

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	Heterodera glycines	
Short description	Identification of Heterodera glycines by PCR	
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	2010-07-07 - Report 10/02	
Validation process according to EPPO Standard PM 7/98:	No	
Reference of the test description	PM 7/089(1) SUBBOTIN S.A., PENG D., MOENS M. (2001). A rapid method for the identification of the soybean cyst nematode Heterodera glycines using duplex PCR. Nematology, 3(4), 365-371.	
Is the test the same as described in the EPPO DP?	Yes	
Is the lab accredited for this test?	No	
Plant species tested (if relevant)		
Matrices tested (if relevant)	isolated nematodes: one cyst per species	
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 in duplex with universal primers (GlyFI-rDNA2 + D2A-D3B) and species specific PCR in simplex (GlyFI-rDNA2)
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?		
<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 calculated, but In duplex, no specific amplification for target and non-target species. In simplex, 3 non target species detected among 13 tested	
Number of strains/populations of target organisms tested	1	
Number of non-target organisms tested	13	
Cross reacts with (specify the species)	In simplex, cross reactions observed for H. betae/trifolii, H. schachtii, H. ciceri (all belonging to the Schachtii group which includes H. glycines).	
<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)		
<u>Repeatability</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)		
<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	
Other information	
Any other information considered useful e.g. robustness, ease of performing the test, etc.	As the analytical specificity of the test is not sufficient, the other performance criteria were not evaluated
The following complementary files are available online:	<ul style="list-style-type: none"> • Populations list and results_Subbotin et al 2001