lot imprecision, and Sr/SWRL, representing the ratio of within-run precision to within-lot imprecision.

These ratios were applied to Table A1 of the CLSI EP26-A guideline [12] to determine both the required sample size and the RL for each analyte.

The RL was calculated using the equation:

$$\text{Rejection Limit (RL)} = \text{CD} \times \text{Multiplier}$$

where the multiplier was obtained from the corresponding column in Table A1, satisfying the requirement for statistical power ≥90%. A new reagent lot was accepted only if the mean difference between results obtained from the old and new reagent lots did not exceed the calculated RL.

STATISTICAL ANALYSIS

Data were analysed using Microsoft Excel. Descriptive and analytical statistics were employed to compute the mean, SD, Coefficient of Variation (CV), MU, TE, bias, CD, and regression parameters (slope and intercept). Results were expressed as absolute values and percentages to facilitate interpretation and comparison across analytes and verification protocols.

RESULTS

In-house Protocol

Lot verification using the in-house method included regression analysis (slope and intercept) and TE assessment [Table/Fig-1]. All analytes demonstrated slope values within the predefined acceptance range of 0.90-1.10 and intercepts below 0.50. The calculated TE for each parameter was well within the respective TEa limits defined by the CLIA [17]. Consequently, all new reagent lots were accepted under the in-house protocol.

Parameters	QC (Acceptable)	Slope	Intercept	Total Error (TE)	Total Allowable Error (CLIA) [18]	Acceptability of New Lot
Glucose	Yes	0.99	0.34	5.62%	±8%	Yes
Creatinine	Yes	1.01	0.03	6.10%	±0.2 mg/dL or ±10% (greater)	Yes
Vitamin B12	Yes	0.98	0.40	19.40%	±25%	Yes
Albumin	Yes	1.00	0.06	6.80%	±8%	Yes
Sodium	Yes	0.99	0.45	3.6 mmol/L	±4 mmol/L	Yes
ALT	Yes	1.03	0.30	12.30%	±15%	Yes
TSH	Yes	0.97	0.35	17.80%	±20% or ±0.2 mIU/L (greater)	Yes

[Table/Fig-1]: Reagent lot verification outcomes based on in-house evaluation protocol.
ALT: Alanine aminotransferase; TSH: Thyroid-stimulating hormone

All analytes met the in-house acceptance criteria, indicating good analytical comparability between the existing and new reagent lots.

NABL 112 Protocol

Under the NABL 112 guideline, differences between results obtained using the existing and new reagent lots were compared with the maximum MU calculated over the previous six months. As shown in [Table/Fig-2], all seven analytes exhibited percentage differences within their respective MU limits. Therefore, all new reagent lots were considered acceptable according to the NABL 112 protocol.

Parameters	Difference between old and New Lots (%)	Maximum MU (6 months)	Acceptability of new lot
Glucose	4.30	5.29%	Yes
Creatinine	5.10	6.57%	Yes
Vitamin B12	16.80	19.21%	Yes
Albumin	6.10	7.64%	Yes
Sodium	5.50	6.27%	Yes
ALT	10.90	11.95%	Yes
TSH	17.40	18.62%	Yes

[Table/Fig-2]: Reagent lot verification outcomes based on NABL 112 protocol.
ALT: Alanine aminotransferase; TSH: Thyroid-stimulating hormone

The MU-based assessment confirmed that the performance of all new reagent lots was consistent with that of the preceding lots, indicating satisfactory analytical stability.

CLSI EP26-A Protocol

As presented in [Table/Fig-3], six of the seven analytes met the acceptance criteria, with observed differences remaining below the calculated RLs. However, the new TSH reagent lot showed a mean difference of 2.3 mIU/L, exceeding the RL of 0.88 mIU/L, and was therefore not accepted under this protocol. All other analytes satisfied the EP26-A requirements.

Across all three verification methods, six analytes-glucose, creatinine, vitamin B12, albumin, sodium, and ALT-met their respective acceptance criteria, demonstrating stable analytical performance across reagent lots. The EP26-A protocol, however, identified a clinically significant deviation in TSH that was not detected by either the in-house or NABL 112 methods.

Parameters	Medical Decision Level (MDL)	Required patient samples	Critical Difference (CD)	Clinical utility factor	Rejection Limit (RL)	Average difference (old vs new)	Acceptability of new lot
Glucose	130 mg/dL	4	10	0.6	6	4.3	Accept
Creatinine	1.3 mg/dL	3	0.2	0.7	0.14	0.1	Accept
Vitamin B12	250 pmol/L	3	63	0.8	50	36	Accept
Albumin	3.5 g/dL	1	0.3	0.7	0.19	0	Accept
Sodium	140 mmol/L	8	4	0.6	2.4	1.6	Accept
ALT	60 U/L	1	9	0.7	6.3	4.2	Accept
TSH	5.5 mIU/L	7	1.1	0.8	0.88	2.3	Reject

[Table/Fig-3]: Reagent lot verification outcomes based on CLSI EP26-A protocol.

This finding highlights the greater analytical sensitivity and statistical stringency of the CLSI EP26-A approach in detecting reagent lot variability. While both the in-house and NABL protocols are practical for routine implementation, the EP26-A guideline provides a more robust framework for ensuring clinical reliability of laboratory results.

DISCUSSION

Reagent LTLV is a critical component of quality assurance in accredited clinical laboratories, as undetected lot-related bias can compromise longitudinal patient monitoring and clinical decision-making. In the present study, three reagent lot verification approaches-an in-house protocol, the NABL 112 guideline, and the CLSI EP26-A protocol-were systematically compared across seven commonly requested biochemical and immunoassay analytes. The findings revealed clear differences in analytical sensitivity and clinical robustness among these approaches.

The in-house protocol employed in this laboratory combined regression analysis, TE assessment, and IQC monitoring. This approach is operationally simple and widely used, particularly in high-throughput laboratories, as it requires a limited number of patient samples and relies on readily available QC data. In the present study, all seven analytes met the predefined acceptance criteria under the in-house protocol. However, this method primarily assesses overall agreement and analytical stability and may fail to detect subtle but clinically meaningful lot-to-lot differences, especially at specific medical decision levels. Similar limitations of in-house and QC-driven lot verification methods have been reported previously, wherein acceptable regression parameters did not necessarily ensure clinical equivalence between reagent lots [16,19].

The NABL 112 guideline adopts measurement uncertainty as the basis for acceptance, thereby linking lot verification to the laboratory's actual analytical performance. In the present study, all analytes demonstrated percentage differences within the calculated MU limits, and all new reagent lots were accepted. This MU-based approach is more structured than purely in-house methods and aligns well with ISO 15189 requirements [10,11]. However, MU is a top-down estimate derived from historical IQC data and does not explicitly incorporate analyte-specific medical decision concentrations or statistical power considerations. Consequently, the NABL 112 approach may permit acceptance of reagent lot differences that are analytically acceptable but potentially clinically significant, particularly for assays used in long-term monitoring or endocrine testing.

In contrast, the CLSI EP26-A protocol applies a statistically rigorous framework by defining analyte-specific Critical Differences (CDs), medical decision levels, and RLs based on predefined statistical power [12]. In the present study, EP26-A required a higher number of patient samples for sodium (n=8) and TSH (n=7), reflecting the higher analytical variability and greater clinical sensitivity associated with these assays. Importantly, while six analytes met the EP26-A acceptance criteria, the TSH reagent lot was rejected under this protocol despite being accepted by both the in-house and NABL methods. This discordance highlights the superior sensitivity of EP26-A in detecting clinically significant lot-to-lot variation that may not be evident using simplified verification strategies.

These findings are consistent with earlier reports demonstrating that EP26-A frequently recommends larger sample sizes and stricter RLs compared with conventional methods [19,20]. Katzman BM et al., observed that immunoassays, in particular, often require more stringent evaluation because of method-specific imprecision and calibration dependency [19]. Similarly, Tao R et al., in a multi-analyte chemiluminescence study, reported that EP26-A identified lot-related differences that were missed by routine QC-based verification, although acceptance thresholds varied depending on how total allowable error was defined [21]. The rejection of the TSH lot in the present study underscores the susceptibility of immunoassays to lot-related shifts and supports the preferential use of EP26-A for such parameters.

Overall, this comparative assessment demonstrates that while the in-house and NABL 112 protocols are practical and suitable for routine implementation, they may lack sufficient analytical sensitivity for high-risk analytes. The CLSI EP26-A protocol, although more resource-intensive, provides a statistically sound and clinically meaningful framework for reagent lot verification. A risk-based strategy may therefore be optimal, whereby EP26-A is applied to analytes with high clinical impact or known analytical variability, while simpler approaches are reserved for low-risk parameters. Such a hybrid approach balances operational feasibility with patient safety and aligns with contemporary quality management principles in accredited laboratories.

Limitation(s)

Although the present study provides valuable insights into reagent lot verification methodologies, it has certain limitations. Ideally, multiple medical decision levels should be used to determine the appropriate sample size for each decision point in order to enhance clinical relevance. The relatively small number of analytes and reagent lots assessed may not capture the full extent of lot-to-lot variability across different biochemical platforms. Additionally, as the present study was confined to a single laboratory setting, the generalisability of the findings may be limited, given potential variations in instrumentation, patient populations, and reagent manufacturing conditions across laboratories. The retrospective use of quality control data for precision estimation may also introduce a degree of bias, potentially affecting the robustness of the analytical performance estimates.

CONCLUSION(S)

This study compared three reagent LTLV approaches-an in-house protocol, the NABL 112 guideline, and the CLSI EP26-A framework-across seven biochemical analytes. While all analytes met acceptance criteria under the in-house and NABL methods, only the EP26-A protocol identified clinically significant variation, with TSH failing acceptance, thereby highlighting its superior analytical sensitivity. Although more resource-intensive, the EP26-A guideline offers a statistically rigorous, analyte-specific approach that incorporates critical differences, medical decision levels, and defined rejection limits. This enables more reliable detection of reagent variability than conventional fixed-sample verification protocols. Based on these findings, our laboratory refined its internal verification process by incorporating additional patient samples at key decision thresholds and introducing regression-based trend monitoring for early detection of analytical shifts. Overall, EP26-A provides a comprehensive, evidence-based framework for ensuring analytical precision and patient safety, and its broader adoption could substantially strengthen quality assurance practices in accredited clinical laboratories.

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