

Revised
and Expanded!

Basic Method Validation

3rd Edition

Training in Analytical
Quality Management for
Healthcare Laboratories

James O. Westgard, Ph.D.

Westgard
QC



ANALYTICAL ERRORS



True vs Observed Results

SYSTEMATIC ERRORS



Comparative Method

EXPERIMENTAL PLAN

Test of Error	Experiment	
	Test Method	Comparative Method
Accuracy	1.00	1.00
Precision	1.00	1.00
Linearity	1.00	1.00
Stability	1.00	1.00
Robustness	1.00	1.00

Experiment

COMPARISON PLOT



Comparative Method

DIFFERENCE PLOT



Comparative Method

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Institute of Validation Technology

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Basic Method Validation James O. Westgard, 2003-01-01 With the publication of the Final CLIA Rule new method validation responsibilities came to the laboratory Previously moderately complex methods did not need to be validated But the Final Rule combined moderately and highly complex methods into a category of non waived methods Now Laboratories must validate all non waived methods introduced after April 24 2003 To help laboratory professionals comply with these new regulatory changes a second edition of this manual was prepared Book jacket

Basic Method Validation and Verification, 4th Edition James O. Westgard, 2020-08 *Analytical Method Validation* Institute of Validation Technology, 2005* *Test Method Validation for Medical Devices* Emmet Tobin, 2017-07-25 This concise book fits right in the Engineers pocket It provides a brief introduction to Test method validation and is a useful resource that defines key terms and concepts The following points are addressed Examples of Test Method Validations What is test method validation Why should TMV be performed When should methods be validated Regulatory Overview US Food and Drug Administration W H O ISO 13485 Definitions and Key Concepts New Test Methods Changes to Existing Methods Accuracy Precision Ruggedness Representative Continuous Sampling Range Resolution Probability Of False Alarms P Fa Probability Of Misses P M Validation Protocols What Can Impact the Accuracy of a Test Method General MSA requirements Variable MSA Studies Attribute MSA Studies Measurement Capability Index In-house Method Validation Bernard King (chimiste.), Great Britain. Department of trade and industry. National Measurement System Valid Analytical Measurement Programme, 2003

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