A122 CALA Checklist for Assessment of Mould Testing
Revision 1.6 – January 03, 2019

Laboratory Name: _____

Appendix Name: _____

Appendix Number: _____

Assessors: _____

Date: _____

CALA
Laboratory Accreditation

Assessor Notes:

CALA CHECKLIST FOR ASSESSMENT OF MOULD TESTING

Item	Clause	Requirement	Document Review Y N N/A Comments	Implementation Y N N/A Comments
	7.2	SELECTION, VERIFICATION AND VALIDATION OF METHODS		
	7.2.1.1	All necessary successive steps in the test procedure (including details on reagent preparation, storage and shelf life, equipment, supplies, etc.) are appropriate. For mould testing, specifics may include but are not limited to: microscope magnification, counting rules, identification of fungal spores and structures, taxonomic keys.	❑ ❑ ❑	❑ ❑ ❑
	7.2.1.2	The test method, procedures and supporting documentation are up to date and are readily available to the analyst. Supporting documentation relevant to mould testing includes, but is not limited to taxonomic keys and instructions on disposal of biohazardous material. Note: For issues related to document control, refer to Clause 8.3.	❑ ❑ ❑	❑ ❑ ❑
	7.2.1.3	The test method is based on the latest valid edition of a published reference method, unless it is not possible or appropriate. The test method is supplemented with additional details to ensure consistent application.	❑ ❑ ❑	❑ ❑ ❑
	7.2.1.5	There is data available to demonstrate that the laboratory verified that it could properly perform the method prior to analysis of customer samples. For spore count methods, include estimates of repeatability and evaluation of measurement uncertainty. Identification methods are generally verified based on performance history.	❑ ❑ ❑	❑ ❑ ❑

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	7.2.2	For non-standard methods, laboratory-developed methods and standard methods used outside their scope or modified, there are method validation results, and a statement that the method is fit for the intended use. The level and rigour of validation will depend on whether there are modifications from the reference method or if it is an in-house developed method (see CALA Policy A12). Modifications from the reference method shall be documented.	❑ ❑ ❑	❑ ❑ ❑
	7.3	SAMPLING		
	7.3.1	Sampling plans for samples are based on appropriate statistical methods and the sampling process addresses the factors to be controlled to ensure the validity of the results; i.e., • Sampling/sub-sampling methods are available and followed; • Sampling plans are statistically based; • Field sampling generates representative samples, and duplicates are routinely taken.	❑ ❑ ❑	❑ ❑ ❑
	7.4	HANDLING OF TEST OR CALIBRATION ITEMS		
	7.4.1	Sample history requirements are appropriate, documented and available where required. For mould testing, particular attention may be required for storage conditions and hold times.	❑ ❑ ❑	❑ ❑ ❑
	7.7	METHOD QUALITY CONTROL		
	7.7.1.a	Method quality control is appropriate; included or referenced in the test method; and, implemented. Resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results.	❑ ❑ ❑	❑ ❑ ❑

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	7.7.1.b	Appropriate QC for spore count methods includes, but is not limited to: duplicates and monthly inter-technician comparison readings to monitor precision.	❑ ❑ ❑	❑ ❑ ❑
	7.7.1.c	Appropriate QC for microscopic analysis includes, but is not limited to: review of a slide from a collection on a rotational basis by each analyst on a regular basis (at least monthly) with set acceptance criteria.	❑ ❑ ❑	❑ ❑ ❑
	7.7.1.d	Appropriate QC for culturing methods includes, but is not limited to: microscopic confirmation of cultures performed by two analysts on a regular basis (at least monthly).	❑ ❑ ❑	❑ ❑ ❑
	7.7.1.e	Appropriate QC for any media used in mould testing includes, but is not limited to: pH, sterility, and a positive control per batch of media.	❑ ❑ ❑	❑ ❑ ❑
	7.7.2	The laboratory participates in proficiency testing, as per CALA P02-03; any unsatisfactory PT results have been investigated.	❑ ❑ ❑	❑ ❑ ❑
	6.3	FACILITIES AND ENVIRONMENTAL CONDITIONS		
	6.3.1	Facilities and environmental conditions shall be suitable and shall not adversely affect the validity of results. For mould testing, a smooth surface on floors, walls, ceiling and benches is recommended. Negative room pressure is encouraged but not required unless the laboratory is involved with Biological Safety Level 3 procedures.	❑ ❑ ❑	❑ ❑ ❑
	6.3.3	The lab shall monitor, control and record environmental conditions (e.g., air monitoring of the area).	❑ ❑ ❑	❑ ❑ ❑
	6.3.4	Measures to control facilities include adequate separation between incompatible activities, especially when working with pathogenic fungi (e.g., biohazard signs, isolated area with restricted access, etc.).	❑ ❑ ❑	❑ ❑ ❑

Item	Clause	Requirement	Document Review Y N N/A Comments	Implementation Y N N/A Comments
	6.4	EQUIPMENT		
	6.4.1.a	All equipment required for correct performance of the test procedure is available. Equipment includes measuring instruments, support equipment, computers, reagents and reference materials.	❑ ❑ ❑	❑ ❑ ❑
	6.4.1.b	Specific requirements for equipment for mould testing may include, but are not limited to: a compound microscope having low, high power, and 100X oil immersion objectives. Microscopic alignment is checked annually and each microscope has an ocular micrometer that is calibrated annually.	❑ ❑ ❑	❑ ❑ ❑
	6.4.1.c	Specific requirements for equipment for mould testing may include, but are not limited to: incubators maintained within the specified temperature range. Incubator temperatures must be monitored and recorded at least once daily (continuous monitoring, twice daily temperature checks, or use of a min-max thermometer is best practice and spatial variability is checked annually.	❑ ❑ ❑	❑ ❑ ❑
	6.4.1.d	Specific requirements for equipment for mould testing includes, but are not limited to: stock cultures. If a culture is purchased, ensure that there is a certificate with the organism name, plus confirmation on selective medium. If the culture is isolated from the environment, ensure that it is properly characterized.	❑ ❑ ❑	❑ ❑ ❑
	6.4.1.e	Specific requirements for equipment for mould testing includes, but are not limited to: reference slides. The slide collection should include various count levels and genera/groups of spores.	❑ ❑ ❑	❑ ❑ ❑
	6.4.1.f	Specific requirements for equipment for mould testing includes, but are not limited to: availability of supplies such as slide sealant, lactophenol cotton blue, slides, microscope bulbs, and a micrometer.	❑ ❑ ❑	❑ ❑ ❑

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	6.4.4	The equipment is compliant with specifications and checked and calibrated prior to use (or when being put back into use if the equipment was outside the permanent control of the laboratory or not in use for a period of time).	❑ ❑ ❑	❑ ❑ ❑
	6.4.5	The equipment is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.	❑ ❑ ❑	❑ ❑ ❑
	6.4.8	All equipment requiring calibration or equipment with a defined period of validity (e.g., reagents, standards, stock cultures, microscopes) is labeled so that the user can readily identify the status of the calibration or period of validity. All reagents are labeled with material, concentration or purity, date prepared and/or expiry date.	❑ ❑ ❑	❑ ❑ ❑
	6.4.9	Out of service equipment is clearly isolated or clearly labeled or marked as being out of service, and that equipment is checked and validated before return to service.	❑ ❑ ❑	❑ ❑ ❑
	6.4.12	The laboratory has taken practicable measures to prevent unintended adjustments that would invalidate results.	❑ ❑ ❑	❑ ❑ ❑
	6.5	METROLOGICAL TRACEABILITY		
	6.5.2	Measurement results are traceable to the SI (e.g., temperature measurements).	❑ ❑ ❑	❑ ❑ ❑
	6.5.3	When metrological traceability to the SI units is not technically possible, the laboratory demonstrates metrological traceability to an appropriate reference. Reference materials must be from accredited RMPs, where available.	❑ ❑ ❑	❑ ❑ ❑
	7.8	REPORTING OF RESULTS		
	7.8.1.1	Results are reviewed and authorized prior to release.	❑ ❑ ❑	❑ ❑ ❑

Item	Clause	Requirement	Document Review Y N N/A Comments	Implementation Y N N/A Comments
	7.5	TECHNICAL RECORDS		
	7.5.1	Records related to the performance of the test method are maintained, including but not limited to the following:	❑ ❑ ❑	❑ ❑ ❑
	7.5.1.a	analyst worksheet or notebook (1)	❑ ❑ ❑	❑ ❑ ❑
	7.5.1.b	record of nonconformities and actions taken (2)	❑ ❑ ❑	❑ ❑ ❑
	7.5.1.c	reagent preparation log (3)	❑ ❑ ❑	❑ ❑ ❑
	7.5.1.d	equipment maintenance log (4)	❑ ❑ ❑	❑ ❑ ❑
	7.5.1.e	culture collection records (5)	❑ ❑ ❑	❑ ❑ ❑
	7.5.1.f	records of gravimetric traceability (6)	❑ ❑ ❑	❑ ❑ ❑
	7.5.1.g	records of volumetric traceability (7)	❑ ❑ ❑	❑ ❑ ❑
	7.5.1.h	records of temperature traceability (8)	❑ ❑ ❑	❑ ❑ ❑

(1) includes, as appropriate, calibration data, test date (including QC data), experimental variables (e.g. temperature, etc.); analyst ID; sample ID; equipment ID; test organism lot no; test method ID; date and time of test.

(2) includes as appropriate, nonconformances related to: test method variances; sample history; method performance; interferences; and data validation.

(3) includes, as appropriate, supplier, grade, batch no; dates of preparation of verification; measurement of weights, volumes, time intervals, temperatures and related calculations; relevant processes (e.g., pH adjustment, sterilization); verification results; discard date.

(4) includes, as appropriate, identity of the equipment and its software; manufacturer, model, serial no; checks that equipment complies with laboratory specifications; date commissioned; repair and maintenance history; calibration history; any damage, malfunction or modification to the equipment; location.

(5) includes, as appropriate, organism name; source and date of acquisition; date of subculture and initial of technician; purity check on non-selective medium each time the working subculture is transferred

(6) includes, as appropriate, traceability of balance and/or weights to a national standard and daily or as-used checks.

(7) includes, as appropriate, checks on the delivery volume of dispensing equipment, auto pipettes, dilutors, etc. that play a defining role in analytical accuracy.

(8) includes, as appropriate, traceability of working thermometers to a national standard for those working thermometers that measure temperatures that play a defining role in analytical uncertainties.