

**EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION  
ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA PROTECTION DES PLANTES  
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.

<b>Laboratory contact details</b>	ClearDetections P.O. Box 170, NL-6700 PD Wageningen, Netherlands
<b>Short description of the test</b>	Diagnostic Real-time PCR assay for identification and detection of <i>Aphelenchoides besseyi</i>
<b>Date, reference of the validation report</b>	2011-01-01 - 86 ; 'Validatie van moleculaire identificatie- en detectiemethoden van <i>Aphelenchoides fragariae</i> , <i>A. ritzemabosi</i> , <i>A. subtenuis</i> en <i>A. besseyi</i> '. Validation report (in Dutch) of FES study.
<b>Validation process according to EPPO Standard PM7/98?</b>	yes
<b>Is the lab accredited for this test?</b>	no
<b>Was the validated data generated in the framework of a project?</b>	no
<b>Description of the test</b>	
<b>Organism(s)</b>	<i>Aphelenchoides besseyi</i> (APLOBE)
<b>Detection / identification</b>	detection and identification
<b>Method(s)</b>	Molecular real time PCR
<b>Method: Molecular real time PCR</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	yes
<b>EPPO Diagnostic Protocol name</b>	PM 7/039 <i>Aphelenchoides besseyi</i> (version 2)
<b>Name of the test</b>	Real-time PCR test based on SSU rDNA (Clear detection)
<b>Is the test modified compared to the reference test</b>	no
<b>Kit</b>	
<b>Is a kit used</b>	yes
<b>Manufacturer name</b>	CLEAR DETECTIONS
<b>Specify the kit used</b>	RT-N-D-0302 ClearDetections Real-Time PCR Diagnostic kit: <i>Aphelenchoides besseyi</i>

Kit used following the manufacturer's instructions?	yes
<b>Other information</b>	
<b>Reaction type</b>	Simplex
<b>Other details on the test</b>	Real-time PCR; based on detection of a fluorescent DNA-binding dye
<b>Are the performance characteristics included in the EPPO diagnostic protocol?</b>	yes
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Aphelenchoides besseyi(APLOBE)</b>
<b>Analytical sensitivity</b>	
<b>What is smallest amount of target that can be detected reliably?</b>	< one individual nematode (~ 3 cells of target nematode)
<b>Diagnostic sensitivity</b>	
<b>Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98</b>	100%
<b>Standard test(s)</b>	Morphological identification
<b>Analytical specificity - inclusivity</b>	
<b>Number of strains/populations of target organisms tested</b>	A. besseyi (2160 and E9192) obtained from Dutch PPO (ref. Gerrit Karssen)
<b>Specificity value</b>	100%
<b>Analytical specificity - exclusivity</b>	
<b>Number of non-target organisms tested</b>	Aphelenchoides subtenuis; A. fragariae; A. ritzemabosi; A. saprophilus; Ditylenchus dipsaci; D. destructor
<b>Specificity value</b>	100% No cross reaction
<b>Diagnostic Specificity</b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	100%
<b>Specify the test(s)</b>	Morphological identification
<b>Reproducibility</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%
<b>Repeatability</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%
<b>Test performance study</b>	
<b>Test performance study?</b>	no
<b>Other information</b>	
<b>Any other information considered useful</b>	Accuracy: 100% Dynamic range: between 10-100 and 0.1 billion copies of target rDNA Selectivity:

	100% Robustness: OK This qPCR assay for identification and detection of <i>A. besseyi</i> is available as all-inclusive molecular kit, including primer sets, positive control DNA, PCR enhancer and PCR mix and a bench-side protocol describing the laboratory procedure (for information visit <a href="http://www.cleardetections.com">www.cleardetections.com</a> ).
The following complementary files are available online:	<ul style="list-style-type: none"><li>• <a href="#">Validation report</a></li></ul>

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