

**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>	ILVO Institute for Agricultural and Fisheries Research 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 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

<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. hedraïandra, 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))

	Robustness and selectivity have also been established.
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*Creation date: 2012-12-07 00:00:00 - Last update: 2021-05-05 23:16:44*