

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	Council for Agricultural Research and Economics– Research Centre for Plant Protection and Certification Via Carlo Giuseppe Bertero, 22, 00156 Rome, Italy
Short description of the test	Intralaboratory validation of Ceratocystis platani_Real-Time PCR_TaqMan (corresponding Pilotti M.)
Date, reference of the validation report	2025-04-22 - Intralaboratory validation of Ceratocystis platani_Real-Time PCR_Taq Man (corresponding Pilotti M.)
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	no
Was the validated data generated in the framework of a project?	Other_project
If yes, please specify	ARNADIA (MIPAAF Project)
Description of the test	
Organism(s)	Ceratocystis platani (CERAFP)
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
EPPO Diagnostic Protocol name	PM 7/014 Ceratocystis fimbriata f. sp. platani (version 2)
Name of the test	Real-time PCR (Pilotti et al., 2012) Test version 2: dual-labelled probe (Taqman)
Is the test modified compared to the reference test	no
Kit	
Is a kit used	no
Other information	

Reaction type	Simplex
Performance Criteria :	
Organism 1.:	Ceratocystis platani(CERAFP)
<u>Analytical sensitivity</u>	
What is smallest amount of target that can be detected reliably?	3 fg
<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	100%
Standard test(s)	Comparison with samples of known status
<u>Analytical specificity - inclusivity</u>	
Number of strains/populations of target organisms tested	see Pilotti et al 2012
Specificity value	100%
<u>Diagnostic Specificity</u>	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	100%
Specify the test(s)	Comparison with samples of known status
<u>Reproducibility</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% - evaluated by two different operators; each operator performed three different experiment testing 8 replicates at the LOD (3 fg)
<u>Repeatability</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% - evaluated on 8 replicates at the LOD (3 fg). The result was also confirmed by testing the gDNA of five additional C. platani strains, each in a single experiment performed by one operator, at the limit of detection and with eight replications.
Test performance study	
Test performance study?	no
The following complementary files are available online:	<ul style="list-style-type: none"> • Lumia et al 2018 • Pilotti et al 2012

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