

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

<b>Specificity value</b>	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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