

Performance Tested MethodsSM Program

REVIEW 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. Inclusivity 2. Exclusivity 3. Linearity 4. Limit of Detection 5. Limit of Quantitation 6. Precision (Intra-laboratory Repeatability) 7. Comparison to Reference Method 8. Recovery 9. Ruggedness 10. Lot-to-lot Variability 11. Shelf-life	1. Inclusivity 2. Exclusivity 3. Specificity rate 4. Sensitivity rate 5. False Positive and False Negative Rates 6. Comparison to Reference Method 7. Recovery 8. Ruggedness 9. Lot-to-lot Variability 10. Shelf-life

- Test kit descriptive insert to include the following information: (see Descriptive Insert Requirements):
 - Intended user statement
 - Environmental factors
 - Applicability statement
 - Instructions on use
 - Shelf life
 - Detection limit and limit of quantitation
 - Precautions
 - Technical assistance
- Test kit labels
- Description of manufacturing quality assurance program and quality control practices
- Suggested technical reviewers
- Suggested independent laboratory
- Application fee