Bulletin OEPP/EPPO Bulletin (2019) **49** (3), 527–529 ISSN 0250-8052. DOI: 10.1111/epp.12628

European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes PM 7/77 (3)

Diagnostics

PM 7/77 (3) Documentation and reporting on a diagnosis

Specific scope

This Standard presents requirements for documenting and reporting on a diagnosis.

Specific approval and amendment

Approved in 2006–09.
Revision approved in 2016–04.
Second revision approved in 2019-09.

1. Introduction

This Standard is designed to be used in conjunction with the specific set of EPPO Standards PM 7 on Diagnostics.

While most individual EPPO Standards on Diagnostics are concerned with the diagnosis of individual pests and describe different methods which can be used to identify a pest, this Standard gives guidance on documenting and reporting on a diagnosis.

This Standard is mainly designed for:

- persons responsible for submitting samples for diagnosis
- persons responsible for documenting and reporting on a diagnosis.

This Standard is only concerned with the report from a laboratory to a customer. Although the customer may need to communicate the result of a diagnosis to other parties (e.g. NPPOs may communicate results to growers, traders, other NPPOs and international organizations), that type of communication is not covered by this Standard.

2. Documentation of a diagnosis

As part of quality assurance programmes and to enable traceability of the results of a diagnosis, laboratories should document all diagnostic tests conducted. The information which has to be recorded is presented in Table 1. It is recommended that documents are kept for at least 5 years, but this time may depend on national requirements.

The laboratory is responsible for all the information in the report except for the information provided by the customer. Data which is provided by the customer should be clearly labelled as such.

Other supporting documentation gathered during diagnosis may be mentioned in the report, such as:

- for morphological/morphometric methods, measurements, drawings or photographs of the diagnostic features (where relevant) and, if applicable, the developmental stage
- for biochemical and molecular methods, documentation of test results, such as photographs of diagnostic gels and ELISA printouts of results, on which the diagnosis was based
- for biological assays, photographs of symptoms or tables with test results
- information on the availability of a culture of the pest or preserved/mounted specimens.

3. Reporting on a diagnosis

In the diagnosis of plant pests, different levels of reporting exist. Depending on local administrative arrangements, reports may be generated by the laboratory for internal use (e.g. quality assurance purposes) or for a customer (e.g. the NPPO, grower or trader). The report may differ according to the customer and reports do not have to fulfil the same requirements. For example, simplified results may sometimes be reported to the inspection service of the NPPO. Minimum requirements for reporting are presented in the second column of Table 1. When the inclusion of some information in the report is noted only as optional, such information should be made available on request.

In the report, the result of a diagnosis should be reported accurately, clearly, unambiguously and objectively. The report should enable further verification by a specialist expert (e.g. whether the diagnostic tests conducted or references used were appropriate). In case of a dispute on a diagnostic result, an accurate report is one of the key elements that will be considered.

Table 1. Information to be recorded for documentation purposes and information to include in the diagnostic report issued by the laboratory

Information to be recorded	Information required in all reports	Additional information required in reports on activities carried out under accreditation*	Optional information to include in reports
Administrative information			
A title (e.g. 'Test Report' or 'Report of Sampling')	✓		
Name and address of the laboratory	✓		
Identity and contact information of the customer	✓		
The date of issue of the report	✓		
Name(s), function(s) and signature(s) of person(s) authorized to sign the report	✓		
Statement that the diagnosis is only valid for the sample that was received	✓		
Indication of the subcontracting laboratory (where applicable)	✓		
Details of additions to, deviations to or exclusions from the test and any special circumstances arising at any point in the diagnosis		✓	
Statement of conformity (where applicable)		✓	
Statement that the report should not be reproduced except in full, without written approval of the laboratory		✓	
Information recorded on the sample			
External sample reference number (where available)	✓		
Date of receipt, date of collection (if known)‡	✓		
Nature of the sample (as relevant, scientific name of host, whether it is a culture of a pest, preserved/mounted specimen etc.)	✓		
Unique identifier or internal sample reference number‡	✓†		
Origin of the sample (if known)			✓
Place of collection of the sample (if different from origin)			✓
Number of units in the sample or quantity submitted to the laboratory			✓
Magnitude of any infection/infestation (how many individual pests found, how much damaged tissue) (where applicable)			✓
When necessary, condition of the sample (poor condition, alive or dead for insects and mites etc.)		✓	
Any symptoms visible (with photographs if possible, preferably of the material as originally collected)			✓
Methods used for the collection of the sample (if known)‡		✓	
Environmental conditions‡			✓
Information recorded during diagnosis			
Tests used for diagnosis and results obtained	✓		
The date(s) of the start and completion of the diagnosis	✓		
Whether the test was performed under accreditation			✓
Information on reference(s) source(s) used in diagnosis (e.g. keys used, database used, date database accessed if used online or date database downloaded)			✓
Controls used during testing (e.g. reference material)			✓
Number of units or quantity tested			✓
Machine used/version, software version, numbers for pipelines (e.g. for HTS)			✓
Conclusion on the identification of the pest (scientific name of the pest), where appropriate the unit(s) of measurement	✓		
For sequence comparison % identity to a named reference sequence (including accession number)	✓		
Indication of the certainty or uncertainty of the measurement/identification in the same unit as that of the measurand or in a term relative to the measurand (where applicable)‡		✓	
Details of opinions and interpretations from authorised personnel (where appropriate). If direct dialogue is given to customer a record of the dialogue must be retained		✓	
Identification of all authorized person(s) who took part in the diagnosis			✓

*Note that laboratories working under accreditation according to ISO 17025 need to fulfil the reporting requirements of that Standard.
†Required when there is no external sample reference number.
‡Laboratories responsible for sampling activity should consult ISO 17025 section 7.8.5 for additional reporting requirements.

When an issued report needs to be changed, amended or re-issued, any change of information should be clearly identified and should be made only in the form of a further document or data transfer which includes the statement 'Amendment to report, serial number' or an equivalent form of wording. Where new reports are issued, they must contain a unique identifier and reference to the original report.

Laboratories working under accreditation to ISO 17025 need to fulfil the reporting requirements of that Standard.

Acknowledgements

Input for this revision to allow adaption to high-throughput sequencing (HTS) was provided by Mr Fox, Fera Science Ltd (GB). It was further worked on by an Expert Working Group composed of Ms Anthoine, Ms Bokuma, Ms de Krom, Ms Ermakovich, Ms Santala and Ms Weekes, and reviewed by the Panel on Diagnostics and Quality Assurance.