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.

Laboratory contact details	Netherlands Institute for Vectors, Invasive plants and Plant health P.O. Box 9102, 6700 HC Wageningen, Netherlands
Short description of the test	detection and identification of Synchytrium endobioticum by Molecular real time PCR (van Gent-Pelzer 2010) in Tubers and Soils
Date, reference of the validation report	2021-12-13 - 2018.molbio.008
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	yes
Was the validated data generated in the framework of a project?	no
Description of the test	
Organism(s)	Synchytrium endobioticum (SYNCEN)
Detection / identification	detection and identification
Method(s)	Molecular real time PCR
Method: Molecular real time PCR	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	yes
EPPO Diagnostic Protocol name	PM 7/028 Synchytrium endobioticum (version 2)
Name of the test	Real-time PCR (Van Gent-Pelzer et al., 2010)
As or adapted from an IPPC diagnostic protocol	no
Is the test modified compared to the reference test	yes A filtration step was added to collect spores from suspension in saturated CalCl2 solution. DNA was extracted with the DNeasy PowerSoil kit (Qiagen).
Kit	
Is a kit used	no
Other information	

Reaction type	Simplex
Performance Criteria :	
Organism 1.:	**Synchytrium endobioticum(SYNCEN)**
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	When analysing DNA extracted from resting spore series, the pathogen was detected in all five subsamples when testing 10 or 5 spores per sample. Mean Cq values of 35.1 ± 0.4 and 37.1 ± 1.4 were obtained for 10 and 5 spores, respectively. When considering the subsamples with 2 spores or 1 spore per sample, four out of five tested positive. LOD was determined at 7 resting spores per reaction.
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	81% (based on 814 samples analysed : 141 controls and 673 diagnostic samples)
Standard test(s)	Direct microscopic examination following PM7/28(2)
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	Resting spores of pathotypes 1(D1), 2(G1), 6(O1), 8(F1), 18(T1) and 38(Nevsehir)
Specificity value	100%
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	97% (based on 814 samples analysed : 141 controls and 673 diagnostic samples)
Specify the test(s)	Direct microscopic examination following PM7/28(2)
Test performance study	
Test performance study?	yes
Brief details of the test performance study and its output.It available, link to published article/report	Euphresco Sendo project
Other information	
Any other information considered useful	Paper TPS: https://doi.org/10.1007%2Fs10658-017-1411-6 Paper Comparison of real-time PCR tests for the detection of Synchytrium endobioticum resting spores in soil: https://doi.org/10.1111/epp.12813

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