

Appendix 5: Data Submission Requirements

Table 1: Performance Parameters¹ for AOAC® Methods Validation Programs

AOAC® Official Methods K		AOAC® Performance Tested Methods K		AOAC® Peer-Verified Methods K	
Quantitative Methods	Qualitative Methods	Quantitative Methods	Qualitative Methods	Quantitative Methods	Qualitative Methods
1. Specificity	1. Specificity rate	1. Specificity	1. Specificity rate	1. Specificity	1. Specificity rate
2. Linearity	2. Sensitivity rate	2. Linearity	2. Sensitivity rate	2. Linearity	2. Sensitivity rate
3. Limit of Detection	3. False Positive and False Negative Rates	3. Limit of Detection	3. False Positive and False Negative Rates	3. Limit of Detection	3. False Positive and False Negative Rates
4. Limit of Quantitation	4. Percent method Agreement	4. Limit of Quantitation	4. Percent method Agreement	4. Limit of Quantitation	4. Percent method Agreement
5. Precision (Intralaboratory Repeatability)	5. Ruggedness	5. Precision (Intralaboratory Repeatability)	5. Ruggedness	5. Precision (Intralaboratory Repeatability)	5. Ruggedness
6. Comparison to Reference Method	6. Matrix	6. Comparison to Reference Method	6. Matrix	6. Comparison to Reference Method	6. Matrix
7. Ruggedness	7. Recovery	7. Ruggedness	7. Recovery	7. Ruggedness	7. Recovery
8. Matrix	8. Inter-Laboratory Reproducibility ⁵	8. Matrix	8. Limited Inter-Laboratory Reproducibility ⁹	8. Matrix	8. Limited Inter-Laboratory Reproducibility ¹¹
9. Recovery	9. Package insert review ⁶	9. Recovery	9. Package insert review	9. Recovery	
10. Laboratory Reproducibility ²	10. Quality Policy Certification ⁷	10. Limited Laboratory Reproducibility ⁸	10. Quality Policy Certification ⁴	10. Limited Laboratory Reproducibility ¹⁰	
11. Package insert review ³		11. Package insert review			
12. Quality Policy Certification ⁴		12. Quality Policy Certification			

1. *Not all performance parameters specified in this table are applicable to all analytes or all methods. The appropriate parameters to be included in the analysis are defined by the GR, Methods Committees, and OMB for OMA methods. For PT and PV methods, they are defined by the GR and expert reviewers with final approval by the GR.*
2. *As defined in AOAC guidelines for conducting collaborative study.*
3. *For proprietary methods only.*
4. *For proprietary methods only.*
5. *As defined in AOAC guidelines for conducting collaborative study.*
6. *For proprietary methods only.*
7. *For proprietary methods only.*
8. *Performance Tested Methods^K evaluated according to the USDA-FSIS memorandum of understanding include laboratory reproducibility studies.*
9. *Performance Tested Methods^K evaluated according to the USDA-FSIS memorandum of understanding include laboratory reproducibility studies.*
10. *Some Peer-Verified Methods^K evaluations may include laboratory reproducibility data.*
11. *Some Peer-Verified Methods^K evaluations may include laboratory reproducibility data.*