Original Article

Lot to Lot Reagent Verification: A Practical Guide on How to Do It?

Manoj A. Kahar[1,*], PrashantKumar Jagubhai Patel[2]

[1]Department of Histopathology, Bhanumati Clinical Laboratory, Navsari, India
[2]Department of Pathology, Kiran Multisuperspeciality Hospital and Research Centre, Surat, India

***Correspondence:** manoj$_k$ahar@yahoo.com

DOI
10.21276/apalm.3731

Article History
Received: 10-10-2025
Revised: 15-01-2026
Accepted: 18-01-2026
Published: 06-02-2026

How to cite this article
Kahar MA, Patel PJ. Lot to Lot Reagent Verification: A Practical Guide on How to Do It?. Ann Pathol Lab Med. 2026;13(2):A94-A100.

Abstract

Background: Lot to Lot reagent verification (LTLV) is done to check suitability of new lot of reagents for use. Except EP26, 2nd edition, 2022 by Clinical and Laboratory standards Institute, hardly any guidance document is available for LTLV. In present study, authors guide on how to perform LTLV using In-house & EP26 protocol with examples of Glucose, Aspartate Amino Transferase (AST) & Cholesterol using Quality control material and Patient Samples. The difficulties using EP26 protocol for LTLV have also been stated.

Methods: For In-house protocol,15 patient samples were assayed using current & candidate lot of reagents for Glucose, AST and Cholesterol. Acceptance Criteria were predetermined to verify the suitability of candidate lot. MedCalc software, current version 23 was used for statistical calculations. For EP26 protocol, in stage1, Total Allowable Error (TEa), Critical difference, Sr (within-run imprecision) & SWRL (within reagent imprecision) & Statistical power of 0.8 were determined. In stage 2, number of patient samples needed to be assayed for LTLV was determined using Appendix A in EP26 & Rejection Limit (RL) was derived. Absolute Mean Difference was calculated and verified to be less than RL.

Results: For In house protocol, all the predetermined Acceptance criteria were met by the candidate lot of reagents. For EP26 protocol, Absolute Mean difference between the results obtained in current and candidate lot was less than the determined RL.

Conclusion: Laboratories Can use Inhouse protocol or EP26 protocol with its inherent difficulties to perform LTLV using guidance provided in this article.

Keywords: lot; reagent; verification; ep26; in-house; protocol

Introduction

Laboratory tests are used for screening & diagnosing a disease, monitoring treatment or for prognosis.[1] For the purpose of monitoring & prognosticating a disease, the laboratories should maintain consistency of results. Verification of new lot of reagents for its suitability for use is a good laboratory practice and is a requirement to be met as per International & National Standards. [2, 3] Reagents lot verification practices vary widely among laboratories with regards to the number of samples evaluated, the type of material tested, and the criteria used for acceptance.[4] Challenges faced with Lot-To-Lot reagent Verification (LTLV) include: Definition of a reagent lot, Selecting acceptance target, Commutability of material used, Range of concentration and number of samples used, Experimental design and statistical analysis to be done.[5] Laboratories use either In-house protocol or EP26: User Evaluation of Acceptability of a Reagent Lot change, 2nd edition, 2022[6] as a

guidance document to verify the consistency of results between consecutive reagent lot changes. Our study provides a guide to implement reagent lot to lot verification with examples for Glucose, Aspartate Amino Transferase (AST) & Cholesterol using patient samples & Quality Control Material by In-house protocol and EP 26 protocol[6]. The current article also discusses the difficulties observed while using EP26 protocol for LTLV in our study.

Materials and Methods

In the current study for Lot-To-Lot Reagent verification (LTLV), two protocols (In-house & EP 26) were used. Assays were carried for Glucose, AST & Cholesterol concurrently on receipt of new lot of lot reagents (candidate lot) & before the old lot (current lot) of reagents got exhausted. Patient samples as well as Internal Quality Control (IQC) material (Bio-Rad) Control Level 1 (Lot No. 89731) and Level 2 (Lot no. 89712) were used in the study. All the above assays were performed in Fully Automated Chemistry Analyser Mispa Nano Plus, Agappe diagnostics.

In-house protocol

Patient's samples were chosen to avoid the issue of commutability seen in IQC material for In-house Protocol. Patient samples for Glucose, AST and Cholesterol were chosen at three concentrations. Guidance in selecting concentration for patient samples in current study was derived from Medical Decision Levels chart provided in Westgard QC [7] and also to span the Analytical Measuring Range (AMR) of the method. A total of 15 patient samples (5 each at three concentrations) were assayed using current & candidate lot of reagents for Glucose, AST and Cholesterol. Mean difference % (Delta difference in %) between the results obtained in both lots were calculated & other calculations were done to meet In-house acceptance criteria as described below.

Acceptance for lot verification for in-house protocol

Acceptance for lot verification for In-house protocol were as followed: - Average delta % (Mean difference) in results obtained in patient's sample results between two lots be $<$10% Delta % = (candidate lot result – current lot result / current lot result x 100) Passing- Bablok regression analysis was done by MedCalc software trial version with the acceptance criteria being Regression line gradient between 0.9 and 1.1 R2 $>$0.95 Mean difference % between the results obtained between two lots $<$1/3 of Total Allowable Error (TEa). For choosing the TEa, Westgard website was consulted.[8] (In case if this criterion is not met than Total TEa rather than 1/3 of TEa was considered as per the Mc Master University Protocol)[9] Paired t -test between the current and candidate lots of reagent – Average relative difference significantly different from zero (alpha is set at 0.005)

EP 26 (User evaluation of acceptability of a reagent lot change, 2nd edition, 2022) protocol using two stages

To use EP 26 document, Bio rad Level 1 & Level 2 IQC material were assayed 20 times in a single run in current lot & candidate lot to calculate Sr (SD obtained for a sample within a single run) & SWRL (SD obtained from 20 readings in different runs).

Stage 1: Protocol parameters determined as below

A Relevant TEa was established for Glucose, AST and Cholesterol as 10%, 20% and 10% respectively using Westgard.[8] Critical difference was taken as half of TEa [10] Sr (within-run imprecision) and SWRL (within-reagent imprecision) values were obtained from IQC data at two decision levels of control material from historic IQC data of laboratory from current lot of reagents. Statistical power was chosen as 0.8 for Glucose, AST and Cholesterol tests. As per Kim et al[10] Rejection Limit (RL) was taken as 0.6x CD as this RL has 90% probability to detect variation in performance of new lot. EP 26 states that 0.70 X CD results in a statistical power close to 0.90, however when we use 0.6xCD the statistical power of RL around 0.9 is achieved for detecting clinically significant change while minimizing the probability of false rejection. Tables A1 to A3 from Appendix A of EP26 were then used to determine how many patient samples need to be tested to detect a reagent lot-to-lot difference that exceeds the CD. CD/SWRL and Sr/SWRL were calculated and used to select patient sample number to be tested for LTLV from tables A1 to A3 given in EP26.

Stage 2: Routine evaluation of candidate reagent lots

Mean Difference (MD) as Absolute difference between the results obtained using patient samples in lots Reagents were calculated. If the mean difference was less than Rejection limit (|MD| <RL), the candidate lot reagent was accepted for routine use. If mean difference was more than RL, a Root Cause Analysis was done to identify the Root Cause and initiated corrective action using troubleshooting guidance provided by Thompson & Chester D.[11]

Results

Five different patient samples at three different concentrations were assayed in current & candidate lots of reagents for Glucose, AST & Cholesterol. The Mean difference % between them was then calculated. The results of this exercise are shown in Table No 1.

Table 1: Results of five patient samples assayed at three concentrations for glucose, AST, and cholesterol.

Patient	Concentration 1		Concentration 2		Concentration 3	
No.	Current	Candidate	Current	Candidate	Current	Candidate
Glucose						
	(57 mg/dl)		(114 mg/dl)		(311 mg/dl)	
1	58	59	113	116	311	313
2	57	58	116	114	310	312
3	59	59	115	114	314	311
4	58	57	114	113	312	313
5	56	57	113	115	311	314
Avg. Conc.	57.6	58.0	114.2	114.4	311.6	312.6
Mean Diff %	−0.69%		−0.18%		−0.32%	
AST						
	(22 U/L)		(35 U/L)		(142 IU)	
1	22	24	36	35	141	142
2	24	23	35	36	145	146
3	23	21	35	36	142	140
4	22	24	34	35	143	145
5	23	22	36	37	143	145
Avg. Conc.	22.8	22.8	35.2	35.8	142.8	143.6
Mean Diff %	0.00%		−1.70%		−0.56%	
Cholesterol						
	(103 mg/dl)		(184 mg/dl)		(245 mg/dl)	
1	103	104	184	182	246	247
2	105	103	185	183	244	245
3	102	104	183	182	247	247
4	104	103	184	185	246	244
5	103	105	185	184	245	246
Avg. Conc.	103.4	103.8	184.2	183.2	245.6	245.8
Mean Diff %	−0.39%		0.54%		−0.08%	

Once the results of Comparison studies were obtained using patient samples in current & candidate lots of reagents, predetermined acceptance criteria for our In-house protocol were used & the findings are depicted in Table 2.

Discussion

Laboratories play a vital role in treatment decision by providing accurate, precise, and consistent results. Consistency in result reporting is of most importance in sequential test results when critical decisions have to be made on any change in treatment modalities. Limited guidance is available on lot-to-lot verification of reagent change.[5, 6, 11, 12, 13] Clinical laboratories use either In-house protocol based on references like B.M. Katzman et al[4], A.C. Don-Wauchope[9], Kim et al[10], Thompson S & Chesher D[11] & Martindale et al [13]or use EP26[6]. Critical issues to be considered while performing LTLV verifications are, Type, number of samples & concentration levels to be used and Acceptance criteria to decide whether the new lot is acceptable or not. As regards number of patient sample and concentrations of samples

Table 2: Reagent lot verification and acceptability using in-house lot to lot verification protocol and predetermined acceptance criteria based on results shown in table 1.

In house acceptance criteria	Glucose Patient sample			AST Patient sample			Cholesterol patient sample		
Concentration of samples assayed	57 mg/dl	114 mg/dl	311 mg/dl	22 U/L	35 U/L	142 IU	103 mg/dl	184 mg/dl	245 mg/dl
Mean Difference (Average Delta) % <10%	0.69%	0.18%	0.32%	0%	1.7%	0.56%	0.39%	0.54%	0.08%
All value below < 10%	All value below < 10%			All value below < 10%			All value below < 10%		
Result	Acceptable			Acceptable			Acceptable		
Mean Difference (average delta) %<1/3 of TEa	0.69%	0.18%	0.32%	0%	1.7%	0.56%	0.39%	0.54%	0.08%
All value below 1/3 TEa i.e 3.33% (TEa 10%, 1/3 TEa=3.33%)	All value below 1/3 TEa i.e 3.33% (TEa 10%, 1/3 TEa=3.33%)			All value below 1/3 TEa i.e 6.66% (TEa 20%, 1/3 TEa=6.66%)			All value below 1/3 TEa i.e 3.33% (TEa 10%, 1/3 TEa=3.33%)		
Result	Acceptable			Acceptable			Acceptable		
Paired T test P value (Two-tailed probability)	0.3739	0.8466	0.3943	0.6483	0.1419	0.7489	1	0.2080	0.3375
Which is > 0.05	Which is > 0.05			Which is > 0.05			Which is > 0.05		
Result	Acceptable			Acceptable			Acceptable		
(Coefficient of determination) >0.95	0.9999	0.995	0.9997						
Result	Acceptable			Acceptable			Acceptable		
Regressing line gradient (Slope)	1	1	1						
Result	Acceptable			Acceptable			Acceptable		

to be tested for LTLV, published studies have used 1 to 20 samples using either Medical Decision Level concentration or Analytical Measuring Range to achieve a statistical power of 0.8 or 0.9.[4, 9, 11, 14] EP26 recommends a minimum of 3 patient's samples always to be tested for LTLV which may be dispersed among the target concentrations. In our study, we have used 5 patient samples at three different concentrations spanning the AMR. Kim et al[10] have concluded that >1/2 of chemistry tests reagent lot to lot difference could be evaluated using only one patient sample. Our In-house protocol for LTLV uses 5 patient samples at three different concentrations & this 5-patient sample number also meets the number of samples required to be assayed as per tables given in appendix A of EP26 based on CD/SWRL and Sr/SWRL. Beside patient samples, IQC material can also be used for LTLV however commutability issues limit its use for this purpose[11]. Cho et al [15] have provided evidence that usefulness of the IQC material data in establishing the suitability of a new lot of reagents is limited. Studies published on acceptance criteria for In-house protocol for LTLV using either patient samples or QC material vary and are summarized below in Table no.3.

Laboratories can decide upon which and how many parameters will be used in their acceptance criteria for LTLV from the Table no.3 and it will depend upon availability of statistical software and expertise with the laboratory. If laboratory choses to use EP26 protocol then clinically relevant Allowable total Error (TEa), Critical Difference (CD), Statistical power & Rejection Limit have to be selected in stage 1 (Determining protocol parameters)[6]. TEa are established based on hierarchy models viz Model 1 (Clinical outcomes), Model 2 (Biological variation) and Model 3 (state of the art) as per Milan criteria [16]. For practical purposes, laboratories can use Westgard website[8] or European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) database[17] to select the TEa.

Critical difference (CD) represents the maximum lot to lot difference at which a candidate lot is acceptable for use without affecting clinical decision making Unfortunately, EP26 does not provide a definite approach to determine CD and the onus is on the laboratory to determine the CD. Kim et al[10] have provided three options for determining CD 1)Reference change value (RCV) = CD (1.96 x 20.5 x (S2 WRL + CVi2)0.5, SWRL is EP26 term for within reagent lot imprecision (intra assay imprecision) and CVi is within Subject biological variation. SWRL is obtained from the historic IQC data available with the laboratory. Alternatively, SWRL value can also be obtained from Manufacturer's Instructions for Use (IFU) stated usually as Interassay Imprecision. CVi data can be obtained from (EFLM) database [17] or from the Westgard website[18] If no CVi data is available on either of the above resources then CVi can be considered as 10.0 % 2) CD = ½ of TEa If TEa data is not available for particular analyte in either EFLM database or Westgard website then CD can be set as 10.0% 3) CD can be based on Analytical Performance Specifications (APS) provided by External Quality Assessment (EQA) agencies. Kim et al[10] recommends to use stricter acceptable criteria either from Clinical Laboratory Improvement Amendments (CLIA) or Rili-BAEK as CD When there are no defined acceptable limits for APS in either of the above EQA agencies then CD can be taken as 10% B.K. Katzman et[4] al have calculated CD based on Target performance goal and Target concentration as CD= Target performance goal x Target concentration Tao et al [19] considers CD as CD=4.36 x CVWRL Out of the above all the approaches for calculating CD, best option would be CD=1/2 of TEa because it avoids complicated calculations and is easy for determining CD. B.M. Katzman et [4]al sets statistical power 0.80 while using EP26. In our study we have chosen statistical power of 0.8 for using EP26. Kim et al [10]have inferred that rejection limit of 0.6 x CD can detect reagent lot-to-lot difference with $\geq$ 90%.

In our study we have used this recommendation to calculate RL which gives a chance to detect variability in the candidate lot reagents performance. 1. To use EP 26 Protocol, information derived from stage 1 is used to determine concentration(s) of patient samples to be tested, number of samples to be evaluated at each concentration & then RL is used to evaluate the average difference observed at each concentration To determine the number of samples to be assayed in current & candidate

Table 3: Acceptance criteria used by various studies for LTLV either using patient samples and/or IQC material.

Material used for LTLV	Cho et al[15]	Thompson S & Chesher D[11]	A.C. Don-Wauchope[9]	B.M. Katzman et al[4]
Patient's sample	Delta % of the patient's sample results of with the new and old lots fall within ± 10%	New lot of reagents acceptable when the results tested with new lots fall into mean +- 2SD derived from the initial evaluation study	In paired t-test between the two lots Average relative difference significantly different from zero (alpha is set at 0.05)?	A comparison based on biological variation – Is the difference between the two sets of results <33% of the within-subject biological variation (CVi)? Based on Royal college of pathologists of Australasia Quality Assurance Programs (RCQAP) – Do any of the individual differences exceed these specifications?
	NA	Difference between results in new & old lot of reagents should be one third of Total Error Allowable (TEa) for a particular analyte	Slope of regression line between 0.9 & 1.1	Linear regression equation should fall within 10% of equivalence
IQC material	Results using QC material with new lot of reagents should fall within 2 standard deviations of the current mean	<10% mean difference between reagent lots	Intercept (<50%)	Lowest reportable concentration slope between 0.90 and 9.10
			Slope between 190 and 1.10	
	R2 > 0.95	NA		

lot, laboratory has to use Table A1 to A3 provided in Appendix A of EP26. For this purpose, laboratory need values of CD/SWRL and Sr/SWRL.

Approaches to determine CD have been discussed earlier. Sr & SWRL values can be obtained from laboratory's historic IQC data & performance verification data for the current lot of reagents. To obtain SWRL value from candidate lot, laboratory has to capture new 20 QC events which makes SWRL from candidate lot impracticable for routine use, so we recommend to use Sr & SWRL values from IQC data of control material at two decision levels from current lot of reagents. Manufactures IFU also provide values for Sr and SWRL, The Sr and SWRL values provided by the manufacturer are derived in highly regulated conditions which may not reflect the infield/real life situation of laboratories, so we recommend to use Sr and SWRL values from laboratory's historic IQC data of control material assayed at two decision levels in both lots of reagents.

In our study as we have used five sets of patient samples at each of the three concentrations, we chose Table A3 to determine the number of patients samples to be assayed in current candidate lots.

Table 4: Parameter used in our study to determine number of patient samples to be assayed for LTLV using table A3 of appendix A in EP26.

Parameter	Decision Levels	Sr	SWRL	TEa	CD=1/2 TEa	CD/ SWRL	Sr/ SWRL	RL	Number of samples to be tested as per Table A3 of Appendix A of EP26
Glucose	Level 1	1.22	1.87	10	5	3.21	0.65	3	5
	level 2	2.59	5.8	10	5	1.03	0.45	3	5
Cholesterol	Level 1	2.42	2.9	10	5	2.07	0.83	3	3
	level 2	3.64	5.88	10	5	1.02	0.62	3	3
AST	Level 1	1.35	2.65	20	10	4.53	0.51	6	5
	level 2	2.23	4.54	20	10	2.64	0.49	6	5

Lastly Rejection Limit is calculated & it is used to see that Absolute Mean Difference between the results obtained between current & candidate lot of reagents is less than RL. (|MD| <RL), Difficulties observed by us and other researchers [4, 9, 10, 11, 20] while using EP26A/EP26 are summarized below: RL is decided by CD which largely depends on TEa

Table 5: Simplified steps to use EP 26 Protocol using worked examples of Glucose, AST & Cholesterol reagents (adapted from Supplementary material in study by Kim et al[10]).

Evaluation Steps	Decision Level 1	Decision Level 2
Glucose		
Step 1: Parameters (S_r, SWRL)	S_r 1.22% SWRL: 1.87%	S_r 2.59% SWRL: 5.8%
Step 2: Critical Difference (CD)	CD using TEa=10, CD=5	CD using TEa=10, CD=5
Step 3: Ratios (CD/SWRL, S_r/SWRL)	CD/SWRL = 3.21, S_r/SWRL = 0.65	CD/SWRL = 1.03, S_r/SWRL = 0.45
Step 4: Sample Size & RL	Power: 0.8, Size: 5, RL: 3 (0.6xCD)	Power: 0.8, Size: 5, RL: 3 (0.6xCD)
Step 5: Assay Results (mg/dl)	Current/Cand: 57.6/58	Current/Cand: 311.6/312.6
Step 6: $\|MD\| < RL$	MD: 0.4, RL: 3	MD: 1, RL: 3
Result	**Acceptable**	**Acceptable**
AST		
Step 1: Parameters (S_r, SWRL)	S_r 1.35% SWRL: 2.65%	S_r: 2.23% SWRL: 4.54%
Step 2: Critical Difference (CD)	CD using TEa=20, CD=10	CD using TEa=20, CD=10
Step 3: Ratios (CD/SWRL, S_r/SWRL)	CD/SWRL = 4.53, S_r/SWRL = 0.51	CD/SWRL = 2.64, S_r/SWRL = 0.49
Step 4: Sample Size & RL	Power: 0.8, Size: 5, RL: 6 (0.6xCD)	Power: 0.8, Size: 5, RL: 6 (0.6xCD)
Step 5: Assay Results (U/L)	Current/Cand: 35.2/35.8	Current/Cand: 142.8/143.6
Step 6: $\|MD\| < RL$	MD: 0.6, RL: 6	MD: 0.8, RL: 6
Result	**Acceptable**	**Acceptable**
Cholesterol		
Step 1: Parameters (S_r, SWRL)	S_r 2.42% SWRL: 2.9%	S_r 3.64% SWRL: 5.88%
Step 2: Critical Difference (CD)	CD using TEa=10, CD=5	CD using TEa=10, CD=5
Step 3: Ratios (CD/SWRL, S_r/SWRL)	CD/SWRL = 2.07, S_r/SWRL = 0.83	CD/SWRL = 1.02, S_r/SWRL = 0.62
Step 4: Sample Size & RL	Power: 0.8, Size: 3, RL: 3 (0.6xCD)	Power: 0.8, Size: 3, RL: 3 (0.6xCD)
Step 5: Assay Results (mg/dl)	Current/Cand: 103.4/103.8	Current/Cand: 245.6/245.8
Step 6: $\|MD\| < RL$	MD: 0.4, RL: 3	MD: 0.2, RL: 3
Result	**Acceptable**	**Acceptable**

Note: Manufacturer's IFU for S_r and SWRL was not used; however, laboratories have the option to use it for detecting S_r and SWRL.

and which TEa to be used is not clearly stated in EP26. Samples sizes and RL vary on the approaches to determine CD viz RCV, TEa or EQA/PT EP26 often suggests large sample size making this protocol at times impractical to be used in terms of technologist's time needed, cost of reagents used, availability of instrument time for LTLV and inaccessibility to the required number of patient samples. Columns in tables A1 to A3 in Appendix A of EP26 at times do not match the CD/SWRL & Sr/SWRL decided by the laboratory, raising difficulties to decide upon the patient samples for LTLV. EP26 is not designed to monitor the long-term trends of lot-to-lot performance.

Conclusion

If change in performance of recent lots is not adequately verified statistically it may affect the quality of the results offered by the laboratory. Different protocols for LTLV are available in literature and laboratory has to take a pragmatic approach in selecting protocols for its own LTLV. EP26 provides guidance on LTLV, however it leaves acceptance criteria for LTLV to be determined by the laboratory, therefore harmonization of acceptance criteria for LTLV is needed. In our study, we have found EP26 protocol to be quite demanding in terms of cost, expertise needed, instrument time and type and number of patient samples needed for LTLV. A small sized laboratory with its limited resources can design its own In-house protocol which provides enough statistical robustness to perform LTLV using guidance provided in this article.

Ethical Clearance

The study used residual patient samples after reporting their results, patients were not harmed during the study and no patient's identity is disclosed in the study so as per Helsinki declaration, the ethical clearance is waived.

Acknowledgement

Authors acknowledge the help offered by Miss Trisha Wade (Laboratory Staff) in typing the manuscript).

Abbreviations: None.

Funding: Nil.

Competing Interests: Biochemistry, Histopathology, Cytology and Immunology.

References

1. Hicks AJ, et al. Using clinical guidelines to assess the potential value of laboratory medicine in clinical decision-making. Biochem Med (Zagreb). 2021;31(1):1–11.
2. Medical Laboratories—Requirements for Quality and Competence. ISO: Geneva, Switzerland, 2022. Fourth. Geneva: SO: Switzerland; 2022. 1–62 p.
3. NABL. Guidance document: Medical Laboratories. Vol. NABL 112B. 2024. 1–43 p.
4. Katzman BM, Ness KM, Algeciras-Schimnich A. Evaluation of the CLSI EP26-A protocol for detection of reagent lot-to-lot differences. Clin Biochem. 2017 Sep 1;50(13–14):768–71.
5. Loh TP, Sandberg S, Horvath AR. Lot-To-lot reagent verification: Challenges and possible solutions. Clin Chem Lab Med. 2022 Apr 1;60(5):675–80.
6. User Evaluation of Acceptability of a Reagent Lot Change A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process. 2nd Edition [Internet]. Available from: www.clsi.org.
7. https://westgard.com/resources/resources/decision.html.
8. https://westgard.com/clia-a-quality/quality-requirements/consolidated-comparison-of-chemistry-per html.
9. Don-Wauchope AC. Lot change for reagents and calibrators. Vol. 49, Clinical Biochemistry. Elsevier Inc.; 2016. p. 1211–2.
10. Kim S, Chang J, Kim SK, Park S, Huh J, Jeong TD. Sample size and rejection limits for detecting reagent lot variability: Analysis of the applicability of the Clinical and Laboratory Standards Institute (CLSI) EP26-A protocol to real-world clinical chemistry data. Clin Chem Lab Med. 2021 Jan 1;59(1):127–38.
11. Thompson S, Chesher D. Lot-to-Lot Variation. Vol. 51, Clin Biochem Rev.
12. Loh TP, Markus C, Tan CH, Tran MTC, Sethi SK, Lim CY. Lot-to-lot variation and verification. Vol. 61, Clinical Chemistry and Laboratory Medicine. De Gruyter Open Ltd; 2023. p. 769–76.
13. Martindale RA, Cembrowski GS, Journault LJ, Crawford JL, Tran C, Hofer TL, et al. Validating New Reagents: Roadmaps Through the Wilderness. Lab Med. 2006 Jun 1;37(6):347–51.
14. Krishnan RA, Kumari SJ, Raj S. Comparison of Sample Size and Rejection Limits for Lot-to-Lot Verification Using Two Different Protocols: A Cross-sectional Study. NATIONAL JOURNAL OF LABORATORY MEDICINE. 2024;
15. Cho MC, Kim SY, Jeong TD, Lee W, Chun S, Min WK. Statistical validation of reagent lot change in the clinical chemistry laboratory can confer insights on good clinical laboratory practice. Ann Clin Biochem. 2014 Nov 8;51(6):688–94.
16. Sandberg S, Fraser CG, Horvath AR, Jansen R, Jones G, Oosterhuis W, et al. Defining analytical performance specifications: Consensus Statement from the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine. In: Clinical Chemistry and Laboratory Medicine. Walter de Gruyter GmbH; 2015. p. 833–5.
17. https://biologicalvariation.eu/bv_specifications/measurand.
18. https://westgard.com/clia-a-quality/quality-requirements/biodatabase1.html.
19. Tao R, Zhang C, Liu M, Yang M, Gao W, Chen J, et al. Research and discussion on the evaluation scheme of reagent lot-to-lot differences in 16 chemiluminescence analytes, established by the EP26-A guidelines of the CLSI. J Clin Lab Anal. 2021 Mar 1;35(3).
20. Algeciras-Schimnich A, Bruns DE, Boyd JC, Bryant SC, La Fortune KA, Grebe SKG. Failure of current laboratory protocols to detect lot-to-lot reagent differences: Findings and possible solutions. Vol. 59, Clinical Chemistry. 2013. p. 1187–94.