Specific Accreditation Criteria

ISO/IEC 17025 Application Document

Life Sciences - Annex

Plant Health Diagnostic Testing

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Purpose

In addition to the *ISO/IEC 17025 Standard Application Document* (SAD) and the accompanying *Life Sciences - Appendix*, this document provides interpretative criteria and recommendations for plant health diagnostic testing for both applicant and accredited facilities, including field and screening services.

Plant heath diagnostic testing covers testing plants for pests and pathogens. Pests are defined by the International Plant Protection Convention (IPPC) as any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

Facilities must comply with all relevant documents in the *NATA Accreditation Criteria* (NAC) package for Agribusiness (refer to *NATA Procedures for Accreditation).*

The clause numbers in this document follow those of ISO/IEC 17025, however, as not all clauses require interpretation, the numbering may not be consecutive.

The establishment of criteria for the accreditation of plant health diagnostic testing in this document was a joint project between the Subcommittee on Plant Health Diagnostics (SPHD) and NATA.

This document also refers to a number of national guidelines and standards (e.g. PLANTPLAN written by Plant Health Australia) and identifies the sections of these documents which are mandatory. Other sections of the documents do not serve as criteria for accreditation, however, their application should be considered as good laboratory practice which contributes to the harmonisation of procedures for Emergency Plant Pest responses.

5 Structural requirements

5.5 Plant Heath Diagnostic facilities must have personnel with appropriate qualifications and experience to direct and control facility operations. Such personnel are expected to be either Senior Plant Health Diagnostic Professionals or Plant Health Diagnostic Professionals (see section 6.2.2) and usually in attendance during normal working hours.

An accredited facility may establish screening / field services under its direct control.

6 Resource requirements

6.2 Personnel

6.2.2

Senior Plant Heath Diagnostic Professional

Is a person who possesses the following qualifications and experience:

- a Doctorate of Philosophy in a relevant biological discipline; and
- who has not less than 5 years full time experience in identification of plant pests;

  or

- expertise that is deemed to be equivalent of the above as assessed by industry peers.

Plant Heath Diagnostic Professional

Is a person who possesses a degree in a relevant biological discipline from a university or other tertiary institutions recognised in Australia.

6.2.5 Personnel authorised to issue results must have undergone training in the relevant discipline(s) for at least six months.

The use of discipline terms in titles is optional. However, each facility shall ensure that the 'function or role' of the reporting staff member is evident on test reports.

6.3 Facilities and environmental conditions

6.3.1 Consideration must be given to providing dedicated work areas including where:

- activities may pose a hazard to other staff (e.g. agricultural chemicals, human pathogenic microorganisms);
- biosecurity containment is required.

Where possible, office areas should be separate from areas used to undertake testing.

6.4 Equipment

6.4.8 Consumables provided by the facility for sample collection or use, in particular tubes containing additives, must be monitored for expiry dates.

6.5 Metrological traceability

6.5.3 Where appropriate, the facility must hold and maintain collections of pests (as references) for the purposes of method validation or verification and quality control.

Microbiology

Reference collections should be sourced from collections registered with the World Federation for Culture Collections. Where reference material is not sourced from recognised collections, the facility must demonstrate the validity of the material used.

The following collections are recommended:

- World Data Centre for Microorganisms (WDCM);
- Victorian Department of Jobs, Precincts and Regions, Plant Disease Herbarium (VPRI), Bundoora (WDCM851);
- Western Australian Department of Primary Industries and Regional Development, Western Australian Plant Pathogen Collection (WDCM77);
- Queensland Department of Agriculture, Fisheries and Forestry , Plant Pathology Herbarium Indooroopilly (WDCM27);
- New South Wales Department of Primary Industries, Plant Pathology Herbarium Orange (WDCM365).

For maintenance of reference collections, refer to the NATA *General Accreditation Criteria: Maintenance of Microbiological Reference Culture Collections (MRCC)* As reference cultures of exotic microorganisms are generally not available in Australia, nucleic acid is acceptable for use as a control (see below).

Morphology

Specimens confirmed by a recognised expert(s) from a suitable host should be used as references. For example, the Pest and Disease Image Library (PaDIL) (https://www.padil.gov.au/).

Nucleic Acid

Nucleic acid control material must be traceable to a verified collection or culture. A specimen, culture or part of the material from which the nucleic acid was derived should be lodged in a recognised culture collection, herbarium or insect collection.

Where diagnosis depends on DNA sequence similarity, the reference sequence should be derived from a confirmed specimen or culture.

Reference collection management

Facilities must hold and maintain, or have ready access to, a physical collection of appropriately-curated, identified (confirmed) material required to perform verification or validation of methods (i.e. the methods can confirm positive specimens)..

Reference and diagnostic specimens must be separately stored / maintained.

Virtual reference material (textbooks, image libraries, published DNA sequences) must be from a validated source.

7 Process Requirements

7.1 Review of requests, tenders and contracts

7.1.1 Where the facility uses external providers to perform specific tests, these arrangements may be advised to customers in collection instructions, handbooks, etc.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 For the initial identification of suspect Emergency Plant Pests (EPPs) in accordance with PLANTPLAN, facilities must select methods based on the following priority:

- International Plant Protection Convention (IPPC) protocols;
- National Diagnostic Protocols (NDPs);
- peer reviewed published procedures;
- best practice diagnostic techniques.

7.2.1.2 Some manufacturers provide method documentation (kit inserts) for their validated methods with their product. These may be used as the facility's procedure if they are included in its document control processes. The kit inserts must be supplemented where they are not sufficiently detailed to cover the facility's needs.

Inserts for new batches received must be checked for changes in procedure and a copy of the new insert retained and be accessible. A record of the check must be available (e.g. signing and dating the insert by the responsible person).

7.2.1.5 The guidelines in the SPHD *Reference Standard No. 2 Development of National Diagnostic Protocols - Procedures for Authors*, should be followed in the drafting of a diagnostic procedure/protocol for a specific pest or pest group. However, the format may vary to meet facility's needs.

7.2.2 Validation of methods

7.2.2.1 Validation of methods, where required, must be in accordance with AS/NZS 4659 *Guide to determining the equivalence of food microbiology test methods*.

Also refer to the NATA document *General Accreditation Guidance: Validation and verification of quantitative and qualitative test methods.*

<u>Rapid Test Systems</u>

Rapid test systems such as lateral flow devices may not require further validation if the validation is applicable to the facility's scope of work and:

- the data can be referenced to a published method;
- has been performed by the manufacturer and is available.

The facility must be able to demonstrate that it can reproduce the method specifications of the rapid test systems.

Thresholds

Published thresholds may be used, however, these should be verified for use with the facility's own test methods. It may be necessary for facilities to establish their own thresholds (e.g. optical density for ELISA), by statistically valid means.

The source of thresholds must be documented.

7.4 Handling of test or calibration items

7.4.1 Facilities must comply with relevant packaging regulations (e.g. International Air Transport Association) when referring samples to other facilities, including those within the same organisation. However, where interstate facilities are involved, compliance with interstate biosecurity regulations must be ensured. If an Emergency Plant Pest is suspected the requirements of PLANTPLAN must also be applied.

A record must be kept of specimens referred for testing to other facilities. A record must also be kept of the return and follow-up of results of referred tests when the facility is responsible for sending the returned result back to the customer who requested the test.

Procedures for handling organisms suspected to be of biosecurity concern (including procedures for transport, according to PLANTPLAN) and for notification of appropriate authorities must be documented.

In testing situations where the pooling of samples is considered acceptable practice, the facility must follow a predefined and documented procedure. Any changes to the procedure must be validated and records of the validation kept.

Unless indicated otherwise by the specimen collector, specimens should be stored under appropriate conditions for a minimum of two weeks after the issue of the final test report. It is assumed that these timelines will be sufficient for the customer to review the test report and, if necessary, confirm the identity of the specimen with the testing facility or request further testing.

Specimen collection

If the collection of specimens is outside the control of the facility, the collector(s) must be informed of the facility's collection requirements. These requirements must be documented and accessible to the external persons who may submit specimens. For example:

- containers/tubes required for each test;
- amount of specimen required;
- labelling requirements;
- specimen storage requirements (e.g. room temperature vs. refrigeration);
- specimen transport requirements;
- requirements with respect to request forms.

Where an Emergency Plant Pest is suspected the requirements of PLANTPLAN in relation to sample handling must be followed.

7.4.2 In general, specimen containers should not be pre-labelled. Additionally, labelling of lids only is not acceptable.

Each specimen container must be labelled with a unique identification (in accordance with PLANTPLAN). Where confusion with another specimen from the

same plant or source is possible, the container must also be labelled with sufficient detail to distinguish the two.

For survey testing, each specimen container must be individually labelled, but need not identify an individual plant.

It is recommended that the date of collection be recorded on the specimen container.

For specimens submitted on glass slides (e.g. thrips or mites) the required labelling must be on the slide itself. The request form received with each specimen (or batch) is required to provide additional information not included on the specimen container itself. For specimens labelled with bar codes, QR codes or RFID chips, the facility must have access to this information.

Additional information should include:

- the host name or source of the specimen or other unique identification;
- the name of owner (or representative);
- the date of collection;
- number of specimens or specimen containers;
- the location where the specimens were collected must be provided (e.g. property name or geographical region and a GPS record to be provided where possible);
- an indication of the type of testing, or specific tests required.

Where an Emergency Plant Pest is suspected, chain of evidence procedures in compliance with PLANTPLAN must be followed.

7.4.3 Where inadequately labelled specimens are received, the facility must assure itself of the identity of the specimen. Where the identity of the specimen cannot be assured and submission of further specimens is possible, testing should not proceed on the initial specimen.

7.7 Ensuring the validity of results

7.7.1 Many factors will influence the frequency with which quality control is performed. The quality control (QC) protocol must take into account these factors and be such that the facility has confidence in the results issued.

Acceptable ranges must be defined for internal quality control results.

Unless otherwise specified in the manufacturer's instructions, QC material must be analysed with each test on each day of testing.

Reference material (e.g. specimens, images, textbooks, etc) suitable to perform the morphological identification of pests, must be available.

Where calibration of an assay is required, appropriate material must be used as a calibrator. If the material selected is not intended for use as a calibrator, ascribed calibration values must be substantiated.

The facility's program to review its ongoing competence to perform infrequently performed tests should include participation by all relevant staff in scheduled internal replicate testing activities (e.g. once every three months) and proficiency testing where possible.

7.7.2 Each facility must participate in a suitable program that covers the appropriate range of tests performed and species diagnosed. Where proficiency testing programs are not available, alternative measures (e.g. exchange of samples with other facilities) must be considered.

Participation in a suitable proficiency testing program is mandatory when the program is local (i.e. in Australia), is plant diagnostic based and is relevant to the work undertaken by the facility. The National Plant Health Proficiency Testing Program (NPHPTP) is currently the only local known program available.

Proficiency testing samples must be performed in accordance with the provider's schedule, irrespective of whether the timing coincides with testing of customer supplied specimens.

On receipt of results of a proficiency testing program, the following actions must be taken:

- proficiency testing performance is reviewed by the Plant Heath Diagnostic Professional providing technical control and discussed with all relevant scientific/technical staff;
- records are kept to demonstrate that the review of results has occurred;
- unsatisfactory results and other deficiencies identified by the program provider(s) are addressed and records kept;
- the implication of unsatisfactory proficiency testing performance on diagnostic test results must be considered and a record of the action taken kept.

As far as practicable, proficiency testing samples must be treated in the same way as diagnostic test specimens. Additionally, consideration should be given to ensuring that all staff involved in diagnostic testing (including part-time and evening staff) participate in the proficiency program.

7.7.3 Graphical presentation of numerical quality control results is recommended as this may assist the early detection of trends.

7.8 Reporting of results

7.8.1 General

7.8.1.1 Any person providing diagnoses shall be a recognised Plant Heath Diagnostic Professional in the relevant discipline, as defined under 6.2.2 and in the State or Territory in which the facility operates.

Suitable members of staff, other than recognised Plant Heath Diagnostic Professionals, may issue test results in accordance with criteria established by the facility.

7.8.1.2 Where the facility allows the issue of results verbally, a documented protocol must be available. A record must be kept of the time and date of verbal results, who received the results and the reporting staff member. It must be clear what results have been reported..

The facility must also have a documented protocol for the handling of telephone or face to face enquiries, taking into account the information being requested (e.g. test results, interpretation of results).

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Standards

ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
AS/NZS 4659	*Guide to determining the equivalence of food microbiology test methods*

NATA Publications

NATA Accreditation Criteria (NAC) package for Agribusiness

General Accreditation Criteria	*Maintenance of Microbiological Reference Culture Collections (MRCC)*
General Accreditation Guidance	*Validation and verification of quantitative and qualitative test methods*

Other Publications

IPPC, *International Standard for Phytosanitary Measures No.27 Diagnostic Protocols for Regulated Pests* (https://www.ippc.int/en/core-activities/standards-setting/ispms/#publications)

Pest and Disease Image Library (PaDIL) (www.padil.gov.au)

PLANTPLAN: Australian Emergency Plant Pest Response Plan, Plant Health Australia (www.planthealthaustralia.com.au/biosecurity/incursion-management/plantplan)

SPHD, *Reference Standard No. 2 Development of National Diagnostic Protocols - Procedures for Authors* (https://www.plantbiosecuritydiagnostics.net.au/initiatives/national-diagnostic-protocols/)

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
5.5	• Deletion of duties for the person in charge. • Deletion of the supervision requirements for screening/field plant health diagnostic facility.
7.2.1.1	Expanded on the criteria for the selection of methods for the initial identification of suspect Emergency Plant Pests.
7.2.2.4	Deletion of reference to *General Accreditation Guidance: Validation and verification of quantitative and qualitative test methods* for details of the method validation decision process.
7.4.1	Specimen collection has been moved from 7.3 to 7.4.1.
7.7.1	Calibration of assays has been moved from 6.5.1 to 7.7.1
7.8.2 and 7.8.2.1	Deletion of common requirements for reports.
Other Publications	Update of websites.
Whole document	Editorially updated and deletion of requirements already specified in the NATA Standard Application Document (SAD) and/or the Life Sciences Appendix.