

EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION
ORGANISATION EUROPEENNE ET MEDITERRANEEENNE 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	Globodera sp.	
Short description	DNA extraction from nematodes juveniles	
Laboratory contact details	Anses Plant Health Laboratory - Nematology Unit Domaine de la Motte au Viconte BP 35327, 35653 Le Rheu, France	
Date and reference of the validation report	2009-08-10 - validation report ref. 09/10	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	0 PM7/40 - not included in appendix in house protocol	
Is the test the same as described in the EPPO DP?	No not included in appendix from PM7/40	
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	DNA extraction using mechanical disruption (bead) associated with chemical and heat treatment (proteinase K)
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		
<u>Analytical sensitivity (= limit of detection)</u>		
What is smallest amount of target that can be detected reliably?	1 J2 from Globodera	
<u>Diagnostic sensitivity</u>		
Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98		
Specify the standard test		
<u>Analytical specificity</u>		
Specificity value	not applicable	
Number of strains/populations of target organisms tested		
Number of non-target organisms tested		
Cross reacts with (specify the species)		
<u>Diagnostic Specificity</u>		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	not applicable	
Specify the standard test		
<u>Reproducibility</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)		
<u>Repeatability</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%	
<u>Test performance study</u>		
Test performance study?	No	
Include brief details of the test performance study and its output.It available, provide a link to published article/report		
<u>Other information</u>		
Any other information considered useful e.g. robustness, ease of performing the test, etc.		

The following complementary files are available online:	<ul style="list-style-type: none">• Validation report ref 09/10