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	ClearDetections P.O. Box 170, NL-6700 PD Wageningen, Netherlands
Short description of the test	Species-specific qualitative identification of DNA from Bursaphelenchus xylophilus originating from individual nematodes, using Real-Time PCR based on fluorescent dye detection
Date, reference of the validation report	2020-07-30 - ClearDetections Validation report B. xylophilus V1.2.pdf
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?	no
Description of the test	
Organism(s)	Bursaphelenchus xylophilus (BURSXY)
Detection / identification	identification
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?	yes
As or adapted from an IPPC diagnostic protocol	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	

Reaction type	Simplex
Performance Criteria :	
Organism 1.:	**Bursaphelenchus xylophilus(BURSXY)**
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	One individual target nematode (B. xylophilus) at a low level of contamination
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)	morphological identification
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	8 targets B. xylophilus (different origin) see table 1, 2 and 3 of validation report
Specificity value	100%
Analytical specificity - exclusivity	
Number of non-target organisms tested	10 non target species, see table 1, 2 and 3 of validation report
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)	morphological identification
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%
Test performance study	
Test performance study?	no
Other information	
Any other information considered useful	Robustness: No test failure was observed when the primer combination was exposed to a temperature gradient. With a devation in Ta of (plus or minus) 1.0 °C from the normal Ta (63 °C), all ΔCt values remain <1. The tests for the detection of B. xylophilus is therefore robust. The qPCR assay for identification of B. xylophilus is available as all-inclusive molecular kit, including primer set, positive control DNA, PCR mix and a bench-side protocol describing the laboratory procedure (for more information visit www.cleardetections.com)

The following complementary files are available online:	• ClearDetections Validation report B. xylophilus V1.2

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