

**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.

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

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

<b>available, provide a link to published article/report</b>	
<b>Other information</b>	
<b>Any other information considered useful e.g. robustness, ease of performing the test, etc.</b>	<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>