

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	Globodera pallida Globodera rostochiensis	
Short description	Species specific identification by conventional PCR test	
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	13/07/2010 - Evaluation comparative de différents outils moléculaires pour l'identification de Globodera pallida et G. rostochiensis (ref. 10/03)	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	N/R PM7/40 (2) - appendix 3 A (Bullman & Marshall, 1997)	
Is the test the same as described in the EPPO DP?	Modified primers concentration was reduced	
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		
<u>Analytical sensitivity (= limit of detection)</u>		
What is smallest amount of target that can be detected reliably?	1 J2	
<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	91% for G. pallida (1 non target species detected among 11 others) 100% for G. rostochiensis	
Number of strains/populations of target organisms tested	11 populations for G. pallida and 4 for G. rostochiensis (details see validation report - annex 2)	
Number of non-target organisms tested	7 populations (details see validation report - annex 2)	
Cross reacts with (specify the species)	G. tabacum "virginiae" detected as G. pallida.	
<u>Diagnostic Specificity</u>		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test		
Specify the standard test		
<u>Reproducibility</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	96% (1J2 stage tested) for G. pallida 100% (1J2 stage tested) for G. rostochiensis	
<u>Repeatability</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% for G. pallida 100% for G. rostochiensis	
<u>Test performance study</u>		
Test performance study?	No	
Include brief details of the test performance study and its output. If 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 full report is available upon request to the laboratory.
The following complementary files are available online:	<ul style="list-style-type: none"> • Validation sheet - Globodera Bullman test