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

1 Purpose

The purpose of this document is to outline the requirements for the Laboratory Approval Program for Microbiological Testing of Poultry Products from the Federal Purchase Program (LAP-FPP). The document describes the technical competency and quality management requirements a laboratory must demonstrate to be a USDA-approved laboratory.

The Laboratory Approval Program (LAP) is administered by the Laboratory Approval Service (LAS) Branch. LAS is part of the Agricultural Marketing Service (AMS), Science and Technology (S&T) Program, Laboratory Approval and Testing Division (LATD).

The LAS approves, or accredits, laboratories to perform testing services in support of domestic and international trade. At the request of industry, other Federal Agencies, or foreign governments, the LAS develops and administers programs to verify that the analysis of food and agricultural products meet country and customer-specific requirements and that the testing of products marketed is conducted by qualified and approved laboratories.

2 Scope

LAP-FPP is for a laboratory seeking to obtain and maintain its status as a USDA-approved laboratory for the analysis of aerobic plate counts, coliform counts, generic *Escherichia coli*, coagulase positive *Staphylococcus aureus*, *Salmonella* species, and *Listeria monocytogenes* in fully cooked, frozen, diced cooked chicken procured for the Federal Purchase Program (FPP) based on the stipulations of the Federal Purchase Program Specifications (FPPS) for Diced Chicken, Fully Cooked Frozen.

LAP-FPP verifies technical and quality control competencies of a laboratory to meet the requirements of this Program. All aspects of a laboratory's quality management system (business processes relevant to the scope of approval) are applicable and critical for ensuring the defensibility of the analytical results produced under the LAP.

3 Table of Contents

4 Glossary of Terms

AMS	Agricultural Marketing Service
AOAC	Association of Official Analytical Collaboration
BAM	Bacteriological Analytical Manual, FDA
CFU	Colony Forming Unit
CSV	Comma Separated Values
FDA	Food and Drug Administration
FPP	Federal Purchase Program
FPPS	Federal Purchase Program Specifications
FSCSD	Food Safety and Commodity Specification Division, LP, AMS
FSIS	Food Safety Inspection Service, USDA
GD	Guidance Document
ILAC	International Laboratory Accreditation Cooperation
ISO/IEC	International Organization for Standardization/ International Electrotechnical Commission.
LP	Livestock & Poultry Program
LAP	Laboratory Approval Program
LAP-FPP	LAP-Microbiological Testing of Poultry Products for the FPP
LAS	Laboratory Approval Service
LATD	Laboratory Approval and Testing Division
MLG	Microbiology Laboratory Guidebook, FSIS
PM	Program Manager
PT	Proficiency Test
S&T	Science & Technology Program
SSD	Standards and Specifications Division, LP, AMS
US	United States
USDA	United States Department of Agriculture

5 References

5.1 The following are referenced in this document. Dated references apply to the edition cited and undated references apply to the latest edition published (including any amendments).

5.2 Laboratory Approval Program:

a) LAP-PR.05, Laboratory Approval Program – General Policies and Procedures

b) LAP-PR.06, Laboratory Approval Program – Fees.

c) USDA AMS LATD LAS Website, https://www.ams.usda.gov/services/lab-testing/lab-approval

5.3 Quality Assurance Standards:

a) AOAC International, Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals. Prepared by the Analytical Laboratory Accreditation Criteria Committee of AOAC International.

b) ISO/IEC 17025:2017. General requirements for the competence of testing and calibration laboratories.

c) USDA AMS Laboratory Standards of Practice.

5.4 USDA Requirements:

a) USDA AMS LP SSD. Federal Purchase Program Specification (FPPS) for Diced Chicken, Fully Cooked, Frozen.

b) USDA AMS LP FSCSD. Instructions for the Notification of Pathogen Test Results by Email to the Agricultural Marketing Service (AMS), AMS Vendors, and the Food Safety and Inspection Service (FSIS).

c) USDA AMS LP, Instructions for the Reporting of Microbiological and Fat Test Results in Spreadsheet and Comma Separated Values (CSV) Text File (database) Format.

5.5 Microbiology Methodology:

a) AOAC International Official Methods of Analysis.

b) USDA FSIS Microbiology Laboratory Guidebook (MLG).

c) US FDA Bacteriological Analytical Manual (BAM).

d) FSIS-GD-2019-0008. Foodborne Pathogen Test Kits Validated by Independent Organizations, February 2020.

5.6 Additional Resources

a) Eurachem Guides

b) Good Laboratory and Clinical Practices, Techniques for the Quality Assurance Professional, edited by P.A. Carson and N.J. Dent, 1990.

c) Guidelines for the Validation of Microbiological Methods for the FDA Foods Program, 3rd Edition, US FDA, FDA Foods and Veterinary Medicine Science and Research Steering Committee, October 17, 2019.

GENERAL REQUIREMENTS

6 Laboratory Approval Program Administrative Policy

6.1 A laboratory seeking admission to the LAP must fulfill the requirements and follow the process described in the program procedure, *LAP-PR.05, Laboratory Approval Program – General Policies and Procedures*. This procedure describes the process for application, assessment audits, acceptance, maintaining program status, suspension, withdrawal, dismissal, appeals, and fees.

6.2 This program is administered on an annual, calendar year, basis.

6.3 The program procedure, *LAP-PR.06*, Laboratory Approval Program – Fees explains the fees for services.

6.4 The administrative procedures above are available on the LAS website, or contact the LAS Program Manager (PM) for the current version.

7 Summary of General Program Requirements

7.1 A laboratory must comply with all requirements set forth in this document to be compliant with the LAP. For the laboratory to maintain good standing, each year it must:

a) meet all program requirements relevant to the scope of approval;

b) comply with mandatory laboratory practices based on the ISO/IEC 17025 standard (See §8);

c) use test method(s) approved by AMS (see §9);

d) validate / verify methods prior to use and ensure the validation / verification data package is available for review upon request (see §10);

e) evaluate analyst competency and maintain satisfactory status (see §11);

f) participate in proficiency testing (PT) programs and maintain satisfactory status (see §11);

g) communicate regularly with the PM to share vital information regarding the laboratory and make all information relevant to the LAP available to the PM upon request (see §5.2.a))

h) notify the PM within 30 days of significant changes relevant to the laboratory's approval status and/or ability to meet the Program's requirements including, but not limited to, legal, organizational, or ownership status; laboratory policies, procedures, and resources; change in key managerial personnel and contact persons, and signatories; and validation / verification of adequate method performance after a

significant change in method, equipment, facilities, working environment, and location. It is at the discretion of LAS whether an onsite visit/audit is required to evaluate any significant change that a laboratory undergoes (see §5.2.a));

i) be available for a biennial (every other year) re-assessment audit, have actual sample(s) ready to demonstrate its competency of performing the test method; and comply with requests for documents and records before and during the audit (see §5.2.a));

j) respond to each nonconformance found with a record of an investigation, root cause analysis, and correction or, if warranted due to time, a corrective action plan, within 30 calendar days of being reported (see §5.2.a));

k) resolve each nonconformance in a timely manner, whether identified by LAS audit, another organization, or internally (see §5.2.a));

l) pay all program fees by the due date on the billing invoice (see §5.2.b)).

8 Mandatory Quality Assurance Practices

8.1 Implement quality assurance and quality control procedures to ensure a validated and qualified analysis, prove competence, and ensure defensible data.

8.2 Maintain formal accreditation to the ISO 17025 standard granted by a third-party that is a member of the International Laboratory Accreditation Cooperation (ILAC).

8.3 Maintain each method approved for the LAP on third party-accreditation scope of approval.

8.4 LAS uses the ISO 17025 standard to evaluate all laboratory quality systems regardless of accreditation status. A nonconformance identified during a LAS assessment audit may be cited to the ISO 17025 standard (see §5.2.a)).

8.5 Maintain records for at least three years (see §5.2.a)).

9 Method Selection

9.1 Use analytical testing methods approved by AMS.

9.2 Use method fit-for-purpose based upon the needs of the customer and consistent with specified requirements.

9.3 Use methods as validated; for the purposes of this Program, consider methods with collaborative studies, specifically those published by USDA FSIS, US FDA BAM, and AOAC; and those identified on the list for Foodborne Pathogen Test Kits Validated by Independent Organizations as validated methods.

10 Demonstration of Method Performance by Validation and Verification Evaluation

10.1 Demonstrate the sample testing method(s) is competently and proficiently performed prior to using it for testing and reporting results by using a validation / verification process, where:

a) Validation is the process of demonstrating that a method is suitable for its intended purpose,

b) Verification is the process of demonstrating a validated method can be performed to the same level of performance determined during the validation, and

NOTE: It is recognized there are multiple ways to demonstrate performance; therefore, the Program does not designate a specific protocol. See §5.6 for resources towards developing a suitable validation / verification plan.

10.2 Demonstrate that variations or modifications to a validated method (e.g., different matrix, different analyte, etc.) are fit-for-purpose.

10.3 Prepare a Method Validation Data Package to record that the procedure has been demonstrated as fit for use.

a) Consolidate pertinent information into an integrated and auditable data package to support the objective's conclusion that includes at least the following: a cover statement containing the conclusion of the validation / verification process, test method procedure, relevant statistics (e.g., linearity, accuracy, precision, measurement uncertainty, etc.), and traceable data (raw and summarized).

b) Send the validation / verification package to the PM for review and approval.

c) Ensure validation / verification data package is readily available at the laboratory for as long as the method is utilized, plus three years past the date of last reported results.

d) Ensure official record of approval for method is maintained and readily available.

11 Analyst Competency and Proficiency Testing

11.1 Analyst Competency:

a) Ensure each key analyst responsible for performing the method(s) participates in a competency evaluation, over time, and maintains satisfactory status.

11.2 Laboratory Analytical Proficiency:

a) Evaluate proficiency for each method at least annually.

b) Use a PT program relevant to the approved method in terms of analyte, concentration range, and matrix on scope of approval—where possible from an ISO 17043 PT provider.

c) Document and implement a PT program to include comparison of results with other laboratories (inter-laboratory) and/or other analysts (intra-laboratory) where available; or a defined program that uses an appropriate collection of data used to demonstrate process control and validity of results when an appropriate ISO 17043 PT program is not available.

d) Review PT report and initiate the corrective action process when unsatisfactory results are observed. When Z scores are used, unsatisfactory results and actions to take are defined as follows:

$\|z\| \geq 3$	Initiate immediate corrective action investigation on the part of the laboratory to establish root cause.
$2 \leq \|z\| \leq 3$	Evaluate the context of other scores obtained in the same test and other PTs over time. Investigate to determine the cause and take action as needed.

11.3 Submit to PM:

a) Documented proficiency program for review for initial approval.

b) Subsequent changes to the previous PT program(s).

c) Copy of the PT report with analyst name, and PT identifier, within 30 days of receipt.

d) Record of corrective action response for unsatisfactory results, within 30 days of receiving the PT report.

e) Record of analyst training when there are changes in analysts running analyses.

TECHNICAL REQUIREMENTS

12 Performance Criteria

12.1 Use methods that meet the performance criteria laid out in the Federal Purchase Program Specification (see §5.4.a)).

Table 12.1. Testing Requirements for the Microbiological Limits in the Federal Purchase Program Specification for Diced Chicken, Fully Cooked, Frozen.

Microbial Test	Sensitivity	Action Level*
Aerobic Plate Count	10 CFU/g	≤ 1,000 CFU/g
Coliform Count	10 CFU/g	≤ 50 CFU/g
Generic *E. coli*	10 CFU/g	< 10 CFU/g
Coagulase-positive *Staphylococcus aureus*	10 CFU/g	< 10 CFU/g
Salmonella	Not detected	0 CFU/g
Listeria monocytogenes	Not detected	0 CFU/g
* USDA AMS LP SSD. Federal Purchase Program Specification (FPPS) for Diced Chicken, Fully Cooked, Frozen		

13 Sample Handling & Preparation

13.1 Take 25-g from composite sample for *Salmonella*, *Listeria monocytogenes*, and coagulase positive *Staphylococcus aureus* analysis.

13.2 Take 50-g from composite sample for Coliform Count, Aerobic Plate Count, and *E. coli* (generic), and coagulase positive *Staphylococcus aureus* analysis.

14 Quality Controls

14.1 Use quality controls to demonstrate testing is performed correctly and factors that could negatively impact the results are mitigated.

14.2 Take immediate action prior to continuing testing and or reporting results when any quality control does not perform as expected.

14.3 Define and justify what constitutes a batch of samples.

14.4 Include quality controls with each batch of samples and set up in the same manner as unknown samples.

14.5 Include at a minimum, a Matrix Spike or Positive Control and a Sterility Control.

14.6 Include at a minimum, the environmental monitoring controls of Surface Swabbing and Air Quality Plate Testing at a defined schedule.

14.7 LAS' interpretation of each quality control and its purpose is defined below.

NOTE: It is not a requirement for the laboratory to use the same terms for each type of control as long as the correct control is used for the correct purpose.

a) Sterility Control: Uninoculated medium. Use as a negative control to verify sterility of medium and consumables.

b) Positive Control: Medium inoculated with target control culture organism. Inoculate at a low concentration for qualitative methods and a known concentration for quantitative methods in the countable range. Use to ensure growth of organism.

c) Matrix Spike: Aliquot of sample prepared by adding a known quantity of target analytes to a specified amount of matrix and subjected to the entire analytical procedure. Use to establish if the method or procedure is appropriate for the analysis of a specific analyte in a specific matrix.

d) Air Quality Plate: Uninoculated medium exposed to laboratory air. Use to ensure the laboratory environment does not contain contaminants that may negatively impact the test. Use alongside quantitative tests.

e) Surface Swabbing: Swab of laboratory surfaces. Use to verify laboratory surfaces are free of contamination by pathogens of interest.

15 Quality Measures

15.1 Evaluate quality controls to identify acceptability of data, trends, and potential problems.

15.2 Take immediate action prior to continuing testing and or reporting results when any quality control does not perform as expected.

15.3 Ensure chemicals, media, reagents, immunoreagents, and commercial test kits are not used past their expiry date without conducting a suitability verification for their intended purpose and use.

15.4 Ensure each batch of medium is tested for sterility and growth promotion / inhibition characteristics before use (preferable) or at time of use if the process is clearly documented, including how to handle nonconforming medium and when results can be reported.

15.5 Record final pH and identifying information for the measurement device and reagents used in pH is a critical factor to method performance.

16 Official Certificate of Analysis/Report

16.1 Meet customer's requirements for reporting results.

16.2 Meet the ISO 17025 standard for reporting results.

17 Reporting

17.1 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."

18 Revision History

New Rev.	Description of Change	Prepared by
03/27/17	Original	TSB
09/04/14	?	TSB
02/06/17	?	LAS
04/13/18	Struck out requirements superseded by LAP-PR.05 and LAP-PR.06.	Branch Chief, LAS
02/27/19	Changed strike out to green highlight with notations in the margin to improve readability. Refer to this version as, "dated 02/06/17 with notes 02/27/9"	Branch Chief, LAS
02/22/23	Updated to align with content and structure of other LAP documents. No requirement changes.	Branch Chief, LAS

19 Review / Approvals

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