

**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 real time PCR for direct detection on wood extracts (Anses-LSV, FR) adapted from François et al. (2007).
<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>	yes
<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 wood chips and nematodes
<b>Plant species tested</b>	Pinus sp.
<b>Method(s)</b>	Molecular Extraction DNA RNA Molecular real time PCR
<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 real time PCR</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPP0 diagnostic protocol</b>	yes
<b>New test being considered for inclusion in the next version of the EPP0 diagnostic protocol?</b>	no
<b>EPP0 Diagnostic Protocol name</b>	PM 7/004 Bursaphelenchus xylophilus (version 3)
<b>Name of the test</b>	Real time PCR protocol for direct detection on wood extracts (Anses-LSV, FR)
<b>Kit</b>	
<b>Is a kit used</b>	no
<b>Other information</b>	
<b>Reaction type</b>	Duplex
<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 either from China or 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 16 participating laboratories from 14 countries. Only 14 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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