A24 – CALA CHECKLIST FOR MICROBIOLOGY

Revision 5.1

March 29, 2023

Laboratory Name: _____

Appendix Name: _____

Appendix Number: _____

Assessor: _____

Date: _____

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SELECTION AND VERIFICATION OF METHODS (7.2.1)

Clause	Requirements	Observation prior the visit	Observation on-site
7.2.1.1	The laboratory uses appropriate methods and supporting procedures, including but not limited to testing, sampling, verification and validation, and estimation of measurement uncertainty procedures.		
7.2.1.2	An approved, documented method is authorized (8.3), up-to-date, available to personnel, and authorized. Any supporting work instructions (e.g., glassware cleaning, sample disposal, report of adverse results, etc.) are documented, authorized, up-to-date and readily available to the analyst. Any equipment manuals are readily available to the analyst.		
7.2.1.3	The method is based on the latest valid edition of a published reference method (where appropriate and possible). As well, the method is adequately documented and supplemented with additional details to ensure consistent application. Steps to look for include, but are not limited to: • Sampling; • Details on reagent preparation, storage and shelf life; • Procedure for media preparation, including labeling, storage, quality control and safety procedures for handling of media; • Colony counting and reporting criteria; appropriate reporting of non- detects, taking dilution factors and sample volumes into consideration; • Equipment and supplies; • Maintenance of stock cultures. (see CALA document P07, section 7.2.1.3)		
7.2.1.4	Methods are published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.		
7.2.1.5	Where there has been no modification from the reference method, the laboratory has verified that it can properly perform the method prior to analysis of customer samples.		

	For water testing: Requirements will vary on whether the method is qualitative or quantitative. Refer to CALA Document P07, Appendix 1, Clause 7.2.1.5. For food-testing: refer to CALA document P07, Appendix 1, Clause 7.2.1.5.		
7.2.1.6	Method development is planned and assigned to competent personnel. Periodic review is carried out confirm the needs of customer are still being fulfilled. Any modifications are approved and authorized.		
7.2.1.7	Deviations from methods are documented, technically justified, authorized and accepted by the customer. See CALA document P07.		

VALIDATION OF METHODS (7.2.2)

Clause	Requirements	Observation prior the visit	Observation on-site
7.2.2.1	In-house developed methods, published methods without validation data, commercial test kits without validation data and standard/reference methods used outside their intended scope or that have been modified are appropriately validated. The level and rigour of validation will depend on the nature/extent of the modification(s). For Food-Testing requirements, see CALA document P07, section 7.2.2.1.		
7.2.2.2	When changes are made to a validated method, influence of such changes is determined and if found to affect the original validation, a new method validation is performed.		
7.2.2.3	Performance characteristics of validated methods are relevant to the customers' needs and consistent with specific requirements.		
7.2.2.4	Validation records are retained, including: the validation procedure; specification of the requirement; determination of the performance characteristics; results obtained; and, statement on the validity, detailing its fitness for the intended use.		

EVALUATION OF MEASUREMENT UNCERTAINTY (7.6)

Clause	Requirements	Observation prior the visit	Observation on-site
7.6.1	For all tests, factors are identified which affect measurement uncertainty.		

7.6.2	For internal calibrations on balances, thermometers and pipettes, there is a documented procedure that includes the estimation of measurement uncertainty and staff with the appropriate training.		
7.6.3	For quantitative tests, the laboratory has calculated measurement uncertainty (see CALA Policy P19). For qualitative tests, the laboratory demonstrates knowledge of the factors affecting measurement uncertainty and has an understanding of the false positives/false negatives, where applicable.		

SAMPLING (7.3)

Clause	Requirements	Observation prior the visit	Observation on-site
7.3.1	A sampling plan and method is established and available at the site of sampling, addresses the factors to be controlled, and is based on statistical methods, whenever reasonable.		
7.3.2	The sampling method describes the selection of samples or sites, the sampling plan, and the preparation and treatment of samples to yield a representative sample for testing.		
7.3.3	Records with respect to sampling are retained and include, where relevant: • Reference to the sampling method used • Date and time of sampling • Data to identify and describe the sample (e.g. number, amount, name) • Identification of the personnel and equipment • Environmental or transport conditions • Diagrams or other equivalent means to identify locations, when appropriate • Deviations, additions to or exclusions		

HANDLING OF TEST OR CALIBRATION ITEMS (7.4)

Clause	Requirements	Observation prior the visit	Observation on-site
7.4.1	There are documented procedures for transportation, receipt, handling, protection, storage, retention and disposal or return of samples, including all provisions necessary to protect the integrity and interests of the laboratory and customers. These procedures include, but are not limited to: • use of sterile approved sample containers; • for water testing only: collection of chlorinated samples in sterilized containers pretreated with sodium thiosulphate (where appropriate); • instruction to ensure that holding time and sample transport / storage meets method / regulatory requirements; • For Food testing: temperature at reception recorded (e.g. 10°C for some types of testing) Precautions are taken to avoid deterioration, contamination, loss or damage. Handling instructions are followed.		
7.4.2	Samples have a unique, unambiguous identification that is retained during the testing and reporting process.		
7.4.3	Deviations from specified conditions are recorded (e.g. samples does not fit, sample leaking). Consultations with customers are recorded. A disclaimer in the report is recorded when the customer is asking for a deviation.		
7.4.4	Storage conditions are maintained, monitored and recorded.		

FACILITIES AND ENVIRONMENTAL CONDITIONS (6.3)

Clause	Requirements	Observation prior the visit	Observation on-site
6.3.1	Environmental conditions are suitable for the laboratory activities. Conditions do not adversely affect the validity of results.		
6.3.2	Requirements for environmental conditions are documented (e.g., incubation temperatures).		
6.3.3	The laboratory monitors, controls, and records environmental		

	conditions with relevant specifications, methods or procedure or where they influence the validity of the results (e.g., monitoring of incubators, fridges, etc…).		
6.3.4	Measures to control facilities are implemented, monitored and periodically reviewed including but not limited to: • Access to laboratory activities • Prevention of contamination, interference or adverse influences • Effective separation of incompatible activities (for example, this is especially important for PCR methods). For food-testing only: Monitoring of the Air quality and records are retained. Monitoring of the Surface quality (swabs) and records are retained. Monitoring is performed for the appropriate bacteria.		
6.3.5	If activities are performed outside the facilities, ensure the requirements of the standard are met.		

EQUIPMENT (6.4)

Clause	Requirements	Observation prior the visit	Observation on-site
6.4.1	All equipment, reagents, media, reference materials, consumables and auxiliary apparatus (including software) required for the test procedure is available, appropriately monitored, and functioning properly. The laboratory has sufficient quantities of equipment and supplies to carry out the volume of work. In microbiology, these items can include, but are not limited to: • sterile rinse buffer / distilled water; • disinfectants available and routinely used for cleaning bench areas; • reference standards (e.g., reference weights, pH standards, etc.); • stock cultures (e.g. ATCC organisms).		
6.4.2	When using equipment outside the laboratory's permanent control, ensure that the requirements of ISO/IEC 17025 are met.		
6.4.3	The procedure and/or supporting procedures include instructions to ensure that equipment, media, reagents, test organisms, etc. are handled, transported, stored, and used in a manner to ensure proper		

	functioning and to prevent contamination or deterioration. This includes but is not limited to: a) When washing and re-using glassware that can impact the recovery of organisms, the laboratory requires a procedure to test for residual detergent. See CALA document P07, Appendix 1 for more direction or guidance. b) b) Procedures for planned maintenance are in place for equipment that requires regular servicing or checks.		
6.4.4	Equipment was verified prior to being put into use or if it was returned to service. Supplies that need to be checked prior to use include but are not limited to: a) A minimum of 1 sample container from each lot of new, certified containers is checked for sterility or for influence on parameters. b) Purchased organisms have certificates with the organism name, and the laboratory confirms the identify of these organisms by either using an acceptable identification method (e.g. API, Biolog, Vitek, etc.) or demonstrating key reactions on selective medium. c) Organisms isolated from the environment are properly characterized, and key reactions are demonstrated on selective medium as required. d) For Water testing only e) For MF methods, hydrophobicity of filters is tested (e.g., "charcoal" test or confluent growth or other method) and inhibitory effects of filters is tested by comparison of recoveries on a membrane filter and a spread plate/pour plate (or equivalent). f) If producing water in house and it is used to dilute samples, or make media or reagents, check conductivity daily or as-used and have procedures in place, including sterility testing, to verify that the water is not having a negative impact on the conduct of the test (see CALA document P07, Appendix 1). g) g) If purchasing distilled water, and it is used to dilute samples or to make media or reagents, have procedures in place, including sterility testing, to verify that the water is not having a negative impact on the conduct of the test. A certificate shall		

	be obtained from the supplier prior to use (see CALA document P07, Appendix 1).		
6.4.5	Equipment for measurement is capable of achieving measurement accuracy and/or measurement uncertainty (e.g., incubators, working thermometers, etc.).		
6.4.6	Equipment is calibrated, if the measurement accuracy or measurement uncertainty affects the test result or to establish traceability (e.g., thermometers, balances).		
6.4.7	A calibration programme is established, reviewed and adjusted to maintain confidence in the status of calibrations.		
6.4.8	Equipment that requires calibration (i.e. semi-automated pipettes, balances and thermometers that are critical to the test result) is labeled to indicate the status, including the date last calibrated and expiry criteria or date when due. Note: labeling is not required for equipment verified daily or as-used. All information required to properly identify organisms appear on their containers (i.e., name or number of organisms, and date subcultured) including working cultures and those stored at lower temperatures (e.g. in refrigerators / freezers, where appropriate).		
6.4.9	Equipment that is out-of-service is isolated or marked as being out of service.		
6.4.10	Intermediate checks on equipment are carried out when necessary.		
6.4.11	Reference values and correction factors are updated and implemented, as appropriate (e.g., a correction factor on a working thermometer).		
6.4.12	Practicable measures are taken to prevent unintended adjustments of equipment that would invalidate results.		
6.4.13	Records are retained for equipment, as applicable. Records generally include: identity of the equipment; the manufacturer's name, serial number, or other unique identification; evidence that the equipment conforms with specified requirements; current location; calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration; maintenance plan and maintenance carried out to date; and details of any unplanned work or repair on the equipment. Records shall be maintained of reference materials, results,		

	acceptance criteria, relevant dates and the period of validity of reference materials.		

METROLOGICAL TRACEABILITY (6.5)

Clause	Requirements	Observation prior the visit	Observation on-site
6.5.1	The laboratory has established and maintained metrological traceability of measurement results (unbroken chain) and measurement uncertainty of each step (see CALA Policy A61-01).		

MEDIA HANDLING AND QUALITY CONTROL

Clause	Requirements	Observation prior the visit	Observation on-site
6.4.8	Media and / or reagents are appropriately labeled with material, concentration or purity (as required), date prepared and /or expiry date.		
6.4.3	Media/ reagents are stored under proper conditions, and storage times are met.		

7.5.1	Records are kept for all media/ reagents prepared or received and include: • date of receipt; • date opened / first use; • date of preparation, and expiry date (if required); • lot number, as required; • shelf-life / expiry date of product; • storage conditions; • performance specifications. For purchased / prepared media / reagents: records are retained of manufacturer's QC and other information, including but not limited to positive and negative control(s), sterility and final pH For in-house prepared media: QC results and sufficient information to enable the test to be repeated under conditions as close as possible to the original. QC records are retained for each batch of in-house prepared or purchased media. NOTE: for guidance on defining a batch, refer to the Interpretation in CALA document P07, Appendix 1. The type and nature of QC testing will depend on the method.		
7.7.1.c	Media QC includes a positive control culture (traceable to ATCC or equivalent). <u>For Water testing only</u> - QC must be performed using the same technique as used for routine analysis. For example, the positive control must be applied using MF for MF methods. As well, a comparison of positive control cultures on selective and non-selective media is done and there is a comparison of recovery rates of the positive control culture (see P07, Appendix 1 for further information; not applicable to tube MPN methods). For other MPN methods (such as quantitray or similar), the lab must demonstrate satisfactory recovery of target organisms (e.g., using selective media tray vs non-selective media or old vs new lot comparisons, or use of quantifiable cultures)		
7.7.1.c	Media QC includes a sterility check.		

7.7.1.c	Media QC includes a negative control culture (traceable to ATCC or equivalent). For Water testing only - The negative culture can be streaked on the media for MF methods.		
7.7.1.c	For Water testing only - For quantitative methods using only non-selective media: compare recovery rates on an old/previous batch of media to a new batch, using the same technique to do test (e.g., MF or spread plate or pour plate).		

ENSURING THE VALIDITY OF RESULTS (7.7)

Clause	Requirements	Observation prior the visit	Observation on-site
7.7.1	A procedure exists to monitor the validity of the results. Resulting data is recorded in a way as to detect trends, and where practicable, statistical techniques are applied to review results (e.g., control charts).		
7.7.1.f	Method/analytical QC includes duplicates to monitor within-run precision for quantitative methods (where appropriate). For further guidance, refer to P07, Appendix 1.		
7.7.1.g	Method/analytical QC includes confirmation of isolates as necessary (applicable only to membrane filtration methods).		
7.7.1.h	There are procedures in place to ensure there is no carryover between membrane filtrations (e.g., UV boxes, hot water).		
7.7.1.j	Method/analytical QC includes monthly inter-technician comparison readings to monitor precision and monthly parallel analyses on at least one positive sample to monitor inter-technician method precision for quantitative tests. Note: Inter-technician comparison readings are generally applicable to any method where a result depends on the judgment of an analyst (e.g., color reaction).		

7.7.2	Laboratory meets CALA PT Policy for Accreditation (see CALA Policy P02-03).		
7.7.3	QC results are analyzed and used to control and, if applicable, improve the laboratory's activities. If QC results are outside pre-defined criteria, appropriate action is taken. If PT did not meet acceptance criteria, confirm that the laboratory has records of corrective action.		

REPORTING OF RESULTS (7.8)

Clause	Requirements	Observation prior the visit	Observation on-sit
7.8.1.1	The results are reviewed and authorized prior to release. For observations related to reporting, cite the appropriate clause in the main checklist (A02 – CALA Rating Guide).		
7.8.1.2	The results are provided accurately, clearly, unambiguously and objectively. For observations related to reporting, cite the appropriate clause in the main checklist (A02 – CALA Rating Guide).		

TECHNICAL RECORDS (7.5)

Clause	Requirements	Observation prior the visit	Observation on-site
7.5.1	Technical records are complete with respect to the specific tests, are recorded at the time they are made and that there is sufficient information to establish an audit trail. Specific records to review include but are not limited to: analyst worksheet or notebook; records of nonconformities; stock culture maintenance logs; records of reference standards (e.g. reference weights, pH standards, etc.) and reference materials certificates (e.g. ATCC strains). For guidance on the type and nature of records that may be needed, please refer to CALA document P07, Appendix 1, Clause 7.5.1- Technical Records.		
7.5.2	Amendments to technical records are tracked to previous or original observations. Both shall be retained including the date of alteration, an indication of the altered aspects and personnel responsible.		

CONTROL OF DATA AND INFORMATION MANAGEMENT (7.11.2)

Clause	Requirements	Observation prior the visit	Observation on-site
7.11.2	Software (e.g. LIMS) is validated for functionality before introduction and any changes to software (e.g. LIMS) are authorized, documented and validated before implementation. For any observations, cite the appropriate clause in the main checklist (A02 – CALA Rating Guide).		

OTHER RESOURCES - PERSONNEL (6.2) AND EXTERNALLY PROVIDED PRODUCTS AND SERVICES (6.6)

Clause	Requirements	Observation prior the visit	Observation on-site
6.2	Personnel are competent and the laboratory has authorized personnel to perform specific lab activities including but not limited to: • Development, modification, verification and validations of methods • Analysis of results including statement of conformity and opinions and interpretations • Reporting, reviewing and authorization of results For any observations related to personnel, cite the appropriate clause in the main checklist (A02 – CALA Rating Guide).		
6.6	For any observations related to purchasing equipment, supplies or services, cite the appropriate clause in the main checklist (A02 - CALA Rating Guide).		

Area	Appendix #	Appendix #	Appendix #	Appendix #	Appendix #	Appendix #
6.2 – Personnel						
6.3 – Environmental Conditions						
6.4 – Equipment						
6.5 – Traceability						
6.6 – Externally provided products and services						
7.2.1 – Method Selection & Verification						
7.2.2- Validation						
7.3 - Sampling						
7.4 – Sample Handling						
7.5 – Technical Records						
7.6 - MU						
7.7 - Trending						
7.7 – Media Prep & QC						
7.7 – Method QC (e.g., dups, intertech etc.)						
7.7 – Confirmation						
7.7 – PT						