

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	Identification of Bursaphelenchus xylophilus by conventional PCR in extracts from cultures performed on mycelium
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?	yes
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	identification
Method(s)	Molecular Conventional PCR
Method: Molecular Conventional PCR	
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	Matsunaga et al. 2004
Is the test modified compared to the reference test	no
Kit	
Is a kit used	no
Other information	

Reaction type	Simplex
Other details on the test	Taq DNA polymerase from MP Biomedicals (ref. EPTQD925)
Performance Criteria :	
Organism 1.:	Bursaphelenchus xylophilus(BURSXY)
<u>Analytical sensitivity</u>	
What is smallest amount of target that can be detected reliably?	1 individual
<u>Diagnostic sensitivity</u>	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	not applicable
<u>Analytical specificity - inclusivity</u>	
Number of strains/populations of target organisms tested	5 populations of B. xylophilus included (originated from China, Portugal and Canada)
Specificity value	100%
<u>Analytical specificity - exclusivity</u>	
Number of non-target organisms tested	19 populations of the following species included: B. macromucronatus, B. doui, B. hoffmani, B. kolymensis, B. mucronatus, B. sexdentati, B. vallesianus, B. willibaldi, B. sp.
Specificity value	100%
<u>Diagnostic Specificity</u>	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	not applicable
<u>Reproducibility</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%
<u>Repeatability</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% (from 8 replicates of DNA solution)
Test performance study	
Test performance study?	no
Other information	
Any other information considered useful	Data obtained in the framework of the VALITEST project, during the preliminary study's phase, prior to the TPS and in a sole laboratory.
The following complementary files are available online:	<ul style="list-style-type: none"> • VALITEST BX1 report