



Laboratory Approval Program for Microbiological Testing of Poultry Products for the Federal Purchase Program

1. Purpose

1.1 This Laboratory Approval Program (LAP) is intended to be used by a laboratory which plans to obtain an official approval of the Agricultural Marketing Service (AMS), Science and Technology (S&T) Program, Laboratory Approval and Testing Division (LATD), Laboratory Approval Service (LAS) on performing confirmatory analysis of aerobic plate count, coliform count, coagulase positive *Staphylococcus aureus*, generic *Escherichia coli*, *Salmonella* species, and *Listeria monocytogenes* in frozen, cooked, diced chicken procured for the Federal Purchase Program (FPP).

1.2 This document provides the procedures and requirements used for the evaluation of the laboratory's technical competence and its quality management system.

2. Scope

This LAP may be used by laboratories that submit their testing program to LAS for approval, verification, and monitoring. It is limited to the analysis of aerobic plate counts, coliform counts, coagulase positive *Staphylococcus aureus*, generic *Escherichia coli*, *Salmonella* species, and *Listeria monocytogenes* in frozen, cooked, diced chicken only and all aspects of a laboratory's documented quality management system that applies to this analysis.

3. References

The following articles are referenced in this document. To the dated references, they only apply to the edition cited. For the undated references, the latest edition of the referenced document (including any amendments) applies.

3.1 AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals. Prepared by the Analytical Laboratory Accreditation Criteria Committee of AOAC INTERNATIONAL, revised March 2010.

3.2 AOAC International Official Method, Appendix E: Laboratory Quality Assurance.

3.3 AOAC International Official Method, Aerobic Plate Count 966.23 and 990.12.

3.4 AOAC International Official Method, Coliform 998.08 and 991.14.

3.5 AOAC International Official Method, Generic *Escherichia coli* 998.08.

3.6 AOAC International Official Method, Coagulase Positive *Staphylococcus aureus* 975.55, 2003.07, and 987.09.



- 3.7** AOAC International Official Method, *Salmonella* species 967.25, and 2002.10.
- 3.8** AOAC International Official Method, *Listeria monocytogenes* 992.18, 992.19, 993.09, 993.12, 994.03, 995.22, and 999.06.
- 3.9** Eurachem Guides <https://www.eurachem.org/index.php/publications/guides>.
- 3.10** Good Laboratory and Clinical Practices, Techniques for the Quality Assurance Professional, edited by P.A. Carson and N.J. Dent, 1990.
- 3.11** ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories.
- 3.12** USDA, AMS Laboratory Standards of Practice.
- 3.13** USDA, AMS, LPS, Instructions for the Reporting of Microbiological and Fat Test Results in Spreadsheet and Comma-separated Values (CSV) Text File (database) Format.
- 3.14** USDA, AMS Product Specifications & Requirements, Commodity Specification for Diced Chicken. <https://www.ams.usda.gov/selling-food/product-specs>
- 3.15** USDA, Food Safety Inspection Service (FSIS), Microbiology Laboratory Guidebook (MLG) 4.09: Isolation and Identification of *Salmonella* from Meat, Poultry, Pasteurized Egg, and Siluriformes (Fish) Products and Carcass and Environmental Sponges. <https://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook>
- 3.16** USDA, FSIS, MLG 8.10: Isolation and Identification of *Listeria monocytogenes* from Red Meat, Poultry, Ready-To-Eat Siluriformes (Fish) and Egg Products, and Environmental Samples. <https://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook>
- 3.17** US Food and Drug Administration (FDA), Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds. <http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM298730.pdf>
- 3.18** US FDA, Bacteriological Analytical Manual (BAM). <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm>

4. Laboratory Approval Procedures

- 4.1** Initial Request for Admission: A laboratory seeking approval must send an email/letter to the Program Manager (PM) requesting admission to the program at the following address:



Program Manager – LAP for the Microbiological Testing of Poultry Products for the Federal Purchase Program

Laboratory Approval & Testing Division

USDA, AMS, S&T

1400 Independence Ave. SW

Room 3533-S

Washington, D.C. 20250-0272

Telephone: (202) 690-0621

Email: LAS@ams.usda.gov

4.2 Submission of Required Information: After providing the initial request for admission, the applicant laboratory must submit an application package that includes laboratory information (Section 4.2.1) and required documentation (Section 4.2.2).

4.2.1 An applicant laboratory must provide the following information, but not limited to: the laboratory

- a) legal name and physical address (number and street, city, state, and zip code);
- b) ownership;
- c) requested scope of approval;
- d) authorized representative's name, title, phone number, and email address;
[NOTE: Authorized representative is the laboratory's point of contact person who is responsible for (1) the information provided in the application package, (2) the commitment to condition of approval (Section 5.1), and (3) ensuring compliance with this LAP requirements.]
- e) staff designated to serve as Approved Signatories of test reports that reference USDA-approved laboratory — listing their names, titles, phone numbers, and email addresses;
- f) billing address, taxpayer identification number (Federal W-9 Form), and accounts payable person's contact information, i.e., name, phone number, and email address;
- g) authorized representative's signature and date.
[NOTE: By signing the application, the laboratory's authorized representative confirms that the application information are correct and commits the laboratory to fulfill the conditions for approval listed in Section 5.1 of this requirements.]

4.2.2 The applicant laboratory must provide the following documentation, but not limited to:



- a) an organizational chart defining relationship that is relevant to the testing performance and the overall laboratory structure;
- b) a general description of the laboratory, including its facilities, and operation;
- c) conflict of interest statement;
- d) an up-to-date copy of the accreditation scope — if the applicant laboratory is currently ISO/IEC 17025 accredited by other accreditation body;
- e) quality manual and related management system documentation, including the latest internal and management review records;
- f) standard operating procedures (SOPs), including the analytical methods used, quality assurance and quality control, instrument calibration, test results issuance, and equipment maintenance;
- g) a list of all equipment, including records of in-house and external calibrations (i.e. equipment calibrations that your laboratory and an external company performs) and rental equipment, used to support the tests;
- h) analysts' qualifications and training procedures/records;
- i) both method validation and verification procedures and their data, see Section 10;
- j) the latest proficiency testing (PT) report and any corrective action responses if an unsatisfactory result was observed;
[NOTE: When required, laboratories must participate in an external ISO/IEC 17043 accredited PT program, where available and applicable, and obtain a satisfactory result.]

4.3 The program is the user-fee supported and all laboratories must pay program fees (see Section 9) upon receiving of the billing invoice.

4.3.1 The admission fee must be received prior to advancing to the next step of approval process.

4.4 Review of Information Submitted: The PM will review the application package. She/he may request further information and/or ask for additional documents/records to facilitate the review.

4.4.1 The PM informs the applicant any nonconformities/discrepancies found. The laboratory must respond, in writing, addressing the nonconformities/discrepancies for further review prior to proceeding the next step of the approval process.



4.5 Performance of Initial Onsite Laboratory Audit: The PM will inform the applicant laboratory after the review has been completed and deemed acceptable.

4.5.1 The AMS auditor contacts the laboratory to schedule a mutually agreeable date for the initial onsite audit.

[NOTE: The initial yearly fee must be received before an onsite laboratory audit can be started.]

4.5.2 During the audit, the auditor gathers objective evidence to verify the applicant laboratory's competence for the requested scope of approval. If any nonconformities found, the auditor will inform laboratory and document in the audit report.

4.5.3 The laboratory must respond in writing within 30 days upon receiving the final audit report addressing all documented nonconformities. The laboratory must supply evidence which clearly demonstrates that the actions taken have fully resolved and prevent the nonconformities.

4.5.3.1 If the laboratory's responses are found to be insufficient, LATD may request additional information.

4.5.4 If substantial nonconformities are cited, LATD may require an additional onsite audit with additional costs to the laboratory prior to granting approval.

4.6 Issuance of Acceptance Letter: AMS will provide a letter of approval to the laboratory after it meets all program requirements and the fees have been received.

4.7 The Official Listing of Approved Laboratories: The PM will list all USDA-approved laboratories on the official list and post on the LATD website.

5. Maintaining Program Status

5.1 Conditions for Approval: To maintain its approval, a laboratory must agree in writing, see the note of Section 4.2.1 g), to comply with the following LAP conditions for approval:

- a) meet all program requirements;
- b) use test method(s) approved by AMS;
[NOTE: Any changes prior to implementing in the laboratory must notify and send verification results to the PM. Significant changes to an approved test method, a validation study may be required by the PM.]
- c) participate in a quarterly check sample and/or external ISO/IEC 17043 accredited PT programs per analyte/matrix, as required, and meet satisfactory status —



- the laboratory must send the PT reports with any corrective action responses, if any unsatisfactory results were observed, to the PM within 30 days of receipt of the report;
 - overtime, every analyst performing the method(s) must participate in the check sample/PT program and submit the results with analyst name to PM;
- d) make all information relevant to the LAP available to PM upon request;
- e) during an onsite laboratory audit — the laboratory must have an actual sample ready to demonstrate its testing competency and allow access to documents/records related to the LAP;
- f) upon analyst changes — the laboratory must inform PM with the training record and the results of method verification study performed by the new analyst;
- g) resolve all nonconformities in a timely manner;
- h) notify the PM within 30 days any significant changes relevant to its approval, status, or operation relating to —
- legal, organizational, or ownership status;
 - main policies and resources;
 - organization, top management, or key personnel including the contact person, approved signatories, and analysts;
 - location, equipment, facilities, and working environment, where significant;
 - scope of approval;
 - other matters that may affect the laboratory’s test results and/or its ability to meet the program requirements;
- i) pay all program fees by the due date on the billing invoice.

5.2 The LAP is managed on a calendar year (January – December).

5.3 Following initial approval, LATD will conduct an onsite laboratory audit during the first year of approval and every two years thereafter.

5.3.1 Onsite audit and nonconformities resolution processes, see the “Performance of Initial Onsite Laboratory Audit” subsection within Section 4.

5.4 Renewal of Approval: Each approved laboratory receives a renewal notification email before the expiration date (the 31st of December) to start the renewal process.

5.4.1 The PM will send a renewal letter to the laboratory after it meets all program requirements with the yearly fee received. Then, the status of laboratory will be updated into the official listing of approved laboratories and posted on LATD website.



5.5 At any time, if there is concern about a laboratory's ability to meet program requirements, AMS may conduct an onsite audit of the laboratory at the laboratory's expense.

6. Removal from the Program

6.1 Voluntary Removal: A laboratory may voluntarily remove itself from the program at any time by submitting a written request to the PM.

6.2 Involuntary Removal or Scope Reduction: A laboratory may be involuntarily removed or scope reduced from the approval program. The PM informs the laboratory through an email/letter with one of the following reasons, but not limited to:

6.2.1 Falsification of analytical results.

6.2.2 Failure to use methods and procedures approved by AMS.

6.2.3 Failure to meet technical requirements.

6.2.4 Failure to maintain an acceptable performance level as indicated by the PT results and/or check samples; i.e., three unsatisfactory analyses in four consecutive sets of PT/or check samples, regardless of the approval year.

6.2.5 Persistently failed to perform corrective actions in a timely manner and/or satisfactory responses.

[NOTE: The yearly fee will not be refunded nor prorated, regardless of voluntary removal or involuntary removal/scope reduction.]

7. Readmission to the Program

7.1 A laboratory removed from the program due to falsification of analytical results may not reapply for approval into the program.

7.2 A laboratory involuntarily removed from the program must wait, at least, for six months before it can reapply for approval (see Section 4).

7.3 A laboratory voluntarily removed from the program may reapply for approval (see Section 4).

8. Appeals

8.1 Within 30 days of receiving of the letter for involuntarily removed from the program, the laboratory may file a written appeal to the LAS Branch Chief with supporting evidence as to why the laboratory should not be removed from the program. Within 30 days of receipt of the written



appeal, the Branch Chief shall make a final determination and take an action, as deemed appropriate, with respect to the removal. The contact information is as follows:

Grace Vaillant, Branch Chief
Laboratory Approval Service
Laboratory Approval & Testing Division
USDA, AMS, S&T
1400 Independence Ave. SW
Room 3533-S
Washington, D.C. 20250-0272
Telephone: (202) 720-8369
Email: Grace.Vaillant@ams.usda.gov

8.2 If the appeal to the LAS Branch Chief cannot be resolved to the satisfaction of a laboratory, an appeal, in writing, may be filed with the LATD Director. Within 90 days of receipt of the written appeal with supporting evidences, the LATD Director shall make a determination and take an action, as deemed appropriate, with respect to the removal. The contact information is as follows:

Kerry R. Smith, Ph.D., Director
Laboratory Approval & Testing Division
USDA, AMS, S&T
1400 Independence Ave. SW
Room 3533-S
Washington, D.C. 20250-0272
Telephone: (202) 690-4089
Email: KerryR.Smith@ams.usda.gov

9. Fee Schedule

9.1 LATD sets the program fees (e.g. admission fee, initial yearly fee, and yearly fee) for each program based on the time required by LATD personnel to perform the desk audit (documents review), onsite audit (travel to and from audit site and audit time), and associated administrative activities. Program fees are reviewed annually and adjusted as necessary to ensure that the fees are adequate to cover the cost of providing the service.

9.2 The admission fee covers the application activities.

[NOTE: If the initial onsite audit cannot be started within 365 days (starting from the date of the applicant submission of required information) due to the applicant's delinquency, the applicant laboratory needs to pay the admission fee again to complete the application process.]

9.3 The initial yearly fee payment is required prior to an initial onsite audit.

[NOTE: The initial yearly fee covers the first calendar year, regardless when your laboratory was accepted into the program.]



9.4 The yearly fee payment is required to continue the status of approval into next year from January to December.

9.5 The admission fee, initial yearly fee, and yearly fee are \$3,670.00, \$7,460.00, and \$6,550.00, respectively.

[NOTE: All fees must be paid by the due date on the billing invoice or interest and penalty charges will be assessed in accordance with the Code of Federal Regulations.]

9.6 All fees are neither refundable nor prorated.

10. Technical Requirements

10.1 Microbiological Analysis

10.1.1 Aerobic Plate Count

10.1.1.1 Methods: AOAC Official Methods 966.23 or 990.12; US FDA Bacteriological Analytical Manual (BAM); USDA/FSIS Microbiology Laboratory Guidebook (MLG); and/or Compendium of Methods for the Microbiological Examination of Foods.

10.1.1.2 Sensitivity: 10 colony forming units (CFU)/gram

10.1.1.3 Critical limit: Shall not exceed 1,000 CFU/gram

10.1.2 Coliform Count

10.1.2.1 Methods: AOAC Official Methods 998.08 or 991.14; US FDA BAM; USDA/FSIS MLG; and/or Compendium of Methods for the Microbiological Examination of Foods.

10.1.2.2 Sensitivity: 10 CFU/gram

10.1.2.3 Critical limit: Shall not exceed 50 CFU/gram

10.1.3 Generic *Escherichia coli*

10.1.3.1 Methods: AOAC Official Method 998.08; US FDA BAM; USDA/FSIS MLG; and/or Compendium of Methods for the Microbiological Examination of Foods.

10.1.3.2 Sensitivity: 10 CFU/gram

10.1.3.3 Critical limit: Shall be less than 10 CFU/gram



10.1.4 Coagulase Positive *Staphylococcus aureus*

10.1.4.1 Methods: AOAC Official Methods 975.55, 2003.07 or 987.09; US FDA BAM; USDA/FSIS MLG; and/or Compendium of Methods for the Microbiological Examination of Foods.

10.1.4.2 Sensitivity: 10 CFU/gram

10.1.4.3 Critical limit: Shall be less than 10 CFU/gram

10.1.5 *Salmonella* species

10.1.5.1 Methods: AOAC Official Methods 967.25 and 2002.10; USDA/FSIS MLG 4.09; US FDA BAM; and/or Compendium of Methods for the Microbiological Examination of Foods.

10.1.5.2 Sensitivity: 0 (negative in 25 grams of test sample)

10.1.5.3 Critical limit: Shall be negative

10.1.6 *Listeria monocytogenes*

10.1.6.1 Methods: AOAC Official Methods 992.18, 992.19, 993.09, 993.12, 994.03, 995.22, and 999.06; USDA/FSIS MLG 8.10; and US FDA BAM.

10.1.6.2 Sensitivity: 0 (negative in 25 grams of test sample)

10.1.6.3 Critical limit: Shall be negative

10.2 Alternate Methods

Detection, isolation and confirmation of foodborne microorganisms is performed using a variety of methods. Methods that have been fully validated for regulatory use, such as those included in the USDA/FSIS MLG and FDA BAM, as well as AOAC Official Methods of Analysis (AOAC-OMA) and International Organization Standards (ISO) methods are preferred. However, modification of these methods and/or the use of other methods, often referred to as “alternate” methods may be used if properly validated according to established microbiological method validation guidelines. Alternate methods may include a variety of rapid screening, isolation and confirmation methods. Established microbiological method validation guidelines are available through a variety of sources, including AOAC, USDA/FSIS and FDA for validation study design, performance and data interpretation considerations. It is expected that laboratories use an established, scientifically sound approach to validate an alternate method and illustrate equivalent performance, including specificity and sensitivity, to an appropriate reference method (e.g., USDA/FSIS MLG, FDA BAM and/or ISO cultural confirmation).



Any samples tested positive by those alternate methods must be confirmed by reference culture methods. Cultural confirmation includes the use of biochemical and serological tests to demonstrate that the other method did properly detect the targeted test organism.

11. Official Analysis Certificate/Report

11.1 An example of official analysis certificate/report must be sent to the PM for review.

11.2 USDA-approved laboratories must report the results of microbiological analyses in accordance with the current edition of “Instructions for The Reporting of Microbiological and Fat Test Results in Spreadsheet and Comma Separated Values (CSV) Text File (Database) Format”.