

Appendix 12: Product Insert Requirements

*Performance Tested Methods*SM Program

PRODUCT INSERT REQUIREMENTS

The test kit insert should include the following items, when applicable:

Intended User - Specify the intended user, such as farmer, milk processor, analytical laboratory, etc.

Environmental Factors - In what environment should the test be conducted? Laboratory? Office? Hot or cold? Good ventilation?

Applicability - Identify the analyte, mode of measurement (e.g., detection or quantitation) and matrices (e.g., specific foods or feeds, specific beverages, specific environmental surfaces, waste water, etc.) for which the kit has been validated. Include precautionary statements on potential interferences and other known limitations of the test.

Instructions - Include complete instructions on how to conduct the test from sample preparation to data interpretation. Describe the use of any internal or external quality control features.

Shelf Life - What is the shelf life of the test kit? What are the required storage conditions for the kit?

Detection Limit and Limit of Quantitation - Express in concentration (parts per million, percent, mg/kg, CFU/g, etc.) the limits of detection and quantitation as defined under "Data Package." These statements should agree with the supporting data.

Precautions - Provide warnings of safety concerns, disposal instructions, and potentially hazardous steps or components.

Technical Assistance - Provide information (email, internet, telephone and FAX numbers) where the user can obtain technical assistance.