Subcommittee on Plant Health Diagnostics

SPHD Reference Standard No. 4
(SPHD RS No. 4)

Guidelines for Peer Review, Verification and NDP Reviews

VERSION NUMBER	V5
STATUS	Endorsed
ISSUE DATE	June 2024
REVIEW DATE	June 2029
ISSUED BY	SPHD
AUTHOR	SPHD

Contents

1. INTRODUCTION

1.1. Scope

The Subcommittee on Plant Health Diagnostics (SPHD) document *Guidelines for Verification and Peer Review Reports* (SPHD RS No. 4) is a Reference Standard providing guidelines on the Peer Review and Verification Process of new diagnostic procedures/protocols (refer to SPHD RS No. 1 for definitions). This document also provides guidance for Peer Review of existing National Diagnostic Protocols to ensure that they are written in accordance with the SPHD RS No. 2.. The Reference Standard has been developed to standardise and incorporate relevant information in a process of verifying and reviewing diagnostic protocols for the identification of plant pests.

1.2. Purpose

The purpose of this Reference Standard is to provide guidelines and instructions to an Independent Expert and/or Independent Laboratory for conducting a verification process on relevant diagnostic procedures specified by DPWG and undertaking a Peer Review of the scientific information in the diagnostic protocol. Once developed, the diagnostic protocol will be submitted to SPHD for endorsement, and when approved and endorsed, the document will be recognised as a National Diagnostic Protocol.

This Reference Standard also provides guidelines and instructions to a Subject Matter Expert (SME) undertaking a Peer Review of a currently endorsed National Diagnostic Protocol.

1.3. Review

The SPHD RS No. 4 will be reviewed every five years or earlier if required. The review will be implemented by the Diagnostic Protocol Working Group (DPWG) (in consultation with the Subcommittee). Changes to the Reference Standard are subject to the DPWG approval and endorsement of SPHD members.

All SPHD Reference Standards can be found on the NPBDN website (https://www.plantbiosecuritydiagnostics.net.au/). Click on the “Resources” tab, and then on the “National Diagnostic Protocols”.

1.4. References

IPPC. 2021. ISPM No. 27 *Diagnostic Protocols for Regulated Pests*. Food and Agriculture Organisation for the United Nations, Rome.

2. SPHD PROCESS FOR PEER REVIEW OF DIAGNOSTIC PROTOCOLS/PROCEDURES BY AN INDEPENDENT EXPERT

2.1. Introduction

This refers to the Peer Review process of a diagnostic protocol that has been prepared in accordance with SPHD RS No. 2 and is submitted to SPHD for endorsement to be recognised as an NDP.

2.2. Definition

Peer Review is a process by which an Independent Expert approved by DPWG, reviews the currency and accuracy of the Procedures/Protocols.

2.3. General considerations

The original author of the protocol may recommend the Independent Expert to Peer Review the protocol. This recommendation will then be considered for approval by DPWG.

2.4. The Process

Peer review of the Diagnostic Protocol must be undertaken by an Independent Expert approved by DPWG according to the following requirements:

- The Independent Expert shall review the relevant sections of the protocol requested by DPWG for currency and accuracy of detail, including the introduction, taxonomic information, citations, applicability of the procedures and any other information specified by DPWG.
- The Peer Review checklist (Appendix 1) should be completed and used as a guide to this process.
- The Independent Expert is required to determine that all text and images are appropriately and correctly acknowledged.
- The Independent Expert is not required to review procedures of the protocol which are undergoing verification.
- Suggested changes to the protocol should be made to the original document as track changes.
- The Independent Expert shall prepare a brief written report of the Peer Review process. Contents must include where relevant, but not be limited to:
    - The Procedure/Protocol being reviewed, author and date.
    - Whether the protocol allows a taxonomically accurate identification of the organism.
    - Accuracy and currency of information.
    - Recommendations for improvements if required.
- The checklist and report should be submitted to NDP Coordinator with the amended protocol.
- The protocol is edited by NDP Coordinator from reviewer's suggestions, in consultation with the author and reviewer.
- The final document will be approved by both author and reviewer before submission for endorsement by SPHD.

3. SPHD PROCESS FOR VERIFICATION OF DIAGNOSTIC PROTOCOLS/PROCEDURES BY AN INDEPENDENT LABORATORY

3.1. Introduction

This refers to the Verification process of a diagnostic protocol that has been prepared in accordance with SPHD RS No. 2 and is submitted to DPWG for approval to be recognised as an NDP.

3.2. Definitions

Verification is a process by which an Independent Laboratory demonstrates that the diagnostic procedures can be followed and gives reproducible results and, if necessary, identifies critical improvements in the methods described.

Independent Laboratory can be public, private, or part of the Author's/Applicant's organisation as long as the personnel used to conduct the verification undertake the procedure/protocol independently of the author and do not use the same equipment (if possible) or supplies. The laboratory should be one where the type of assay in question is undertaken on a routine basis.

In the case where verification occurs within a project (together with development, validation and review), the verification laboratory is preferred to be an external organisation and/or laboratory.

3.3. General considerations

Relevant diagnostic procedure(s) described in the protocols need to be verified by an Independent Laboratory in order to prove reproducibility of the procedure(s).

The purpose of the Independent Laboratory is to verify the reproducibility of procedures within the protocol specified by DPWG, but not to duplicate all the data generated by the original author(s).

Where appropriate, sample/s should be provided to the verification laboratory by the Author/Applicant.

The original author of the protocol may recommend an Independent Laboratory for approval by DPWG to undertake the verification.

3.4. The process

Verification of the Diagnostic Protocol must be undertaken by an Independent Laboratory approved by DPWG according to the following requirements:

- The Independent Laboratory shall review the relevant sections of the protocol requested by DPWG.
- Where possible, the Author(s) should prepare any necessary samples and send them together with the protocol to the Independent Laboratory under the appropriate approvals.
- The Independent Laboratory shall conduct the diagnostic procedure(s) step-by-step according to the protocol submitted in the application addressing the following issues:
    - Clarity and completeness of the documented diagnostic procedure(s); and
    - Reproducibility of the diagnostic procedure(s).
- The Verification Checklist (Appendix 2) should be completed and used as a guide to this process.
- Suggested changes to the protocol can be made to the original document, preferably as track changes, or specified in the report.
- The Independent Expert shall prepare a brief written report of the Verification process. Contents must include where relevant, but not be limited to:

  - Title page – included protocol being verified, author and date.
  - Methodology.
    - What procedures are being verified?
    - If procedures cannot be verified an explanation should be provided.
    - What samples were used?
  - Results.
    - Were the methods comprehensive and clear?
    - Were the methods reproducible (show data)?
    - Where used, are data from international sequence databases (e.g. GenBank) derived from appropriately validated specimens?
  - Recommendations for improvements.
  - References, if required.

- The checklist and report and any associated paperwork should be submitted to the NDP Coordinator.
- The protocol is edited by NDP Coordinator from verifier/reviewer's suggestions, in consultation with the author and reviewer.

The final document will be approved by author, reviewer, and the verification laboratory before submission for endorsement by SPHD.

4. SPHD PROCESS FOR PEER REVIEW OF A NATIONAL DIAGNOSTIC PROTOCOLS/PROCEDURES BY AN SME

4.1. Introduction

This refers to the Peer Review process of an NDP that has been recommended for review, either after five years from previous endorsement, or when required by new science.

4.2. Definition

Peer Review is a process by which an SME reviews the currency and accuracy of the NDP.

4.3. General considerations

The original author of the protocol may recommend the SME to peer review the NDP. This recommendation will then be considered for approval by DPWG.

4.4. The Process

Peer review of the NDP must be undertaken by an SME according to the following requirements:

- The SME shall review the NDP for currency and accuracy and determine whether the procedures will still allow a taxonomically accurate identification of the organism.
- The SME should note whether the protocol conforms to SPHD RS No. 2.
- The SME shall include new procedures if available: and provide justification and indicate if able to do verification.
- The NDP Peer Review checklist (Appendix 3) should be completed and used as a guide to this process.
- Suggested changes to the protocol should be made to the original document, preferably as track changes.
- The SME shall prepare a brief written report of the Peer Review process. Contents must include where relevant, but not be limited to:
    - The Procedure/Protocol being reviewed, author and date.
    - Whether the protocol allows a taxonomically accurate identification of the organism.
    - Accuracy and currency of information.
    - Recommendations for improvements if required. If new procedures are recommended, the following is required
        - Reviewer to recommend the new procedures to be added, NDP Coordinator will send back to original author to undertake or
        - If original author is not available or not able to undertake verification of new procedures, then reviewer would undertake them and document in the NDP.
- The checklist and report should be submitted to the NDP Coordinator with the amended protocol.
- The protocol is edited by the NDP Coordinator from the reviewer's suggestions. If changes are only editorial, the edited NDP is endorsed by SPHD as the new version.

If new procedures are added, the NDP must go through the verification process outlined in Section 3.

APPENDIX 1. PEER REVIEW REPORT CHECKLIST

Protocol:

Date of review:

Notes

Please answer the questions listed below to complete the table. **Yes** or **No** answers are sufficient for most questions. However, for some questions, we also ask that you fill out the "comments" column. The "Issues to be considered" column is intended as a guide to consider when recording comments and to assist in identifying possible improvements.

Suggested changes to the protocol should be made to the original document, preferably as track changes.

Also summarise your review of the protocol with recommendations in a separate letter or report. General comments may be made at the end of this document or in your report. If there is some problem with the protocol that is not addressed in the questions provided, please note the problem at the end of the document or in the report.

For more information on the requirements of a protocol and the peer review and verification process please refer to SPHD RS 2 *Development of National Diagnostic Protocols - Procedures for Authors* and SPHD RS 4 *Guidelines for Peer Review, Verification and NDP Reviews* (relevant sections included).

Reviewer:

Signature:

Summary

	Question	Issues to be considered	Y/N	Comments
1	**Will the protocol allow a taxonomically accurate identification of the organism?** *You may wish to answer this question in conjunction with the specific questions on identification listed below.*	If not, then please note the elements of the protocol that could hinder taxonomic identification. Please note how an ambiguity could arise.		
2	**Is the entire document concise?**	Please briefly identify sentences, paragraphs or sections that are unnecessary for detection or identification or that could be shorter.		
3	**Is every section of the document clear?**	Please briefly note any section that may be confusing. Identify inconsistencies and contradictions.		
4	**Does the document include information about geographic distribution, control or risk potential?** *No such information should be included.*	If so, please identify the section where this information is given.		
5	**Are you aware of any material in the protocol very similar or identical to material published elsewhere? This may be significant for copyright reasons.**	If so, please identify the material.		

Question		Issues to be considered	Y/N	Comments
6	**Does the document include images or illustrations?**	Are they of sufficient quality? (i.e., do they meet RS No. 2 criteria?) Are they correctly referenced? (Images need the region or country identified where the photograph was taken, and the photographer acknowledged.)		

Section 1. <u>Introduction</u>

Question		Issues to be considered	Y/N	Comments
1.1	**Are the pest species causing the damage or disease clearly described and referenced?**			
1.2	**Is the information directly relevant to diagnostic identification, accurate and up to date?**	Please identify any sentences or paragraphs unnecessary for identification of the species or that could be replaced by an appropriate reference.		
1.3	**Does it contain information that would be better placed in another section of the protocol, or included as an appendix?**	Please identify any such sentences or paragraphs and indicate where they should be placed.		
1.4	**Is the host range listed necessary for diagnosis?**			

Question		Issues to be considered	Y/N	Comments
1.5	**Is the host range properly described, taking account of taxonomic revisions, and using primary reference sources?**			

Section 2. Taxonomic identification

Question		Issues to be considered	Y/N	Comments
2.1	**Has a complete taxonomic classification been provided and properly referenced with all recognised taxonomic levels and the correct authority?**	If not, then please indicate what is missing.		
2.2	**Is the taxonomy accurate and taking into account the most recent revisions?**	If not, please note the reference for the current accepted taxonomy.		

Section 3. Detection

Question		Issues to be considered	Y/N	Comments
3.1	**Does the protocol provide adequate information for detection of the organism?**			
3.2	**Is there information in this section that would be better placed in the identification section?** *For some insects there may be significant overlap of the information.*	Is so, please identify the sentences, paragraphs or and sections and specify where they would be best placed.		

Question		Issues to be considered	Y/N	Comments
3.3	**Are detection methods described in sufficient detail to be followed without referring to other literature?**	If not, then please identify the methods or elements requiring more details.		
3.4	**Are signs or symptoms associated with the pest adequately described and illustrated with images?**	If not, please indicate which signs or symptoms require further explanation and/or images.		
3.5	**Are the life stages that are likely to be encountered adequately described?**	If not, please indicate which life stages require further description and explanation.		
3.6	**Is there sufficient information to distinguish the pest from other organisms or symptoms with which it may be confused?**	If not, please indicate possible areas of confusion.		
3.7	**If a sampling procedure is included, is it necessary and does it identify aspects of the sample that may impact on detection and diagnosis?**	If not, please indicate possible areas of confusion.		
3.8	**Is there any point of contention, uncertainty or ambiguity in the detection information?**	Please briefly note these potential problems.		
3.9	**Is the most up-to-date information on detection provided?**	If not, please note the sources of more up-to-date information.		

Section 4. Identification

Question		Issues to be considered	Y/N	Comments
4.1	**If multiple procedures are included, are the minimum requirements for identification clearly stated?**			
4.2	**Are the suggested steps sufficient for accurate identification, and are the steps in a suitable order?**			
4.3.	**Is information for identification of the pest from asymptomatic plants or plant products provided?**	If not, is it required?		
4.4.	**Has the author selected the most useful and accurate method(s)?**	If not, then please briefly comment on the deficiency in terms of utility.		

For each identification method required for definitive diagnosis, please answer each of the following questions. Where there is more than one identification method, please duplicate the table below, label the table as per the detection method, and answer the questions specific to that particular identification method. Later tables contain additional questions that relate to morphological and molecular identification.

Method 1 (duplicate as necessary)

Name of method:

Question		Issues to be considered	Y/N	Comments
M1.1	**Is the method the most suitable / appropriate?**	If not, please note the suitable / appropriate method(s) and if an update is needed.		

Question		Issues to be considered	Y/N	Comments
M1.2	**Is there any point of contention or uncertainty in the method?**	Please briefly note any point of contention or uncertainty in the method.		
M1.3	**Is the method described in sufficient detail to be followed without referring to other literature?** *If a commercial kit is used as per manufacturer's instructions, these do not need to be repeated.*	If not, then please note the elements that require more detail.		
M1.4	**Are the results and observations required for identification clearly stated?**	Please note where any lack of clarity occurs.		
M1.5	**Does the method require a specific control and if it does, is the control properly described**	Please note the kind of information that is lacking.		
M1.6	**If reference material (a positive control) is required, is a source of the reference material noted in the document?**			
M1.7	**Are unambiguous criteria provided for positive and negative results?**			
M1.8	**Is guidance provided on distinguishing the pest organism from related species or taxa?**			

Section 4.1. <u>Morphological identification</u>

If morphological identification is included, then please answer the following questions in addition to those above.

Question		Issues to be considered	Y/N	Comments
4.1.1	**Are methods for preparing, mounting and examining the pest provided?**			
4.1.2	**Are the extraction methods provided in sufficient details so that this may be done without referring to other literature?**	Extraction methods include isolation and culturing (if the pest can be cultured).		
4.1.3	**Is an identification key provided?**	Is it required?		
4.1.4	**If provided, could the key be followed by a diagnostician who is not an expert on the family of organisms?**	If not, then please note the part of the key that would present difficulty.		
4.1.5	**Does the morphological description include all necessary information and indications of difficulties?** *For example, descriptions of each gender sex, illustrations of diagnostic features, morphometric data, taxonomic description of organism, culture characteristics.*	If not, then please indicate what is missing and the significance, if any, of the deficiency.		

Section 4.2 Molecular and serological tests

Question		Issues to be considered	Y/N	Comments
4.2.1	**If a nucleic acid test is described, does the protocol identify a reference sequence in a publicly available database.**	Is an accession code included?		
4.2.2	**Is the reference sequence from a specimen that has been sufficiently described (validated) in a collection, publication or database?**			
4.2.3	**If a commercial kit is used, is it readily available?**			
4.2.4	**If a commercial kit is available but is not used, are adequate reasons given for using an alternative?**			

Please complete the following table. If no **(N)** is indicated please briefly state why the criteria were not met in the comments column. Duplicate table if more than three methods are included.

Is adequate information provided on the following for each identification method:	**Method 1 Y/N N/A**	**Method 2 Y/N N/A**	**Method 3 Y/N N/A**	**Comments**
Accuracy				
Specificity				
Reproducibility				
Sensitivity				
Positive control				
Negative control				
Reference material				
Sources of test reagents				
Specifications of test reagents				
Equipment				
Specifications of equipment				

Section 5. Contacts

Question		Issues to be considered	Y/N	Comments
5.1	**Are the full details of a contact person or laboratory with expertise on the organism provided?**	Is this up-to-date e.g., has the person retired?		

Section 6. Acknowledgements

Question		Issues to be considered	Y/N	Comments
6.1	**Are the names and addresses of the authors of the protocol provided?**			
6.2	**Have the major contributors been appropriately acknowledged?**			

Section 7. References

Question		Issues to be considered	Y/N	Comments
7.1	**Is all information appropriately referenced?**	Please identify significant information used in the document that is not referenced.		
7.2	**Is the reference list complete?**	Identify references that have been used but not entered in the reference list or vice versa.		
7.3	**Are the most important references used?**	Identify important papers and other sources that have been missed.		

Section 9. Diagnostic procedures to support surveillance

9.1 Introduction

Question		Issues to be considered	Y/N	Comments
9.1.1	**Does the introduction include information on the scope and type of tests included**	Please identify areas of deficiency.		

9.2 Sampling

9.2.1	**Is the information provided sufficient to ensure correct sampling?**			
9.2.2	**Are illustrations and/or images included of sufficient quality to show required detail**	Identify any issues with referencing of photos or illustrations		

9.3, 9.4. In-field tests and laboratory tests. Please use tables from section 4 below.

Section 4. Identification

Question		Issues to be considered	Y/N	Comments
4.1	**If multiple procedures are included, are the minimum requirements for identification clearly stated?**			
4.2	**Are the suggested steps sufficient for accurate identification, and are the steps in a suitable order?**			

Question		Issues to be considered	Y/N	Comments
4.3.	**Is information for identification of the pest from asymptomatic plants or plant products provided?**	If not, is it required?		
4.4.	**Has the author selected the most useful and accurate method(s)?**	If not, then please briefly comment on the deficiency in terms of utility.		

For each identification method required for definitive diagnosis, please answer each of the following questions. Where there is more than one identification method, please duplicate the table below, label the table as per the detection method, and answer the questions specific to that particular identification method. Later tables contain additional questions that relate to morphological and molecular identification.

Method 1 (duplicate as necessary)

Name of method:

Question		Issues to be considered	Y/N	Comments
M1.1	**Is the method the most suitable / appropriate?**	If not, please note the suitable / appropriate method(s) and an update is needed.		
M1.2	**Is there any point of contention or uncertainty in the method?**	Please briefly note any point of contention or uncertainty in the method.		
M1.3	**Is the method described in sufficient detail to be followed without referring to other literature?** *If a commercial kit is used as per manufacturer's instructions, these do not need to be repeated.*	If not, then please note the elements that require more detail.		

Question		Issues to be considered	Y/N	Comments
M1.4	**Are the results and observations required for identification clearly stated?**	Please note where any lack of clarity occurs.		
M1.5	**Does the method require a specific control and if it does, is the control properly described**	Please note the kind of information that is lacking.		
M1.6	**If reference material (a positive control) is required, is a source of the reference material noted in the document?**			
M1.7	**Are unambiguous criteria provided for positive and negative results?**			
M1.8	**Is guidance provided on distinguishing the pest organism from related species or taxa?**			

Section 4.1. <u>Morphological identification</u>

If morphological identification is included, then please answer the following questions in addition to those above.

Question		Issues to be considered	Y/N	Comments
4.1.1	**Are methods for preparing, mounting and examining the pest provided?**			

Question		Issues to be considered	Y/N	Comments
4.1.2	**Are the extraction methods provided in sufficient details so that this may be done without referring to other literature?**	Extraction methods include isolation and culturing (if the pest can be cultured).		
4.1.3	**Is an identification key provided?**	Is it required?		
4.1.4	**If provided, could the key be followed by a diagnostician who is not an expert on the family of organisms?**	If not, then please note the part of the key that would present difficulty.		
4.1.5	**Does the morphological description include all necessary information and indications of difficulties?** *For example, descriptions of each gender, illustrations of diagnostic features, morphometric data, taxonomic description of organism, culture characteristics.*	If not, then please indicate what is missing and the significance, if any, of the deficiency.		

Section 4.2 <u>Molecular and serological tests</u>

Question		Issues to be considered	Y/N	Comments
4.2.1	**If a nucleic acid test is described, does the protocol identify a reference sequence in a publicly available database.**	Is an accession code included?		
4.2.2	**Is the reference sequence from a specimen that has been sufficiently described (validated) in a collection, publication or database?**			
4.2.3	**If a commercial kit is used, is it readily available?**			
4.2.4	**If a commercial kit is available but is not used, are adequate reasons given for using an alternative?**			

Please complete the following table. If no **(N)** is indicated please briefly state why the criteria were not met in the comments column. Duplicate table if more than three methods are included.

Is adequate information provided on the following for each identification method:	**Method 1 Y/N N/A**	**Method 2 Y/N N/A**	**Method 3 Y/N N/A**	**Comments**
Accuracy				
Specificity				
Reproducibility				
Sensitivity				
Positive control				
Negative control				
Reference material				
Sources of test reagents				
Specifications of test reagents				
Equipment				
Specifications of equipment				

9.5 Acknowledgements. Please use tables from section 6 as below.

Section 6. <u>Acknowledgements</u>

Question		**Issues to be considered**	**Y/N**	**Comments**
6.1	**Are the names and addresses of the authors of the protocol provided?**			

Question		Issues to be considered	Y/N	Comments
6.2	**Have the major contributors been appropriately acknowledged?**			

9.6 References. Please use tables from section 7 above.

Section 7. <u>References</u>

Question		Issues to be considered	Y/N	Comments
7.1	**Is all information appropriately referenced?**	Please identify significant information used in the document that is not referenced.		
7.2	**Is the reference list complete?**	Identify references that have been used but not entered in the reference list or vice versa.		
7.3	**Are the most important references used?**	Identify important papers and other sources that have been missed.		

APPENDIX 2. VERIFICATION REPORT CHECKLIST

Protocol:

Date of verification:

Notes

Please provide a report on the verification of the protocol and complete the table below. In your report, please describe the results of testing the protocol and include a brief description of the samples that were used. Please comment on the usefulness of the protocol for diagnosing the described species, and if you consider the protocol could be improved, briefly describe the desired improvements and outline possible amendments. If preferred, improvements may be included as track changes to the protocol.

To complete the table, **Yes** or **No** answers are sufficient for most questions. However, we also ask that for some questions you fill out the "comments" column. The "Issues to be considered" column is intended as a guide to consider when recording comments and to assist in identifying possible improvements. Please note that not all questions may be applicable to the protocol you are testing. If an answer is negative or critical, please provide some explanation and include any information requested. These comments can be included in the table or in the report but need not be duplicated. If included in the report, please reference the number of the question.

General comments may be made at the end of this document or in your report. If there is some problem with the protocol that is not addressed in the questions provided, please note the problem at the end of the document or in your report.

For more information on the requirements of a protocol and the peer review and verification process please refer to SPHD RS 2 *Development of National Diagnostic Protocols - Procedures for Authors* and this document.

Verified by:

Signature:

1. Verification and reproducibility

Question		Issues to be considered	Y/N	Comments
1.1	**Were all procedures in the protocol tested?**	Identify any procedures not tested and briefly note reasons. If you were only requested to verify some procedures, just answer for those procedures.		
1.2	**What procedures and parts of the protocol were verified?**	If there is some uncertainty about verification of some part of the protocol, please note it and provide some explanation. If a procedure or part of a procedure failed, please provide details on that failure.		
1.3	**Were all procedures in the protocol reproduced and done without technical difficulty?**	If a procedure was not reproduced or was difficult to reproduce, please note it and provide some detail of what occurred.		
1.4	**Was the protocol verified without a positive control?**	If no positive control was used, please comment on the value of a positive control to verification.		

2. Diagnosis

Question		Issues to be considered	Y/N	Comments
2.1	**Will the protocol allow reliable detection?**			
2.2	**Will the protocol allow identification of the organism?**			

Question		Issues to be considered	Y/N	Comments
2.3	**Does the protocol clearly state what results are required for identification?**			

3. Clarity and comprehensiveness

For each method described in the protocol, please answer each of the following questions. Where there is more than one method, please duplicate the table below, label the table as per the method, and answer the questions specific to that particular method.

Method 1

Name of method:

Question		Issues to be considered	Y/N	Comments
3.1	**Is the description of the procedure comprehensive and clear?**			
3.2	**Was there any problem following the procedure?**	If yes, please provide some details.		
3.3	**If a commercial kit is used is it readily available?**			
3.4	**Are sufficient details provided so that the procedure could be done without referring to other literature?** *If a commercial kit is used as per manufacturer's instructions, these do not need to be repeated.*			
3.5	**Is there any point of contention, uncertainty or ambiguity in the procedure?**	Please briefly note any point of contention, uncertainty or ambiguity.		

Question		Issues to be considered	Y/N	Comments
3.6	**Are the procedure parameters clearly described?**			
3.7	**Is the source of each reagent adequately described?**			
3.8	**Is there a sufficient description of equipment used?**			
3.9	**Does the procedure require any specialised equipment that would not be available in all laboratories?**	If so, please comment on whether this is a barrier to detection or diagnosis.		
3.10	**Does the procedure state what positive and negative controls are to be used?**			
3.11	**If a specific control is required, is it properly described?**	Please note the kind of information that is lacking		
3.12	**Does the procedure clearly state what the expected results should be?**			
3.13	**Are unambiguous criteria provided for positive and negative results?**			
3.14	**If a specific sampling method is required, is it adequately described?**			

4. Results of verification tests

Duplicate this section for each procedure described in the protocol.

Method 1

Name of method:

Question		Issues to be considered	Y/N	Comments
4.1	**What samples were used for verification?**			
4.2	**Was a positive control available for testing?**			
4.3	**Did you test the sensitivity of the procedure (if relevant)?**	If not, then please provide a reason for not testing sensitivity		
4.4	**Was the procedure sufficiently sensitive (if tested)?**	Please indicate the maximum level of dilution or minimum concentration of pathogen that was detected.		
4.5	**Did your results agree with those supplied with the procedure (if any)?**	Please provide data from the experiments and address any discrepancy.		
4.6	**Were there any false positive or false negative results?**			
4.7	**Did you test the specificity of the procedure?**	If yes, then please supply details?		
4.8	**Did you vary the procedure in any way? (perhaps use a different extraction method for DNA)**	If so, then please provide evidence that your method was as sensitive and specific as the supplied procedure		

5. Sequencing

Where sequencing is included in the protocol, please answer the following.

Question		Issues to be considered	Y/N	Comments
5.1	**Is sequencing required to complete this diagnosis?**	If not, please briefly describe why not.		
5.2	**Is an accession number for a reference sequence noted in the procedure?**			
5.3	**Are all reference sequences in a publicly available database, such as GenBank?**			
5.4	**Is the reference sequence from an isolate or specimen that has been sufficiently described (validated) in a collection, publication or database?**			

6. General comments

Please comment on the suitability of the protocol for definitive diagnosis and suggest improvements if appropriate.

APPENDIX 3 NDP PEER REVIEW REPORT CHECKLIST

Protocol:.....

Date of review:.....

Name of reviewer.....

Signature.....

Scope

Peer review of a NDP is aimed at determining whether the protocol will still allow a taxonomically accurate identification of the organism.

The reviewer does not need to verify the procedures in the laboratory. However, if the reviewer does identify new methods or assays are required as a part of the revision, it is recommended that they revise the NDP and add the new method in the NDP if the original author is not able to. The new method will be required to be independently verified.

Notes

Please answer the questions listed below to complete the table. **Yes** or **No** answers are sufficient for most questions. However, for some questions, we also ask that you fill out the “comments” column. The “Issues to be considered” column is intended as a guide to consider when recording comments and to assist in identifying possible improvements.

Suggested changes to the protocol can be made to the original document, preferably as track changes.

Please summarise your review of the protocol with recommendations in a separate letter or report. General comments may be made at the end of this document or in your report. If there is some problem with the protocol that is not addressed in the questions provided, please note the problem at the end of the document or in the report.

For more information on the requirements of a protocol and the NDP peer review process please refer to SPHD RS 2 *Development of National Diagnostic Protocols - Procedures for Authors* and SPHD RS 4 *Guidelines for Peer Review, Verification and NDP Reviews* (relevant sections included).

Question		Issues to be considered	Y/N	Comments
1	**Will the protocol allow a taxonomically accurate identification of the organism?** *You may wish to answer this question in conjunction with the specific questions on identification listed below.*	If not, then please note the elements of the protocol that could hinder taxonomic identification. Please note how an ambiguity could arise.		
2	**Is the taxonomy of the pest current?**	Does the taxonomy cited reflect the most recent name changes? Are there new strains or other issues in the taxonomic classification of this organism?		
3	**If there are changes in the taxonomy, will this impact on the protocol?**	Is the current protocol still applicable to the new organism?		
4	**Is the science current and accurate?**	Is there new literature that should be included? Please advise areas of concern		
5	**Are the current diagnostic procedures still able to diagnose the organism?**	Are the procedures still useable and achieve the aim? Do they need to be re-verified to confirm this?		
6	**Are there new diagnostic procedures and techniques that should be included?**	Do these new techniques improve the accuracy or specificity of the diagnosis? If yes, please add		
7	**Are the experts listed in section 5 of the NDP current?**			
8	**Does the document follow the RS2 format? (See style guide in Protocol Proforma).**	*It is not necessary for the reviewer to correct this, just note if observed.*		