

<p style="text-align: center;">FOOD AND DRUG ADMINISTRATION Human Foods Program (HFP), Office of Regulatory Testing and Surveillance (ORTS) <i>and</i> Office of Chief Scientist (OCS), Office of Science and Laboratory Advancement</p>	<p style="text-align: center;">Document Number: MAN:000051</p>	<p style="text-align: center;">Revision #: 04 Revised: 02/08/2025</p>
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Attachment D - Private Laboratory Package Review Guide

1. SAMPLING

- a. Lot is described.
- b. Sample is collected randomly.
- c. Sample is collected from sufficient number of cartons (proper distribution).
- d. Proper size sample is collected.
- e. Sufficient number of subs are collected.
- f. Collection is documented/collector is identified.

2. SAMPLE DATA

- a. Sample number on worksheet relates to final report.
- b. Sample is accurately described and relates to invoice (e.g. dimensions for ceramic ware, size of fish, shrimp, etc.).
- c. Contents of each sub composited (or portion taken, if whole sub).
- d. The correct portion of composite is taken and weight is shown.
- e. Where individual subs are analyzed, the correct number of subs examined.
- f. Sample is correctly prepared.
- g. Sample is correctly stored e.g. temperature.
- h. Label is submitted if present on the product.

3. ANALYTICAL METHOD

- a. The correct method is used and cited. Non-official methods are validated. Current versions of official methods are used.
- b. Each step of the method is followed.
- c. Deviations from official method are explained and validated.
- d. Use of special reagents and equipment is described.
- e. All equipment is identified to be traceable to its QA records.
- f. No unresolved analytical problems are evident.
- g. All analytical attempts are included, and discarded results are explained.
- h. Recovery and blank data are acceptable.
- i. Calculations are clear, accurate, and easy to follow.
- j. All raw data, including chromatograms and spectra and reproductions of TLC plates, are submitted, as well as printouts of reader instruments, e.g. Vidas.
- k. Laboratory conclusions are supported by analytical results.
- l. All analysts sign worksheet and 'who did what' is clearly indicated. 'When' can also be determined as called for by the method (e.g. for microbiological analysis).

4. STANDARD DATA

- a. Source of standard is cited.
- b. Preparation dates *and* preparer of primary and working standards are cited.
- c. Weights, dilutions, and concentrations of standard materials are documented.
- d. Standard curve has the correct number of points; sample results are within the limits of the standard

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curve.

- e. Standard curve submitted unless regression analyses used to calculate sample results.
- f. Standard and/or blank injections bracket sample injection, as needed.

5. INSTRUMENT PARAMETERS

The following parameters are documented:

- a. Name & model of instrument, accessories used
- b. Parameters for operation of instrument
- c. Wavelength used
- d. Lamp power settings
- e. Type of flame used
- f. Column type, ID., and length used
- g. Gas/Liquid phases used
- h. Flow rates
- i. Detector and mode used
- j. Temperature settings
- k. Attenuation
- l. Chart speed

6. CONDOMS/GLOVES

- a. Sample is of a single type and brand.
- b. Proper sample size is collected and examined according to method and is of scheduled number to be examined (lots, glove size, use).
- c. Label is reviewed.

7. MICROBIOLOGICAL ANALYSIS

- a. Batches of media are identified with QA numbers.
- b. Positive and negative controls traceable to reference cultures are run concurrently with sample analysis and carried through until the sample is completed. Controls are within range for a valid assay.
- c. Refrigerators, freezers, and water baths are identified on the worksheet.
- d. Biochemical reactions/patterns are obtained in the analysis.
- e. Expired media, reagents or test kits are not used in the analysis.
- f. FDA guidelines followed on such items as number of colonies to pick.
- g. Each step of the method is followed, with media, incubation temperatures, amounts transferred, etc. being documented.

To be confirmed during on-site assessment visits:

- a. Media used in microbiological analysis undergoes QA checks for pH, sterility, and growth promotion.
- b. Batches of media have expiration dates.
- c. Batches of media are traceable to autoclaves and autoclave runs.
- d. Autoclave processing cycles are validated with biological indicators.
- e. Refrigerator, freezer, and water bath temperatures are monitored daily.
- f. Laboratory grade water, free from traces of dissolved metal, bactericidal, and inhibitory compounds is used to prepare media, reagents, and dilution blanks.

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8. PERSONNEL

Analyst CVs are on file or are submitted with worksheet packages. CVs should include analyst's training or experience or both in the areas covered by the analysis.