

Table of Contents

1. Is quality still an issue for laboratory tests?	1
Myths of quality	3
2. How do you manage quality?	13
The need for standard processes and standards of quality...	15
3. What is the purpose of a method validation study?	31
MVV – The inner, hidden, deeper, secret meaning	32
4. What are the regulatory requirements for basic method validation?	41
MVV – The regulations, by Sten Westgard, MS.....	42
5. How is a method selected?	65
MVV – Selecting a method	66
6. What experiments are necessary to validate or verify method performance?	75
MVV – The experimental plan	76
7. How are the experimental data analyzed?	89
MVV – The data analysis tool kit.....	90
8. How is the reportable range of a method determined?	101
MVV – The linearity or reportable range experiment	102
Problem set – Cholesterol method validation data	115
9. How is the imprecision of a method determined?	117
MVV – The replication experiment.....	118
Problem set – Cholesterol method validation data	130
10. How is the inaccuracy (bias) of a method determined?	133
MVV – The comparison of method experiments	134
Problem set – Cholesterol method validation data	156
11. What's another way to determine accuracy?	159
MVV – How to assess the trueness of a method.....	160
12. How do you test for specific sources of inaccuracy?	171
MVV – The interference experiment.....	172
Problem set – Cholesterol method validation data	176

13. What is the lowest test value that is reliable?	179
MVV – The detection limit experiment	180
Problem set – Cholesterol method validation data	188
14. How is a reference interval verified?	189
MVV – Reference interval transference.....	190
15. How do you judge the performance of a method?	199
MVV – The decision on method performance.....	200
16. What's a practical plan for validating/ verifying?	213
MVV – The real world applications	214
MVV – The worksheets.....	227
17. How do you validate a qualitative method?	233
MVV – Evaluation of Qualitative Tests.....	234
18. How can claims be evaluated on the Sigma scale?	251
Translating performance claims into Sigma metrics.....	252
19. Self-Assessment Answers	259
Cholesterol Problem Set answers.....	278
The Statistical Appendix	289
Index	305