

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

Reaction type	Simplex
<b>Performance Criteria :</b>	
Organism 1.:	<b>Bursaphelenchus xylophilus(BURSXY)</b>
<b><u>Analytical sensitivity</u></b>	
What is smallest amount of target that can be detected reliably?	One individual target nematode (B. xylophilus) at a low level of contamination
<b><u>Diagnostic sensitivity</u></b>	
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
<b><u>Analytical specificity - inclusivity</u></b>	
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%
<b><u>Analytical specificity - exclusivity</u></b>	
Number of non-target organisms tested	10 non target species, see table 1, 2 and 3 of validation report
Specificity value	100%
<b><u>Diagnostic Specificity</u></b>	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	100%
Specify the test(s)	morphological identification
<b><u>Reproducibility</u></b>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%
<b><u>Repeatability</u></b>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%
<b>Test performance study</b>	
Test performance study?	no
<b>Other information</b>	
Any other information considered useful	Robustness: No test failure was observed when the primer combination was exposed to a temperature gradient. With a deviation in Ta of (plus or minus) 1.0 °C from the normal Ta (63 °C), all $\Delta C_t$ 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 <a href="http://www.clear-detections.com">www.clear-detections.com</a> )

The following complementary files are available online:	<ul style="list-style-type: none"><li>• <a href="#">ClearDetections Validation report B. xylophilus V1.2</a></li></ul>

*Creation date: 2020-09-09 13:41:34 - Last update: 2020-12-21 14:10:31*