

**EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION  
ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA PROTECTION  
DES PLANTES**

(11-17239)

**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>Target Organism</b>	Bursaphelenchus xylophilus	
<b>Short description</b>	Identification of Bursaphelenchus xylophilus by specific PCR Castagnone et al. 2005	
<b>Laboratory contact details</b>	Anses, Laboratoire de la Santé des Végétaux - Unité de Nématologie Domaine de la Motte au Viconte BP 35327, 35653 Le Rheu, France	
<b>Date and reference of the validation report</b>	2011-05 - Evaluation d'outils moléculaires d'identification de Bursaphelenchus xylophilus sur individus isolés	
<b>Validation process according to EPPO Standard PM 7/98:</b>	Yes	
<b>Reference of the test description</b>	0 Appendix 2 Castagnone C., Abad P & Castagnone-Serneno P (2005) Satellite DNA-based species specific identification of single individuals of the pinewood nematode Bursaphelenchus xylophilus EJPP 112, 191-193	
<b>Is the test the same as described in the EPPO DP?</b>	Yes	
<b>Is the lab accredited for this test?</b>	No	
<b>Plant species tested (if relevant)</b>		
<b>Matrices tested (if relevant)</b>	Nematodes	
<b>List of methods used</b>		
<b>Method for extraction / isolation / baiting of target organism from matrix</b>		
<b>Molecular methods, e.g. hybridization, PCR and real time PCR</b>	X	satellite DNA species specific PCR
<b>Serological methods: IF, ELISA,</b>		

<b>Direct Tissue Blot Immuno Assay</b>		
<b>Plating methods: selective isolation</b>		
<b>Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.</b>		
<b>Pathogenicity test</b>		
<b>Fingerprint methods: protein profiling, fatty acid profiling &amp; DNA profiling</b>		
<b>Morphological and morphometrical methods intended for identification</b>		
<b>Biochemical methods: e.g. enzyme electrophoresis, protein profiling</b>		
<b>Other</b>		
<b><u>Analytical sensitivity (= limit of detection)</u></b>		
<b>What is smallest amount of target that can be detected reliably?</b>	2-5 nematods	
<b><u>Diagnostic sensitivity</u></b>		
<b>Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98</b>	Not performed	
<b>Specify the standard test</b>	Not relevant	
<b><u>Analytical specificity</u></b>		
<b>Specificity value</b>	100%	
<b>Number of strains/populations of target organisms tested</b>	7 populations (see table1)	
<b>Number of non-target organisms tested</b>	15 populations (see table1)	
<b>Cross reacts with (specify the species)</b>	none	
<b><u>Diagnostic Specificity</u></b>		
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	Not performed	
<b>Specify the standard test</b>	Not relevant	
<b><u>Reproducibility</u></b>		
<b>Provide the calculated % of</b>	95.8% for 2 nematodes	

<b>agreement for a given level of the pest (see PM 7/98)</b>	100% for 5 nematodes
<b><u>Repeatability</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%
<b><u>Test performance study</u></b>	
<b>Test performance study?</b>	No
<b>Include brief details of the test performance study and its output. If available, provide a link to published article/report</b>	
<b><u>Other information</u></b>	
<b>Any other information considered useful e.g. robustness, ease of performing the test, etc.</b>	See table 2. The full report is available upon request to the laboratory.
<b>The following complementary files are available online:</b>	<ul style="list-style-type: none"> <li>• <a href="#">Table 1 List of species and population tested to evaluate specificity</a></li> <li>• <a href="#">table 2 comparison of tests</a></li> </ul>