

**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.

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| <b>Laboratory contact details</b>                                      | ILVO Institute for Agricultural and Fisheries Research<br>Burg. Van Gansberghelaan 96, 9820 Merelbeke, Belgium       |
| <b>Short description of the test</b>                                   | Detection of <i>Phytophthora ramorum</i> by plating infected plant material and morphological evaluation the culture |
| <b>Date, reference of the validation report</b>                        | 2009-03-31 - F16_S08   |
| <b>Validation process according to EPPO Standard PM7/98?</b>           | no   |
| <b>Is the lab accredited for this test?</b>                            | yes  |
| <b>Was the validated data generated in the framework of a project?</b> |  |
| <b>Description of the test</b>   |  |
| <b>Organism(s)</b>   | <i>Phytophthora ramorum</i> (PHYTRA)   |
| <b>Detection / identification</b>                                      | detection  |
| <b>Method(s)</b>   | Isolation<br>Morphological   |
| <b>Method: Isolation</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 7/066 <i>Phytophthora ramorum</i> (version 1)   |
| <b>Name of the test</b>  | Isolation from plant material with P5ARP [H]   |
| <b>Is the test modified compared to the reference test</b>             | yes slight modification in composition of semi-selective medium  |
| <b>Other information</b>   |  |
| <b>Other details on the test</b>                                       | Pieces of surface sterilized infected material are plated on semi-selective media (P5ARP)                            |
| <b>Method: Morphological</b>   |  |
| <b>Reference of the test description</b>                               |  |
| <b>As or adapted from an EPPO diagnostic protocol</b>                  | yes  |

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| <b>EPPO Diagnostic Protocol name</b>   | PM 7/066 Phytophthora ramorum (version 1)   |
| <b>Other information</b>   |   |
| <b>Other details on the test</b>   | Morphological identification using a microscope and checklist (F03_S03) with most important morphological characters of the fungus. |
| <b>Are the performance characteristics included in the EPPO diagnostic protocol?</b>   | <b>no</b>   |
| <b>Performance Criteria :</b>  |   |
| <b>Organism 1.:</b>  | <b>Phytophthora ramorum(PHYTRA)</b>   |
| <b>Analytical sensitivity</b>  |   |
| <b>What is smallest amount of target that can be detected reliably?</b>  | Two plated pieces of freshly infected leaf material out of 20 plated pieces   |
| <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%. All samples that were also analysed with real-time PCR gave identical results, i.e. there were no false negatives             |
| <b>Standard test(s)</b>  | real-time PCR   |
| <b>Analytical specificity - inclusivity</b>  |   |
| <b>Number of strains/populations of target organisms tested</b>  | One in our own validation scheme but the test gave correct results with several isolates from proficiency tests.                    |
| <b>Specificity value</b>   |   |
| <b>Analytical specificity - exclusivity</b>  |   |
| <b>Number of non-target organisms tested</b>   | 5 (Phytophthora multivora, P. kernoviae, P. hedraiandra, P. syringae, P. lateralis)   |
| <b>Specificity value</b>   | none known  |
| <b>Diagnostic Specificity</b>  |   |
| <b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>        | 100%. All samples that were also analysed with real-time PCR gave identical results, i.e. there were no false positives.            |
| <b>Specify the test(s)</b>   | real-time PCR   |
| <b>Reproducibility</b>   |   |
| <b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>   | 100%  |
| <b>Repeatability</b>   |   |
| <b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>   | 100%  |
| <b>Test performance study</b>  |   |
| <b>Test performance study?</b>   | no  |
| <b>Other information</b>   |   |
| <b>Any other information considered useful</b>   | Participation in proficiency tests, including a published one (EPPO Bulletin, 38: 191-197, (2008))                                  |

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|  | Robustness and selectivity have also been established. |
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