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# Basic Method Validation and Verification

4TH EDITION

## Training in Analytical Quality Management for Healthcare Laboratories



James O. Westgard, Ph.D.

### ANALYTICAL ERRORS



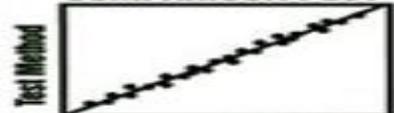
True vs Observed Results

### SYSTEMATIC ERRORS



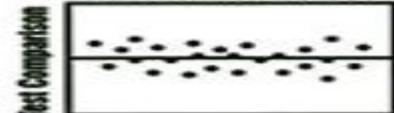
Comparative Method

### COMPARISON PLOT



Comparative Method

### DIFFERENCE PLOT



Comparative Method

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**Bernard King (chimiste.), Great Britain.  
Department of trade and industry.  
National Measurement System Valid  
Analytical Measurement Programme**

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**Basic Method Validation** James O. Westgard, Patricia L. Barry, Elsa F. Quam, 1999 *Basic Method Validation and Verification, 4th Edition* James O. Westgard, 2020-08 **In-house Method Validation** Bernard King (chimiste.), Great Britain. Department of trade and industry. National Measurement System Valid Analytical Measurement Programme, 2003

**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 **Analytical Method Validation** Institute of Validation Technology, 2005\*

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