

**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<br>, , EUPHRESCO                                                                                                                                         |
| <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>                                          | EUPHRESCO DNA Barcoding - Optimizing and validating DNA barcoding protocols for plant pests                                                                                 |
|                                                                        |                                                                                                                                                                             |
| <b>Description of the test</b>                                         |                                                                                                                                                                             |
|                                                                        |                                                                                                                                                                             |
| <b>Organism(s)</b>                                                     | 'Candidatus Phytoplasma mali' (PHYPPMA)<br>'Candidatus Phytoplasma solani' (PHYPSO)<br>'Candidatus Phytoplasma pyri' (PHYPPY)<br>'Candidatus Phytoplasma prunorum' (PHYPPR) |
| <b>Detection / identification</b>                                      | identification                                                                                                                                                              |
| <b>Method(s)</b>                                                       | Molecular Sanger seq<br>Molecular other                                                                                                                                     |
| <b>Method: Molecular Sanger seq</b>                                    |                                                                                                                                                                             |
| <b>Reference of the test description</b>                               |                                                                                                                                                                             |
| <b>Other information</b>                                               |                                                                                                                                                                             |
| <b>Method: Molecular other</b>                                         |                                                                                                                                                                             |
| <b>Reference of the test description</b>                               |                                                                                                                                                                             |
| <b>As or adapted from an EPPO diagnostic protocol</b>                  | yes                                                                                                                                                                         |
| <b>EPPO Diagnostic Protocol name</b>                                   | PM 7/129 DNA barcoding as an identification tool for a number of regulated pests (version 1)                                                                                |
| <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>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>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>Reproducibility</b>                                                                                                               |                                                                                     |
| <b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>                                             | See report                                                                          |
| <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>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> | 90% and 100%                                                                        |
| <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>Reproducibility</b>                                                                                                               |                                                                                         |
| <b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>                                             | See report                                                                              |
| <b>Organism 3.:</b>                                                                                                                  | <b>'Candidatus Phytoplasma pyri'(PHYPPY)</b>                                            |
| <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>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>Reproducibility</b>                                                                                                               |                                                                                         |
| <b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>                                             | See report                                                                              |
| <b>Organism 4.:</b>                                                                                                                  | <b>'Candidatus Phytoplasma prunorum'(PHYPPR)</b>                                        |
| <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> | 90 % (100% after re-analysing the consensus sequence data provided by TPS participants) |
| <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>Reproducibility</b>                                                                                                               |                                                                                         |
| <b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>                                             | See report                                                                              |
| <b>Test performance study</b>                                                                                                        |                                                                                         |
| <b>Test performance study?</b>                                                                                                       | 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.

*Creation date: 2020-07-01 14:56:25 - Last update: 2026-01-22 11:33:28*