

EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION
ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA PROTECTION DES PLANTES
(11-17239)

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.

Target Organism	Monilia fructicola	
Short description	Detection of Monilia fructicola by PCR in plant material	
Laboratory contact details	Anses Plant Health Laboratory - Mycology Unit Mycology Unit Domaine de Pixérécourt, Bât. E, 54220 Malzéville, France	
Date and reference of the validation report	2008 - loos, R., and G. Iancu. 2008. European collaborative studies for the validation of PCR-based detection tests targeting regulated fungi and oomycetes. Bulletin OEPP/EPPO Bulletin 38(2):198-204.	
Validation process according to EPPO Standard PM 7/98:	No	
Reference of the test description	0 loos, R., and G. Iancu. 2008. European collaborative studies for the validation of PCR-based detection tests targeting regulated fungi and oomycetes. Bulletin OEPP/EPPO Bulletin 38(2):198-204.	
Is the test the same as described in the EPPO DP?	Yes	
Is the lab accredited for this test?	Yes	
Plant species tested (if relevant)	Prunus spp. Malus spp. Pyrus spp.	
Matrices tested (if relevant)	fruit, flower, bud, stem canker	
List of methods used		
Method for extraction / isolation / baiting of target organism from matrix		
Molecular methods, e.g. hybridization, PCR and real time PCR	X	end point PCR
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay		
Plating methods: selective isolation		
Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.		
Pathogenicity test		

Fingerprint methods: protein profiling, fatty acid profiling & DNA profiling		
Morphological and morphometrical methods intended for identification		
Biochemical methods: e.g. enzyme electrophoresis, protein profiling		
Other		
<u>Analytical sensitivity (= limit of detection)</u>		
What is smallest amount of target that can be detected reliably?	2 10 ⁴ plasmidic copies per PCR tube	
<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%	
Specify the standard test	Use of standard samples of known status (artificially spiked with the target)	
<u>Analytical specificity</u>		
Specificity value		
Number of strains/populations of target organisms tested	6	
Number of non-target organisms tested	M. fructigena (16 strains) M. laxa (17 strains)	
Cross reacts with (specify the species)		
<u>Diagnostic Specificity</u>		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	100%	
Specify the standard test	Use of standard samples of known status (artificially spiked with water)	
<u>Reproducibility</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%	
<u>Repeatability</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%	
<u>Test performance study</u>		
Test performance study?	No	
Include brief details of the test performance study and its output.It		

available, provide a link to published article/report	
Other information	
Any other information considered useful e.g. robustness, ease of performing the test, etc.	<p>The authors recommend that the integrity of the PCR primers is ensured when ordering. Primers ordered with an additional purification step are recommended, in order to make sure that they are full length. Primers that are not full length may generate cross reaction with DNA from closely related species, such as <i>M. laxa</i> or <i>M. fructigena</i>.</p>