

Antonelli G, Padoan A, Aita A, Sciacovelli L, Plebani M. Verification or validation, that is the question. *J Lab Precis Med* 2017; 2: 58.

Antonelli G, Padoan A, Aita A, Sciacovelli L, Plebani M. Verification of examination procedures in clinical laboratory for imprecision, trueness and diagnostic accuracy according to ISO 15189:2012: a pragmatic approach. *Clin Chem Lab Med* 2017; 55: 1501-1508.

Clinical Laboratory Improvement Amendments (CLIA), final rule 2013 and Brochures.  
CLIA Brochure #2 Verification of Performance Specification.

FDA Method Verification and Validation ORA-LAB.5.4.5 (2014)

WHO TGS-4 2017

NATA Australia 2012

ISO15193:2009 en In-vitro-diagnostische systemen; Meting van grootheden in monsters van biologische oorsprong – Eisen voor inhoud en prestatie van procedures voor referentiemeting.

Clinical Laboratory Standards Institute, Evaluation protocols: EP5, 7, 9, 10, 12, 14, 15, 17, 23, 26 en 28.

ISO/IEC 17000, Conformity assessment — Vocabulary and general principles.

ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.

ISO/IEC Guide 2, Standardization and related activities — General vocabulary.

JCGM 2000:2012 International vocabulary of metrology – Basic and general concepts and associated terms (VIM) 3rd edition 2008 version with minor corrections.

Khatami Z, Hill R, Sturgeon C, Kearney E, Breadon P, Kallner A. Measurement verification in the clinical laboratory: A guide to assessing analytical performance during the acceptance testing of methods (quantitative examination procedures) and/or analysers. 2009.  
[http://www.acb.org.uk/docs/default-ource/committees/scientific/guidelines/measurement-verification/Measurement\\_verification\\_final\\_090608.pdf](http://www.acb.org.uk/docs/default-ource/committees/scientific/guidelines/measurement-verification/Measurement_verification_final_090608.pdf)

FDA. Code of Federal Regulations: [Title 21](#), [Chapter I](#), [Subchapter H](#), Part 862

Friedecký B, Šprongl L, Kratochvíla J. Validation and verification of analytical methods in clinical laboratories - Recommendation of the Board of the Czech Society for Clinical Biochemistry. 2004.  
<http://www.cskb.cz/res/file/dokumenty/validation-and-verification-of-analytical-methods.pdf>

Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices. Study Group 5 Final Document GHTF/SG5/N8:2012.

Oosterhuis WP, Severens M. Performance specifications and six sigma theory: Clinical chemistry and industry compared. *Clin Biochem* 2018; 57: 12-17.

Vassault A, Grafmeyer D, de Graeve J, Cohen R, Beaudonnet A, Bienvenu J. [Quality specifications and allowable standards for validation of methods used in clinical biochemistry]. *Ann Biol Clin (Paris)* 1999; 57: 685-695. French. Erratum in: *Ann Biol Clin (Paris)* 2000; 58: 110.