

References

1. Clinical and Laboratory Standards Institute. EP12-A2 User protocol for evaluation of qualitative test performance, Approved guideline. 2nd ed. Wayne (PA): CLSI, 2008.
2. Westgard JO, Barry PL, Hunt MR, Groth T (1981). A multi-rule Shewhart chart for quality control in clinical chemistry. *Clin Chem*, 27(3):493-501.
3. Levey S, Jennings ER (1950). The use of control charts in the clinical laboratory. *Am J Clin Pathol*, 20(11):1059-66.
4. Bureau International des Poids et Mesures. JCGM 200 International vocabulary of metrology - Basic and general concepts and associated terms. 3rd ed. (2008 version with minor corrections). Sèvres: The Organization, 2012. Retrieved from: <https://www.bipm.org/en/publications/guides/vim.html>. Accessed: October 1, 2019.
5. Bureau International des Poids et Mesures. Evaluation of measurement data - Guide to the expression of uncertainty in measurement. JCGM 100:2008, GUM 1995 with minor corrections. Sèvres: BIPM, 2008. Retrieved from: <https://www.bipm.org/en/publications/guides/gum.html>. Accessed: October 1, 2019.
6. Pereira P, Seghatchian J. Letter to the Editor: Balance of the unsuccessful systematization of measurement uncertainty in medical laboratories. *Transfus Apher Sci* 2017, 56(2):103-104.
7. EURACHEM/CITAC. Quantifying uncertainty in analytical measurement. 2nd ed. Europe: The Organizations, 2000.
8. Pereira P, Magnusson B, Theodorsson E, Westgard J, Encarnação P. Measurement uncertainty as a tool for evaluating the “grey-zone” to reduce the false negatives in immunochemical screening of blood donors for infectious diseases. *Accred Qual Assur* 2016, 21(1):25-32.
9. Pereira P, Westgard J, Encarnação P, Seghatchian J. Analytical model for calculating indeterminate results interval of screening tests, the effect on seroconversion window period: a brief evaluation of the impact of uncertain results on the blood establishment budget. *Transfus Apher Sci* 2014, 51(2):126-131.
10. Pereira P, Westgard J, Encarnação P, Seghatchian J. Evaluation of the measurement uncertainty in screening immunoassays in blood establishments: Computation of diagnostic accuracy models. *Transfus Apher Sci* 2015, 52(1):35-41.

11. International Organization for Standardization. ISO 15189 Medical laboratories - Requirements for quality and competence. 3rd ed. Geneva: ISO, 2012.	1
12. International Organization for Standardization. ISO 9001 Quality management systems - Requirements. 5th ed. Geneva: ISO, 2015.	1
13. Grubbs FE. Sample criteria for testing outlying observations. Ann Math Stat 1950, 21 (1): 27-58.	1
14. D'Agostino RB, Belanger A; D'Agostino, Jr RB. A suggestion for using powerful and informative tests of normality. Am Stat 1990, 44 (4): 316-321.	1
15. Joint Committee for Guides in Metrology (2012). International vocabulary of metrology - Basic and general concepts and associated terms. JCGM 200:2012, JCGM 200:2008 with minor corrections. JCGM. Retrieved from: https://www.bipm.org/en/publications/guides/vim.html Accessed: October 1, 2019.	6
16. Clinical and Laboratory Standards Institute (2019). Harmonized terminology database. Retrieved from: http://htd.clsi.org/ . Accessed: October 1, 2019.	9
17. Nordin G, Dybkaer R, Forsum U, Fuentes-Arderiu X. Vocabulary on nominal property, examination, and related concepts for clinical laboratory sciences (IFCC-IUPAC Recommendations 2017). Pure Appl Chem 2018, 90(5): 913-935. Retrieved from: https://doi.org/10.1515/pac-2011-0613 . Accessed: October 1, 2019.	12
1.5.3 ISO 9001 requirements crossed with medical laboratory technical specifications	12
1.5.4 ISO 9001 added-value to the medical laboratory	13
1.6 Discussion / Conclusion	13
References	18
Chapter 2 – Significant causes of error in qualitative tests	
2.1 Introduction	23
2.2 Analytical uncertainty components	24
2.2.1 Effect on the trueness of binary results	24
2.2.2 Lack of the equilibrium of immunoassay reaction	27
2.2.3 Carry-over	28
2.2.4 Reagent and calibrator lot effects	28
2.2.5 Biased results caused by interfering factors	29
2.2.6 Quality policy to reduce the impact of analytical uncertainty to weak positive results using the "gray zone" and trinary classification	32