

EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION
ORGANISATION EUROPÉENNE ET MEDITERRANÉENNE POUR LA PROTECTION DES PLANTES
Summary sheet of validation data for a diagnostic test

The EPPO Standard PM 7/98 *Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity* describes how validation should be conducted. It also includes definitions of performance criteria.

Laboratory contact details	EUPH DNA Barcoding , , EUPHRESCO
Short description of the test	DNA Barcoding - Optimizing and validating DNA barcoding protocols for Phytoplasma
Date, reference of the validation report	2016-06-30 - Final_report_DNA barcoding.doc
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	no
Was the validated data generated in the framework of a project?	Euphresco
If yes, please specify	EUPHRESCO DNA Barcoding - Optimizing and validating DNA barcoding protocols for plant pests
Description of the test	
Organism(s)	'Candidatus Phytoplasma mali' (PHYPMA) 'Candidatus Phytoplasma solani' (PHYPSO) 'Candidatus Phytoplasma pyri' (PHYPPY) 'Candidatus Phytoplasma prunorum' (PHYPPR)
Detection / identification	identification
Method(s)	Molecular Sanger seq Molecular other
Method: Molecular Sanger seq	
Reference of the test description	
Other information	
Method: Molecular other	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/129 DNA barcoding as an identification tool for a number of regulated pests (version 1)
As or adapted from an IPPC diagnostic protocol	no
Is the test modified compared to the reference test	no

Kit	
Is a kit used	no
Other information	
Other details on the test	BIO-X-ACT™ Short Mix (Bioline) See report for details about the primers & protocols
Are the performance characteristics included in the EPPO diagnostic protocol?	yes
Performance Criteria :	
Organism 1.:	'Candidatus Phytoplasma mali'(PHYPMA)
<u>Analytical sensitivity</u>	
What is smallest amount of target that can be detected reliably?	See report
<u>Diagnostic sensitivity</u>	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	100%
<u>Analytical specificity - inclusivity</u>	
Number of strains/populations of target organisms tested	See report
Specificity value	
<u>Analytical specificity - exclusivity</u>	
Number of non-target organisms tested	See report
Specificity value	
<u>Reproducibility</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	See report
Organism 2.:	'Candidatus Phytoplasma solani'(PHYPSO)
<u>Analytical sensitivity</u>	
What is smallest amount of target that can be detected reliably?	See report
<u>Diagnostic sensitivity</u>	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	90% and 100%
<u>Analytical specificity - inclusivity</u>	
Number of strains/populations of target organisms tested	See report
Specificity value	
<u>Analytical specificity - exclusivity</u>	
Number of non-target organisms tested	See report
Specificity value	

<u>Reproducibility</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	See report
Organism 3.:	'Candidatus Phytoplasma pyri'(PHYPPY)
<u>Analytical sensitivity</u>	
What is smallest amount of target that can be detected reliably?	See report
<u>Diagnostic sensitivity</u>	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	100%
<u>Analytical specificity - inclusivity</u>	
Number of strains/populations of target organisms tested	See report
Specificity value	
<u>Analytical specificity - exclusivity</u>	
Number of non-target organisms tested	See report
Specificity value	
<u>Reproducibility</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	See report
Organism 4.:	'Candidatus Phytoplasma prunorum'(PHYPPR)
<u>Analytical sensitivity</u>	
What is smallest amount of target that can be detected reliably?	See report
<u>Diagnostic sensitivity</u>	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	90 % (100% after re-analysing the consensus sequence data provided by TPS participants)
<u>Analytical specificity - inclusivity</u>	
Number of strains/populations of target organisms tested	See report
Specificity value	
<u>Analytical specificity - exclusivity</u>	
Number of non-target organisms tested	See report
Specificity value	
<u>Reproducibility</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	See report
<u>Test performance study</u>	
Test performance study?	yes

Brief details of the test performance study and its output. It available, link to published article/report	Test performance study involving 13 laboratories (10 of which provided data). See report for more information.
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