

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Laboratory Operations and Applied Science

Office of Regulatory Testing and Surveillance

Irvine Human and Animal Food Laboratory

Effective Date: May 13, 2024

1. Irvine Human and Animal Food Laboratory (DCRMAE).

- A. Plans, schedules, and controls laboratory operations; and formulates, implements, and coordinates domestic and import analytical laboratory work plans and schedules.
- B. Performs laboratory analysis of human and animal food samples, as requested to:
 - a. Assess each sample's compliance with applicable laws and regulations enforced by the Food and Drug Administration (FDA).
 - b. Determine the extent to which findings provide evidence of violative conditions and practices.
 - c. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
- C. Provides science-based laboratory evidence regarding analytical findings as requested.
- D. Serves as a national resource for microbiological, chemical, and nutritional testing.
- E. Conducts and participates in applied research to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.

- F. Conducts reviews of data provided from contract, State or local, and private laboratories in support of FDA's regulatory mission.
- G. Serves as a resource in scientific expertise and training regarding laboratory techniques and technological developments to FDA stakeholders, other federal agencies, State and local agencies, foreign counterpart agencies, and industry.
- H. Assists the human and animal food programs, as appropriate in the conduct of complex inspections requiring an in-depth knowledge of laboratory techniques and practices and potential causes of adulteration.
- I. Maintains an effective internal quality management system (ISO 17025 accredited) to ensure that continuous improvement occurs in the quality and integrity of work performed at the laboratory.
- J. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- K. Provides court testimony regarding analytical findings as requested.
- L. Collaborates with Human Food Program (HFP) directors, researchers, and subject matter experts to meet the priorities of the HFP and the mission of the FDA.

2. Irvine Chemistry Branch (DCRMAE1)

- A. Performs laboratory analyses for pesticides, industrial chemicals, antibiotics at the residue and therapeutic levels, filth, BSE, vitamins, and other analyses as needed to assess each sample's compliance with applicable laws and regulations enforced by the FDA and to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- B. Implements and maintains an effective internal quality assurance program (ISO 17025 accredited).
- C. Plans, schedules, and manages branch operations.
- D. Implements and coordinates work plans with the served HFP organizations, Centers, and Offices.
- E. Conducts reviews of data provided from contract, State or local, and private laboratories in support of FDA's regulatory mission.
- F. Conducts research and participates in collaborative studies to develop and refine methodology used in the analyses of samples and to explore new techniques and systems of analysis.

- G. Provides expert advice and training regarding laboratory techniques and technological developments to other federal agencies; to State, local and foreign counterpart agencies, and to industry.
- H. Provides court testimony regarding analytical findings as requested.
- I. Assists the human and animal food programs, as appropriate, in the conduct of inspections and investigations involving complex testing procedures and production processes.
- J. Maintains liaisons and collaborative relationships with scientists and scientific institutions, allied public health labs, and other partners with interest pertinent to their respective scientific specialties.
- K. Serves as a resource in scientific knowledge, laboratory methodology, and problem solving pertinent to chemical analyses of food.
- L. Conducts single-lab and participates in multi-lab studies for matrix extension, platform extension, method verification and method validation for chemical analyses.

3. Irvine Microbiology Branch (DCRMAE2).

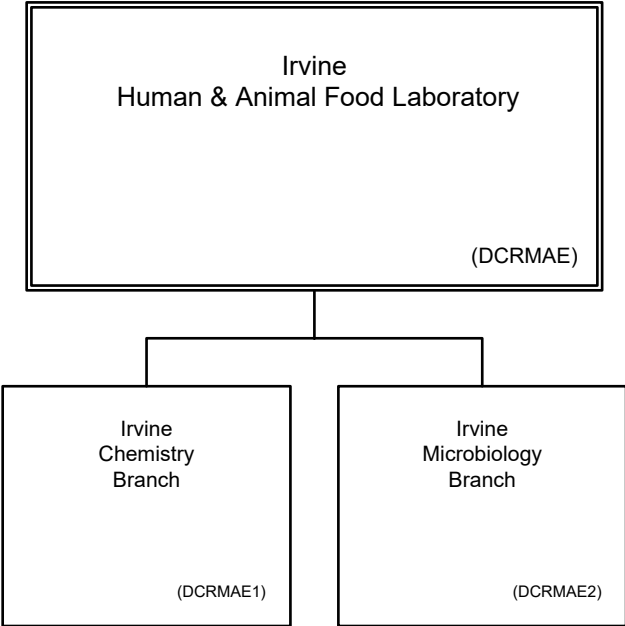
- A. Plans, schedules, and manages branch operations.
- B. Implements and coordinates work plans with the served HFP organizations, Centers, and Offices.
- C. Performs microbiological, virological, and parasitic analyses to assess each sample's compliance with applicable laws and regulations enforced by the FDA; and if applicable, to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- D. Conducts research and participates in collaborative studies to develop and refine methodology used in the analyses of microbiological samples and to explore new techniques and systems of analysis.
- E. Conducts single-lab and participates in multi-lab studies for matrix extension, platform extension, method verification and method validation for quantitative and qualitative microbiological screening and confirmatory assays.
- F. Performs genomics analysis for characterization of organisms recovered from food and environmental samples.
- G. Conducts reviews of data provided from contract, State or local, and private laboratories in support of FDA's regulatory mission.

- H. Serves as a resource in scientific knowledge, laboratory methodology, and problem solving pertinent to microbiological analyses of food.
- I. Provides expert advice and training regarding laboratory techniques and technological developments to other federal agencies, to State, local and foreign counterpart agencies, and to industry.
- J. Provides court testimony regarding analytical findings, as requested.
- K. Assists the human and animal food programs, as appropriate, in the conduct of complex inspections requiring an in-depth knowledge of laboratory techniques and practices and potential causes of adulteration.
- L. Maintains liaisons and collaborative relationships with scientists and scientific institutions, allied public health labs, and other partners with interest pertinent to their respective scientific specialties.
- M. Implements and maintains an effective internal quality assurance program (ISO 17025 accredited).

4. Authority and Effective Date.

The functional statements for the Irvine Human and Animal Food Laboratory were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Human Foods Program
Office of Laboratory Operations and Applied Science
Office of Regulatory Testing and Surveillance
Irvine Human and Animal Food Laboratory**



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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Laboratory Operations and Applied Science, Office of Regulatory Testing and Surveillance, Irvine Human and Animal Food Laboratory organization structure depicting all the organizational structures reporting to the Director:

Irvine Chemistry Branch (DCRMAE1)

Irvine Microbiology Branch (DCRMAE2)