

**EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION**  
**ORGANISATION EUROPEENNE ET MEDITERRANEENNE 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.

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

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

<b><u>Diagnostic sensitivity</u></b>	
<b>Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98</b>	90% and 100%
<b>Standard test(s)</b>	
<b><u>Analytical specificity - inclusivity</u></b>	
<b>Number of strains/populations of target organisms tested</b>	See report
<b>Specificity value</b>	
<b><u>Analytical specificity - exclusivity</u></b>	
<b>Number of non-target organisms tested</b>	See report
<b>Specificity value</b>	
<b>Cross reacts with</b>	
<b><u>Diagnostic Specificity</u></b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	
<b>Specify the test(s)</b>	
<b><u>Reproducibility</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	See report
<b><u>Repeatability</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	
<b>Organism 3.:</b>	'Candidatus Phytoplasma pyri'(PHYPPY)
<b><u>Analytical sensitivity</u></b>	
<b>What is smallest amount of target that can be detected reliably?</b>	See report
<b><u>Diagnostic sensitivity</u></b>	
<b>Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98</b>	100%
<b>Standard test(s)</b>	
<b><u>Analytical specificity - inclusivity</u></b>	
<b>Number of strains/populations of target organisms tested</b>	See report
<b>Specificity value</b>	
<b><u>Analytical specificity - exclusivity</u></b>	
<b>Number of non-target organisms tested</b>	See report
<b>Specificity value</b>	
<b>Cross reacts with</b>	

<b>Diagnostic Specificity</b>	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	
Specify the test(s)	
<b>Reproducibility</b>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	See report
<b>Repeatability</b>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	
Organism 4.:	'Candidatus Phytoplasma prunorum'(PHYPPR)
<b>Analytical sensitivity</b>	
What is smallest amount of target that can be detected reliably?	See report
<b>Diagnostic sensitivity</b>	
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)
Standard test(s)	
<b>Analytical specificity - inclusivity</b>	
Number of strains/populations of target organisms tested	See report
Specificity value	
<b>Analytical specificity - exclusivity</b>	
Number of non-target organisms tested	See report
Specificity value	
Cross reacts with	
<b>Diagnostic Specificity</b>	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	
Specify the test(s)	
<b>Reproducibility</b>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	See report
<b>Repeatability</b>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	
<b>Test performance study</b>	
Test performance study?	yes

<b>Brief details of the test performance study and its output. It available, link to published article/report</b>	Test performance study involving 13 laboratories. See report for more information.
<b>Other information</b>	
<b>Any other information considered useful</b>	

*Creation date: 2020-07-01 14:56:25 - Last update: 2020-07-01 15:16:26*