

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	
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	2015-02 - validation report	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	N/R YE W. (2012). Development of PrimeTime-Real-Time PCR for species identification of soybean cyst nematode (Heterodera glycines) in North Carolina. Journal of Nematology, 44(3), 284-290.	
Is the test the same as described in the EPPO DP?		
Is the lab accredited for this test?	No	
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 real time PCR test
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 juvenile (Ct value < 30 in our conditions)	
<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	100%	
Number of strains/populations of target organisms tested	6	
Number of non-target organisms tested	20	
Cross reacts with (specify the species)	Cross reaction observed with <i>H. goettingiana</i> with a Ct value > 30	
<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)	100% (with 1 or 2 juveniles)	
<u>Repeatability</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% (with 1 or 2 juveniles)	
<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.	Robustness evaluated when changing annealing temperature (+/- 1]C), results were conform.
The following complementary files are available online:	<ul style="list-style-type: none">• Populations list and results_Ye 2012