

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.

Target Organism	Bursaphelenchus xylophilus	
Short description	Identification of Bursaphelenchus xylophilus by species specific PCR	
Laboratory contact details	Anses, Laboratoire de la Santé des Végétaux - Unité de Nématologie Domaine de la Motte au Viconte BP 35327, 35653 Le Rheu, France	
Date and reference of the validation report	2011-05 - Validation report may 2011	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	0 PM7/04 (2) not included in appendix Matsunaga K. & Togashi K. (2005). A simple method for discriminating Bursaphelenchus xylophilus and B. mucronatus by species-specific polymerase chain reaction primers pairs. Nematology 6(2), 273-277.	
Is the test the same as described in the EPPO DP?	No not included in appendix	
Is the lab accredited for this test?	Yes	
Plant species tested (if relevant)		
Matrices tested (if relevant)	Isolated nematodes	
List of methods used		
Method for extraction / isolation / baiting of target organism from matrix		
Molecular methods, e.g. hybridization, PCR and real time PCR	X	species specific PCR
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay		
Plating methods: selective isolation		
Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.		
Pathogenicity test		

Fingerprint methods: protein profiling, fatty acid profiling & DNA profiling		
Morphological and morphometrical methods intended for identification		
Biochemical methods: e.g. enzyme electrophoresis, protein profiling		
Other		
Analytical sensitivity (= limit of detection)		
What is smallest amount of target that can be detected reliably?	5 nematodes	
Diagnostic sensitivity		
Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98	100%	
Specify the standard test	no standard test, samples artificially infested	
Analytical specificity		
Specificity value	100%	
Number of strains/populations of target organisms tested	7 populations (for details see table 2 in validation report)	
Number of non-target organisms tested	15 populations (for details see table 2 in validation report)	
Cross reacts with (specify the species)	none	
Diagnostic Specificity		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test		
Specify the standard test		
Reproducibility		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% for 5 B. xylophilus individuals	
Repeatability		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% for 5 B. xylophilus individuals	
Test performance study		
Test performance study?	No	
Include brief details of the test performance study and its output.It available, provide a link to published article/report		

Other information	
Any other information considered useful e.g. robustness, ease of performing the test, etc.	The full report is available upon request to the laboratory.
The following complementary files are available online:	<ul style="list-style-type: none">• Table 2_comparison of different PCR tests