

Appendix 8: Check List

***Performance Tested Methods* Program**

APPLICATION CHECK LIST

- () Completed and signed application form
- () Method Validation Study Report with following data as applicable: (see Data Submission Requirements):

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

Test kit descriptive insert to include the following information: (see Descriptive Insert Requirements):

- () Intended user statement
- () Applicability
- () Interpretation criteria
- () Instructions on use
- () Shelf life
- () Environmental factors
- () Detection limit and limit of quantitation
- () Sampling protocol
- () Precautions
- () Technical assistance
- () Test kit labels
- () Description of manufacturing quality assurance program and quality control practices
- () Suggested technical reviewers
- () Suggested independent laboratory
- () Application fee