

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 SPHDS RS 2 Technical Procedures V3.0 (Section Part B) and SPHDS RS 4 Verification and Peer Review V1.0 (relevant sections included).

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?			

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

Question		Issues to be considered	Y/N	Comments
3.4	Are sufficient details provided so that the procedure could be done without referring to other literature? <i>If a commercial kit is used as per manufacturer's instructions, these do not need to be repeated.</i>			
3.5	Is there any point of contention, uncertainty or ambiguity in the procedure?	Please briefly note any point of contention, uncertainty or ambiguity.		
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?			

Question		Issues to be considered	Y/N	Comments
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.		

Question		Issues to be considered	Y/N	Comments
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 for 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.

Verified by:

Signature:
