

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	Real Time PCR for the identification of <i>Phyllosticta citricarpa</i> (van Gent-Pelzer et al., 2007)
Date, reference of the validation report	2014-01-01 -
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?	
Description of the test	
Organism(s)	<i>Phyllosticta citricarpa</i> (GUIGCI)
Detection / identification	identification
Method(s)	Molecular Extraction DNA RNA Molecular real time PCR
Method: Molecular Extraction DNA RNA	
Reference of the test description	
Kit	
Is a kit used	yes
Manufacturer name	MACHEREY-NAGEL
Specify the kit used	Nucleospin plant II kit
Kit used following the manufacturer's instructions?	yes
Other information	
Method: Molecular real time PCR	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/017 <i>Guignardia citricarpa</i> (version 2)
Name of the test	Real-time PCR (van Gent-Pelzer et al., 2007)

Is the test modified compared to the reference test	yes
Other information	
Reaction type	Simplex - Probe
Other details on the test	See details in report
Are the performance characteristics included in the EPPO diagnostic protocol?	no
Performance Criteria :	
Organism 1.:	Phyllosticta citricarpa(GUIGCI)
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	10 fg of DNA
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	3 target strains
Specificity value	100%
Analytical specificity - exclusivity	
Number of non-target organisms tested	3 non-target strains (see validation report)
Specificity value	100% no cross reaction
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%
Test performance study	
Test performance study?	yes
Brief details of the test performance study and its output.It available, link to published article/report	The robustness of the method was verified through a Test Performance Study among 6 laboratories. For each lab 6 positive samples (3 containing the target DNA slightly above the relative limit of detection and 3 containing the target DNA ten times the relative limit of detection) and 6 negative samples (3 containing no DNA and 3 containing DNA of non-target strains) were tested. The results showed: -100% relative sensitivity -100% relative specificity -100% repeatability -100% reproducibility
Other information	
Any other information considered useful	When verifying the performance criteria cross reactions with the non-target organism <i>Phyllosticta citriasiana</i> was noted so the protocol was slightly changed and a new validation was performed. It is suggested to use the amplification commercial kit in RealTime-PCR to avoid no specific amplification

	with P. citriasiana.
The following complementary files are available online:	<ul style="list-style-type: none"> • Validation process of the Real Time PCR for the identification of Phyllosticta citricarpa (van Gent-Pelzer et al., 2007)

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