

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

<b>Reaction type</b>	Simplex
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Synchytrium endobioticum(SYNCEN)</b>
<b><u>Analytical sensitivity</u></b>	
<b>What is smallest amount of target that can be detected reliably?</b>	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 $35.1 \pm 0.4$ and $37.1 \pm 1.4$ 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.
<b><u>Diagnostic sensitivity</u></b>	
<b>Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98</b>	81% (based on 814 samples analysed : 141 controls and 673 diagnostic samples)
<b>Standard test(s)</b>	Direct microscopic examination following PM7/28(2)
<b><u>Analytical specificity - inclusivity</u></b>	
<b>Number of strains/populations of target organisms tested</b>	Resting spores of pathotypes 1(D1), 2(G1), 6(O1), 8(F1), 18(T1) and 38(Nevsehir)
<b>Specificity value</b>	100%
<b><u>Diagnostic Specificity</u></b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	97% (based on 814 samples analysed : 141 controls and 673 diagnostic samples)
<b>Specify the test(s)</b>	Direct microscopic examination following PM7/28(2)
<b><u>Test performance study</u></b>	
<b>Test performance study?</b>	yes
<b>Brief details of the test performance study and its output.It available, link to published article/report</b>	Euphresco Sendo project
<b><u>Other information</u></b>	
<b>Any other information considered useful</b>	Paper TPS: <a href="https://doi.org/10.1007%2Fs10658-017-1411-6">https://doi.org/10.1007%2Fs10658-017-1411-6</a> Paper Comparison of real-time PCR tests for the detection of Synchytrium endobioticum resting spores in soil: <a href="https://doi.org/10.1111/epp.12813">https://doi.org/10.1111/epp.12813</a>

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