

**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>	Anses Plant Health Laboratory - Nematology Unit Domaine de la Motte au Viconte BP 35327, 35653 Le Rheu, France
<b>Short description of the test</b>	Detection of Bursaphelenchus xylophilus using LAMP test Kikuchi et al. 2009
<b>Date, reference of the validation report</b>	2019-12-10 - Bx1
<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>	Other_project
<b>If yes, please specify</b>	VALITEST
<b>Description of the test</b>	
<b>Organism(s)</b>	Bursaphelenchus xylophilus(BURSXY)
<b>Detection / identification</b>	detection
<b>Method(s)</b>	Molecular Extraction DNA RNA Molecular LAMP
<b>Method: Molecular Extraction DNA RNA</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>	no
<b>EPPO Diagnostic Protocol name</b>	PM 7/004 Bursaphelenchus xylophilus (version 3)
<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>	yes
<b>Manufacturer name</b>	QIAGEN
<b>Specify the kit used</b>	QIAamp DNA Mini Kit

Kit used following the manufacturer's instructions?	yes
<b>Other information</b>	
<b>Method: Molecular LAMP</b>	
<b>Reference of the test description</b>	
As or adapted from an EPPO diagnostic protocol	no
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	yes
As or adapted from an IPPC diagnostic protocol	yes
IPPC diagnostic Protocol name	ISPM 27 Annex 10 DP 10: Bursaphelenchus xylophilus (version 2016)
Name of the test	Kikuchi et al. 2009
Is the test modified compared to the reference test	yes fluorescence used (FAM dye) for the detection of the reaction insted of color changes in the original publication
<b>Kit</b>	
Is a kit used	no
<b>Other information</b>	
Other details on the test	LAMP master mix used was from Optigene, reference Isothermal master mix ISO-004
<b>Performance Criteria :</b>	
Organism 1.:	<b>Bursaphelenchus xylophilus(BURSXY)</b>
<b>Analytical sensitivity</b>	
What is smallest amount of target that can be detected reliably?	5 individuals
<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	100%
Standard test(s)	Comparison with samples of known status
<b>Analytical specificity - inclusivity</b>	
Number of strains/populations of target organisms tested	2 populations of Bursaphelenchus xylophilus from China and Portugal
Specificity value	100%
<b>Analytical specificity - exclusivity</b>	
Number of non-target organisms tested	One population for each of the following species: B. macromucronatus, B. doui, B. hoffmani, B. kolymensis, B. mucronatus, B. sexdentati
Specificity value	100%
<b>Diagnostic Specificity</b>	

<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	100%
<b>Specify the test(s)</b>	Comparison with samples of known status
<b>Test performance study</b>	
<b>Test performance study?</b>	yes
<b>Brief details of the test performance study and its output. It available, link to published article/report</b>	Test performance study organised in the framework of the VALITEST project in 2019, including 4 participating laboratories from 4 countries. All sets of data were considered for the analysis and calculation of performance criteria.
The following complementary files are available online:	
	<ul style="list-style-type: none"> <li>• <a href="#">VALITEST BX1 report</a></li> </ul>

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