

Appendix 6: Descriptive Insert Requirements

Performance Tested Methods^K Program

DESCRIPTIVE 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.

Applicability - Identify the matrix(es) the kit is designed for, such as swine urine, plant material, specific foods, whole milk, waste water, etc. Include precautionary statements on potential interferences and other known limitations of the test.

Interpretation Criteria - Explain how the test is interpreted. For example, what does the test response mean? Does it respond to analytes other than the one it is intended to detect? Does it respond to a class of analytes?

Instructions - Describe test sample reduction or any analyte extraction that is required. How is the test solution applied to the test? Include complete instructions on how to conduct the test. 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?

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

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

Sampling Protocol - Within the intended applicability of the test kit, describe the laboratory sample size required, how the laboratory samples are collected and stored prior to testing, and any information critical to sampling, handling, mixing, and subsampling needed prior to the analysis. If there are established "industrial" sampling protocols to be applied, they should be referenced.

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

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