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.

Laboratory contact details	Anses Plant Health Laboratory - Nematology Unit Domaine de la Motte au Viconte BP 35327, 35653 Le Rheu, France
Short description of the test	Detection of Bursaphelenchus xylophilus using LAMP test Kikuchi et al. 2009
Date, reference of the validation report	2019-12-10 - Bx1
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	no
Was the validated data generated in the framework of a project?	Other_project
If yes, please specify	VALITEST
Description of the test	
Organism(s)	Bursaphelenchus xylophilus (BURSXY)
Detection / identification	detection
Method(s)	Molecular Extraction DNA RNA Molecular LAMP
Method: Molecular Extraction DNA RNA	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	no
EPPO Diagnostic Protocol name	PM 7/004 Bursaphelenchus xylophilus (version 3)
As or adapted from an IPPC diagnostic protocol	no
Is the test modified compared to the reference test	no
Kit	
Is a kit used	yes
Manufacturer name	QIAGEN
Specify the kit used	QIAamp DNA Mini Kit

Kit used following the manufacturer's instructions?	yes
Other information	
Method: Molecular LAMP	
Reference of the test description	
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
Kit	
Is a kit used	no
Other information	
Other details on the test	LAMP master mix used was from Optigene, reference Isothermal master mix ISO-004
Performance Criteria :	
Organism 1.:	**Bursaphelenchus xylophilus(BURSXY)**
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	5 individuals
Diagnostic sensitivity	
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
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	2 populations of Bursaphelenchus xylophilus from China and Portugal
Specificity value	100%
Analytical specificity - exclusivity	
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%
Diagnostic Specificity	

Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	100%
Specify the test(s)	Comparison with samples of known status
Test performance study	
Test performance study?	yes
Brief details of the test performance study and its output.It available, link to published article/report	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:	• VALITEST BX1 report

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