

How BioFoodTech's Microbiology Laboratory's Processes and Analytical Performance are Measured and Monitored:

BioFoodTech's microbiology laboratory operates under a systematic approach to quality assurance and management to ensure it achieves a high degree of reliability in analytical results. This is composed of measurement activities, such as **internal assessments** (internal quality control and quality audits), **external assessments** (proficiency testing, laboratory accreditation, external audits and quality registration/licensing), and **client satisfaction feedback**.

EXTERNAL ASSESSMENTS

The microbiology lab participates in proficiency panels from three providers: CALA (the Canadian Association for Laboratory Accreditation Inc.), USFDA (the United States Food and Drug Administration) and FEPAS (Food Examination Performance Assessment Scheme). The laboratory tests or examines sample materials prepared and sent by these organizations, the results of which are compared with similar laboratories.

BioFoodTech's laboratory accreditation is administered by the Standards Council of Canada (SCC) and involves assessing the laboratory against the ISO 17025 requirements. Deficiencies are issued for identified non-conformances that require subsequent corrective actions for the laboratory to maintain the accreditation. (See link to BioFoodTech's [Scope of Analysis](#) on the SCC website.)

Another external assessment, the reason for which our laboratory undergoes periodic external auditing of our quality management and technical programs, includes registration to ISO 9001: 2008.

INTERNAL ASSESSMENTS

The laboratory routinely practices two types of internal assessments: quality indicator measurements and laboratory audits.

Quality indicator measurements

Quality indicators are measurements of process performance that are tracked and documented. This is based on data derived from internal quality control (IQC) procedures.

Internal quality control ensures the quality and reliability of the analytical results and involves a set of procedures undertaken by laboratory staff for the continuous monitoring of operations and the results of measurements in order to decide whether the results are reliable. These

procedures include the use of control and calibration samples which are included in the analytical batch and treated in the same way as the test samples. For qualitative procedures, only control samples (positive or negative) are used. For quantitative methods, calibration samples (CAL) are also included in each analytical batch and control samples are used to verify the calibration. The IQC parameters include the following:

Negative control samples

Negative control samples are samples free from the microorganism(s) of interest, which are used to check for potential sources of contamination and to verify the selectivity/specificity of the analytical procedure. Negative control samples include microbial cultures different from the organism(s) of interest used to test for the performance of media, and physiological and biochemical reactions counter to the organism(s) of interest.

Positive control samples

Positive control samples are prepared in the laboratory by spiking blank samples with the organism(s) of interest. These are used to check against similar reactions expected of the organism(s) of interest.

Calibration samples

Calibration samples are prepared by spiking blank samples (with or without matrix) with known concentrations of an organism. For confirmatory quantitative procedures, calibration samples are prepared the day of the analysis. Calibration samples, with known concentrations of an organism(s) obtained from an independent source, may also be used to prevent a possible undetectable bias into the analytical results.

Laboratory internal quality audit

A laboratory audit is the process of comparing observations of actual conditions with requirements and presenting an evaluation of the results to management. Annually, the laboratory environment, and technical and management processes are audited to determine conformance of each of these components to the laboratory's established policies, processes, and procedures, as well as to external regulatory and accreditation requirements. Audit findings point to process problems that need corrective action. This ensures a process of continuous improvement in the laboratory's quality system.

Verification of Technician Competencies

One of the essential components of our IQC identified as necessary to ensure high-quality test results is employee training and laboratory technologist competency assessment. This takes

place once hired and every six months thereafter. This includes (i) direct observation of routine test performance; (ii) monitoring the recording and reporting of test results; (iii) review of intermediate test results, QC records, proficiency testing results, and preventive maintenance records; (iv) direct observation of performance of instrument maintenance and function checks; and (v) assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

CLIENT SATISFACTION FEEDBACK

In providing analytical and other technical services to the food processing industry the laboratory provides test results, interpretations, and reports to its clients. In order to adequately measure and monitor the laboratory's performance, feedback is actively and routinely solicited from these clients regarding their satisfaction with the laboratory services they have received, including their satisfaction in dealing with the laboratory staff. BioFoodTech's client satisfaction scores are often above 95%. Any client complaints are dealt with immediately or within a reasonable period of time. The client is always informed of the actions taken regarding a complaint.