

**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 in extracts from wood chips or from cultures of nematodes performed on mycelium
<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 real time PCR
<b>Method: Molecular real time PCR</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>	no
<b>As or adapted from an IPPC diagnostic protocol</b>	no
<b>Reference of the test</b>	Cleardetection kit
<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>	CLEAR DETECTIONS
<b>Specify the kit used</b>	RT-N-D-0401 ClearDetections Real-Time PCR Diagnostic kit: Bursaphelenchus xylophilus

Kit used following the manufacturer's instructions?	yes
<b>Other information</b>	
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Bursaphelenchus xylophilus(BURSXY)</b>
<b>Analytical sensitivity</b>	
<b>What is 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>	91%
<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>	99%
<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>	99%
<b>Cross reacts with</b>	Bursaphelenchus macromucronatus
<b>Diagnostic Specificity</b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	99%
<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 12 participating laboratories from 10 countries. Only 11 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>

Creation date: 2020-06-21 13:43:10 - Last update: 2023-02-14 11:50:32