

# Guidance for Selecting a Commercial or Private Laboratory

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## Introduction

Microbiological testing is a valuable tool for verifying an establishment's process management system is under control. It is the establishment's obligation to comply with internal requirements, customer specifications, and with Food Safety and Inspection Service (FSIS or agency) requirements by ensuring that the company's microbiological testing is supportable and fit for the intended purpose. To achieve this objective, an establishment must decide if microbiological testing will be conducted "in-house" or by an outside third-party. If the third-party option is chosen, an establishment must select a competent commercial laboratory<sup>1</sup> to perform appropriate microbiological or other analyses on the establishment's product samples. Regardless of the approach chosen, the establishment is ultimately responsible to ensure the methodologies and practices followed by the laboratory meet the company's food safety needs and the agency's requirements. The guidance in this document is equally applicable to the expectations companies should have of third-party laboratories, and of all in-house analysis conducted by companies.

If an establishment determines an in-house laboratory best fits the company's needs, it is critical to have experienced and properly trained personnel responsible for laboratory methodology to ensure all methods and procedures are conducted properly. Lab staff should also be able to analyze and interpret data.

For companies utilizing a third-party, that laboratory may provide needed technical and scientific support. When selecting a microbiology laboratory, it is critical to consider a laboratory that not only provides the needed services, but also has a technical support team that understands your business technical needs. Communication between the establishment and the third-party laboratory is crucial to ensuring that correct analyses are performed and are fit for use.

The criteria provided below applies to both in-house and third party laboratories and should aid an establishment in selecting the microbiological testing approach that works best for the company.

### **Factors to Consider when Selecting a Microbiological Testing Laboratory**

An establishment should ensure the selected laboratory meets the establishment's needs, *e.g.* the laboratory can accurately perform the proper microbiological methods and conduct analyses correctly. Consideration should be given to the experience and competency of the laboratory personnel, history of customer service, among other factors. The laboratory must know and understand

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<sup>1</sup> A commercial laboratory is an outside or off-site contracting testing laboratory.

the agency's Microbiology Laboratory Guidebook (MLG) because the methods described by the MLG are used by FSIS laboratories. Although FSIS does not require the methodologies used by an in-house laboratory or third-party laboratories to be the same as those in the MLG, FSIS will utilize the MLG methods when comparing other methods utilized by an in-house or third party lab.

It is extremely important the establishment has a professional, working relationship including excellent communication with the laboratory, whether in-house or a third party.

### Laboratory Methodology

The methodology used by the laboratory should support and reflect the establishment's needs and testing methods used should "fit for purpose" or the method used by the laboratory to analyze samples should be appropriate for its intended purpose. Independent third-party associations, such as AOAC International and International Organization for Standardization (ISO), have developed voluntary standards to ensure products and services have the expected quality, safety, and efficiency. For many establishments utilizing AOAC or ISO certified methods and laboratories provide additional reassurance that analyses are handled correctly. However, establishments also must ensure the proper method is being correctly used. Complicating the decision-making is the fact that many methods and laboratories are not AOAC or ISO "certified," but can provide excellent and accurate service to meet an establishment's needs.

It is the responsibility of the establishment to ensure the laboratory (in-house or third-party) is knowledgeable in the method or methods utilized and those methods can provide accurate results. For example, the laboratory personnel should understand how intrinsic factors, *e.g.* fat, pH, or water activity, and extrinsic factors, *e.g.* environmental sanitizers, can influence method sensitivity. When selecting a method, laboratory personnel should understand the method's limitations, including detection limits. Careful consideration of a method's ability to detect cells, including injured cells, is needed to ensure the method is "fit for purpose".

Although a method may meet AOAC or ISO standards, it may not mean it is "fit for purpose" and will provide the needed results. For example, if an establishment is collecting beef trim samples for purposes of product disposition decisions and providing a Certificate of Assurance (COA) to downstream customers, it is important to consider whether the chosen method is equivalent to the FSIS MLG method. A rapid in-plant testing kit may meet AOAC or ISO standards, but if

it does not ensure that the detection capabilities are at least as sensitive as the FSIS MLG method, screen testing of the product may not be considered sufficient for the intended use by FSIS. In practice, FSIS may not accept that the negative results meet a customer's purchase specifications or an agency regulatory requirement, *e.g.*, tests conducted for validation or verification purposes.

### Lab Quality Assurance

FSIS defines quality assurance (QA) as a program used to ensure timely and reproducible results that are useful to customers and minimize human error. Provided below are components of a laboratory QA program to be considered by an establishment to determine whether a laboratory is capable of producing accurate and reliable results.

- The laboratory must have a written QA and quality control (QC) program that is: readily available to the establishment and includes the following: written procedures with data collection tools; sample traceability; sample chain of custody; equipment maintenance and calibration procedures; documentation that testing methods are properly validated and fit for purpose; proficiency testing; and analysis controls.
- For quality assurance of all samples, the lab should have a sterility control, a negative control, and a positive control inoculated with the microorganism(s) of interest.
- All laboratory equipment must be regularly calibrated.
- ISO has developed internationally recognized standards for laboratory management. ISO 17025 focuses on QA and QC management in laboratories. Although ISO accreditation is not required, it adds credibility to the laboratory. FSIS labs are audited by an external body to demonstrate their compliance with ISO standards and the AOAC Guidelines.
- Laboratory must maintain accurate records of sample preparation, procedures performed, and sample results.
- Establishments should understand how the laboratory reduces the chance of cross-contaminating a sample within the laboratory.
- The establishment should request annually a letter stating that the laboratory meets the establishment's QA and QC guidelines and expectations. Similar documentation should be developed and kept on file if the establishment has an in-house laboratory.
- Laboratories should maintain quality control by participating in proficiency testing programs at least twice per year. These proficiency programs evaluate the competency of the laboratory to perform microbiological tests. The accuracy, precision, and efficiency of the laboratory's procedures are reviewed during such proficiency testing.
- FSIS recommends laboratories be audited annually.

### Sample Shipping

- It is the responsibility of the establishment to collect and ship samples in the manner previously agreed upon by the establishment and the laboratory.
- Packaging and state of sample, *i.e.* refrigerated, frozen, room temperature, should be based upon the analytical method. If the proper shipping method is not followed, results may be questionable. When this problem occurs, the establishment and the laboratory must implement the appropriate corrective action.

### Sample Receipt and Handling

- The establishment should ensure and understand the laboratory's standard operating procedures (SOP) for transport and receipt of samples. The SOP's are needed to ensure sample integrity, *e.g.* if a sample is damaged or packaging is not intact when received by the laboratory, and understand how the laboratory will handle this situation if sample integrity is not as expected.
- Laboratories should have documentation, *e.g.* receiving log, samples have been received and inspected. The samples will either be accepted or discarded and not analyzed based on the laboratory's policy.
- The laboratory should demonstrate that a system exists to track samples once received and accepted. The laboratory must ensure the sample identity and integrity is maintained at all times, which includes, but is not limited to holding the samples at the proper temperature and giving the samples a unique identifier. The chain-of-custody (COC) document is used to demonstrate that the sample has always been under the control of the establishment or the laboratory. The COC documents transfer responsibility and possession of the sample between the laboratory and the establishment.
- The test results must be well documented and be traced back to the appropriate sample.
- Many laboratories utilize a Laboratory Information Management System to store all pertinent data electronically.

## Reporting Results

The establishment should receive from the third-party laboratory a Certificate of Analysis or laboratory report accurately providing the results of submitted microbiological samples. The COA or laboratory report should at a minimum include:

- the analysis results with the appropriate units of measurement;
- sample description;
- unique sample identifier, which may include an internal laboratory number;
- location of sample collection or type of product sampled;
- sample collection date;
- analysis date;
- date result reported;
- documentation of method utilized, including any modifications and citations;
- name, title, and signature of individual preparing the results;
- interpretation of test results; and
- name, title, date, and signature of person reviewing results and authorizing the results.

Additional information may be provided and will vary based on establishment's internal and customer specifications. Often COA or laboratory reports are available from the third-party laboratory via email, an online database, fax, or mail. The Establishment must ensure the best communication method is utilized for timely reporting.

## **Conclusion**

When establishments determine that some form of analysis must be conducted as part of their food safety system, it is critical the recommendations in this Guidance be considered to determine if the services being offered by a third-party laboratory, or the results obtained using a given analytical process in-house, will provide sufficiently supportable data to meet the needs of the food safety system. To be clear, cheaper is not always better. Obtaining or generating laboratory results, supportable for the intended purpose, is paramount. Following this Guidance will assist establishments in verifying this is the case.

## References

AOAC Official Methods of Analysis search engine at: <http://eoma.aoac.org>

Food Safety and Inspection Service (June 2013). *Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory*. Accessed May 21, 2015.

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## Glossary and Useful Terms

**AOAC International:** A globally recognized, independent, not-for-profit association that develops standards in scientific research. AOAC develops consensus based method performance requirements and has a Laboratory Proficiency Testing Program.

**Certificate of Analysis (COA):** A document issued by the laboratory confirming the product conforms to regulatory requirements and commonly contains testing results.

**Chain-of-Custody (COC):** A tracking system; a document or documents used to ensure the sample is or was always in control of either the establishment or the laboratory.

**Commercial Laboratory:** An offsite or outside laboratory contracted by the establishment to perform microbiological analysis on products.

**FSIS Microbiology Laboratory Guidebook:** Contains protocols for analytical tests required by FSIS. Specifically, methods are described for sample preparation, isolation, and identification of foodborne pathogens and their toxins, meat tissues species identification, and antimicrobial residues.

**Laboratory Information Management System (LIMS):** A software based computer system that assists with data management and sample tracking

**Laboratory Report:** Document that lists the results of a microbiological test.

**Private Laboratory:** Owned and managed by the processing establishment

**Standard Operating Procedures (SOP):** Written documents for procedures conducted in the laboratory