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 ClearDetections Real-Time PCR Diagnostic kit in extracts from wood chips or on isolated nematodes
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 real time PCR
Method: Molecular real time 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?	no
As or adapted from an IPPC diagnostic protocol	no
Reference of the test	Cleardetection kit
Is the test modified compared to the reference test	no
Kit	
Is a kit used	yes
Manufacturer name	CLEAR DETECTIONS
Specify the kit used	RT-N-D-0401 ClearDetections Real-Time PCR Diagnostic kit: Bursaphelenchus xylophilus

Kit used following the manufacturer's instructions?	yes
Other information	
Performance Criteria :	
Organism 1.:	**Bursaphelenchus xylophilus(BURSXY)**
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	10 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	5 populations of B. xylophilus included (originated from China, Portugal and Canada)
Specificity value	100%
Analytical specificity - exclusivity	
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%
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	not applicable
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%
Repeatability	
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:	• VALITEST BX1 report

Creation date: 2020-06-21 14:25:18 - Last update: 2021-05-27 15:17:24