A24 – CALA Checklist for Microbiology
Revision 4.1 – February 16, 2018

Laboratory Name: _____

Appendix Name: _____

Appendix Number: _____

Assessor: _____

Date: _____

CALA
Laboratory Accreditation

CALA CHECKLIST FOR MICROBIOLOGY

Item	ISO/IEC17025:2005 Clause (ISO/IEC17025:2017 Clause)	Requirement	Observations Yes	No	Not applicable
01		SAMPLING AND SAMPLE HANDLING			
01.01	5.7, 5.8 (7.4)	Customers are informed of the sampling protocol and acceptance criteria, and there are written criteria for sample rejection (e.g., poor condition, physical deterioration, incorrect temperature, deficient labeling, etc.)	❑	❑	❑
01.02	5.7, 5.8 (7.4)	There are any special sampling and handling instructions depending on the matrix or reference method (where appropriate).	❑	❑	❑
01.03	5.7, 5.8 (7.4)	If the laboratory is responsible for sampling, ensure there are procedures for sampling available where sampling is done and they are, whenever reasonable, based on appropriate statistical methods.	❑	❑	❑
01.04	5.7, 5.8 (7.4)	For sample handling, verify that there are documented procedures specified to protect the integrity of the sample from time of sampling to sample processing (including pre and post analysis storage) including, but not limited to: • use of sterile approved sample containers; • 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.	❑	❑	❑
01.05	5.7, 5.8 (7.4)	For sample preparation/testing, verify that the laboratory can demonstrate that the test portion is a representative sample of the product as much as possible (when relevant) and suitable for analysis.	❑	❑	❑
01.06	5.7, 5.8 (7.4)	For sample preparation/testing, verify that the laboratory can demonstrate that steps have been taken to prevent interference by environmental conditions that can invalidate the test result and that records are maintained (e.g., storage records).	❑	❑	❑
01.07	5.7, 5.8 (7.4)	Ensure that there is effective separation of incompatible activities (for example, this is especially important for PCR methods).	❑	❑	❑
02		DOCUMENT CONTROL/TEST METHOD			
02.01	4.2.1, 4.3, 5.4.1, 5.4.2 (7.2)	Verify that there is an approved, documented method and deviations from the reference method are documented. Confirm versions are the same as in the QMS and within the actual lab, and that it and any supporting work instructions are readily available to the analyst.	❑	❑	❑

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02.02	4.2.1, 4.3, 5.4.1, 5.4.2 (7.2.1.3)	Verify that all necessary successive steps in the test procedure are based on the latest valid edition of a published reference method (where appropriate and possible) and adequately documented. 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, supplies, etc	❑	❑	❑
03		TEST METHOD VALIDATION/VERIFICATION			
03.01	4.2.1 (7.2.1.1)	Verify that there is a documented procedure for method validation and /or verification as appropriate.	❑	❑	❑
03.02	5.4 (7.2.2)	Verify that there are method validation and / or verification records. If there are deviations from the reference method, ensure validation is adequate. (The level and rigour of validation will depend on the nature/extent of the modification(s)).	❑	❑	❑
03.03	5.4 (7.2.1.5)	Verify that the: • method meets performance characteristics • method meets customer requirements and • validation / verification records include a statement that the method is "Fit for the intended use" .	❑	❑	❑
03.04	5.4 (7.2.1.5)	Verify that verification for Quantitative tests is conducted appropriately and includes repeatability using a minimum of 10 replicates of a known positive sample or duplicate data collected over a period of time.	❑	❑	❑
03.05	5.4 (7.2.1.5)	Verify that the verification for qualitative tests is based upon reliability of detection using a minimum of 10 of known positive samples, performance history, or media QC.	❑	❑	❑
03.06	5.4 (7.2.2.1)	Verify that in-house developed methods, published methods without validation data or commercial test kits without validation data are appropriately validated to establish relevant performance characteristics.	❑	❑	❑
03.07	CALA Policy (7.7.2)	Verify that the laboratory has successfully participated in PT as per P02-03 - Proficiency Testing Policy for Accreditation; if PT did not meet acceptance criteria, confirm that the laboratory has records of corrective action.	❑	❑	❑
03.08	5.4.6 (7.6)	Confirm that the laboratory has identified factors that affect measurement of uncertainty and has estimated measurement uncertainty for quantitative tests.	❑	❑	❑
04		METHOD QUALITY CONTROL			

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04.01	4.2.1 (7.7)	Verify that method quality control is documented.	❑	❑	❑
04.02	5.9.1 (7.7.1)	Verify that resulting data is recorded in such a way to detect trends, and where practicable, statistical techniques are applied to review results.	❑	❑	❑
04.03	5.9 (7.7.1)	Confirm that method/analytical QC includes, duplicates to monitor within-run precision for quantitative methods (where appropriate). For further guidance, refer to P07.	❑	❑	❑
04.04	5.9 (7.7.1)	Confirm that method/analytical QC includes method blanks (where appropriate).	❑	❑	❑
04.05	5.9 (7.7.1)	Confirm that method/analytical QC includes monthly inter-technician comparison readings to monitor precision. Generally applicable to any method where a result depends on the judgment of an analyst (e.g., colour reaction).	❑	❑	❑
04.06	5.9 (7.7.1)	Confirm that method/analytical QC includes monthly parallel analyses on at least one positive sample to monitor inter-technician method precision for quantitative tests.	❑	❑	❑
04.07	5.9 (7.7.1)	Confirm that method/analytical QC includes confirmation of isolates as necessary (applicable only to membrane filtration methods).	❑	❑	❑
05		**MEDIA / REAGENT HANDLING AND QUALITY CONTROL**			
05.01	4.2.1 (7.2.1.3)	Verify that media / reagent handling requirements and quality control are documented.	❑	❑	❑
05.02	4.13.2 (6.4.8)	Verify that media and / or reagents are appropriately labeled with material, concentration or purity (as required), date prepared and /or expiry date.	❑	❑	❑
05.03	4.6.2, 5.3 (6.3.1)	Verify that media/ and or reagents are stored under proper conditions, and storage times are met.	❑	❑	❑
05.04	4.13.2 (7.5)	Verify that 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 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	❑	❑	❑

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		enable the test to be repeated under conditions as close as possible to the original.			
05.05	4.13.2 (7.5)	Confirm that the laboratory has QC records for each batch of in-house prepared or purchased media. NOTE: for guidance on defining a *batch*, refer to the Interpretation in P07. The type and nature of QC testing will depend on the method, but generally involves the items listed in 05.06 to 05.10 (below).	❑	❑	❑
05.06	5.9, 4.13.2 (7.7.1)	Media QC includes a sterility check.	❑	❑	❑
05.07	5.9, 4.13.2 (7.7.1)	Media QC includes a positive control culture (traceable to ATCC or equivalent) performed using the same technique as used for routine analysis. For example, if media is used for MF, then the positive control must be applied using MF.	❑	❑	❑
05.08	5.9, 4.13.2 (7.7.1)	Media QC includes a comparison of positive control cultures on selective and non-selective media and comparison of recovery rates of the positive control culture (see P07 for further information; not applicable for MPN methods);	❑	❑	❑
05.09	5.9, 4.13.2 (7.7.1)	Media QC includes a negative control culture (traceable to ATCC or equivalent). N.B. For MF methods, the negative culture can be streaked on the media.	❑	❑	❑
05.10	5.9, 4.13.2 (7.7.1)	For quantitative methods using non-selective media only: 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).	❑	❑	❑
06		**STOCK CULTURES**			
06.01	4.2.1 (7.7.1.2)	Verify that documented procedures are in place for the maintenance of stock cultures.	❑	❑	❑
06.02	4.13.2 (6.4.8)	Confirm that all information required to properly identify organisms appear on their containers (i.e., name or number of organism, and date subcultured) including working cultures and those stored at lower temperatures (e.g. in refrigerators / freezers, where appropriate).	❑	❑	❑
06.03	4.6.2, 4.13.2 (6.4.1)	Confirm that purchased organisms have certificates with the organism name, plus ID confirmation by the laboratory using an acceptable identification method (e.g. API, Biolog, Vitek, etc.) or key reactions are demonstrated on selective medium.	❑	❑	❑
06.04	4.6.2, 4.13.2 (6.4.1)	Confirm that organisms isolated from the environment are properly characterized, and key reactions are demonstrated on selective medium as required.	❑	❑	❑
07		**SUPPLIES/LABWARE QC**			

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07.01	4.6.2, 5.5.1, 5.7, 5.9 (6.4.1)	Verify that a minimum of 1 sample container from each lot of new, certified containers is checked for sterility or for influence on parameters.	❑	❑	❑
07.02	4.6.2, 5.5.1 (6.4.1)	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.	❑	❑	❑
07.03	4.6.2, 5.4.1, 5.4.2 (7.2.1)	There are procedures in place to ensure there is no carryover between membrane filtrations (e.g., UV boxes, hot water).	❑	❑	❑
07.04	5.6 (6.4.6)	Accuracy of funnel volumetric graduations is checked (see A61).	❑	❑	❑
07.05	4.6.2, 5.5.1 (6.4.1)	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 P07).	❑	❑	❑
07.06	4.6.2, 5.5.1 (6.4.1)	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 P07).	❑	❑	❑
07.07	4.6.2, 5.5.1 (6.4.1)	Verify that all labware is adequate cleaned. When washing and re-using glassware that can impact the recovery of organisms, verify that there is a procedure in place to test for residual detergent. See P07 for more direction.	❑	❑	❑
08		**SUPPLIES – AVAILABILITY**			
08.01	4.6.2, 5.5.1 (6.4.1)	Verify that all supplies (e.g., test organisms, media, reagents, reference materials, commercial kits, etc.) required for the test procedure are in sufficient quantities to carry out the volume of work.	❑	❑	❑
08.02	4.6.2, 5.5.1 (6.4.1)	Verify that all supplies (e.g., test organisms, media, reagents, reference materials, commercial kits, etc.) required for the test procedure meet requirements and/or specifications.	❑	❑	❑
08.03	4.6.2, 5.5.1 (6.4.1)	Verify that all supplies (e.g., test organisms, media, reagents, reference materials, commercial kits, etc.) required for the test procedure are stored under appropriate conditions (as specified in reference method or by regulator, etc.) and in a manner which satisfies requirements for safety, security, separation of incompatible materials / activities, and ease of retrieval.	❑	❑	❑
08.04	4.6.2, 5.5.1 (6.4.1)	Verify the following are available: • sterile rinse buffer / distilled water;	❑	❑	❑

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		• disinfectants available and routinely used for cleaning bench areas; • records of reference standards (e.g. reference weights, pH standards, etc.) and reference materials certificates (e.g. ATCC strains).			
09		**OTHER WORK INSTRUCTIONS (Procedures)**			
09.01	4.2.1, 4.3 (7.2.1.2)	Verify that all necessary supporting work instructions are documented and readily available.	❑	❑	❑
09.02	4.2.1, 4.3 (7.2.1.2)	Confirm that requisite reference texts / methods are available.	❑	❑	❑
09.03	4.2.1, 4.3 (7.2.1.2)	Confirm that supporting test methods (e.g., pH) are authorized and available.	❑	❑	❑
09.04	4.2.1, 4.3 (7.2.1.2)	Confirm that equipment instruction manuals are available.	❑	❑	❑
09.05	4.2.1, 4.3 (7.2.1.2)	Confirm that computer software related procedures (including LIMS procedures, such as data entry and approval) are authorized and available.	❑	❑	❑
09.06	4.2.1, 4.3 (7.2.1.2)	Confirm that glassware cleaning procedures are authorized and available.	❑	❑	❑
09.07	4.2.1, 4.3 (7.2.1.2)	Confirm that there are procedures in place for reporting of adverse results to authorities having jurisdiction.	❑	❑	❑
09.08	4.2.1, 4.3 (7.2.1.2)	Confirm that sample disposal procedures are authorized and available, including but not limited to disinfection / sterilization, disposal of biohazardous material, spill procedures and any safety considerations.	❑	❑	❑
10		EQUIPMENT			
10.01	5.5 (6.4.1)	Verify that all equipment required for the test procedure and equipment supporting the test is available, uniquely identified, appropriately monitored, functioning properly, and safeguarded from adjustments that would invalidate results. (Note to laboratories and assessors: the list of equipment was removed from this checklist; it is incumbent to review the reference method and/or laboratory test method and confirm that equipment required for the test is available).	❑	❑	❑
10.02	5.5 (6.4.3)	Verify that equipment that requires regular servicing or checks to ensure conformance is included in a maintenance program.	❑	❑	❑
10.03	5.5 (6.4.3)	Verify that there is availability of backup equipment or a back-up plan.	❑	❑	❑
10.04	5.5 (6.4.8)	Verify that equipment requiring calibration (i.e. semi-automated pipettes, balances and thermometers that are critical to the test result) are labeled to indicate the status, including the date last calibrated and expiry criteria or date	❑	❑	❑

Item	ISO/IEC17025:2005 Clause (ISO/IEC17025:2017 Clause)	Requirement	Observations Yes No Not applicable
		when due. Note: labeling is not required for equipment verified daily or as-used; see P07.	
11		**CONDUCT OF TESTING**	
11.01	4.2.1, 5.4.1 7.2.1.1	Verify that the test procedure and all supporting work instructions are performed as documented.	❑ ❑ ❑
12		**RECORD KEEPING**	
12.01	4.13 7.5	Verify that 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. For guidance on the type and nature of records that may be needed, please refer to the appropriate section of P07.	❑ ❑ ❑