

**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>	Anses Plant Health Laboratory - Mycology Unit Mycology Unit Domaine de Pixérécourt, Bât. E, 54220 Malzéville, France
<b>Short description of the test</b>	Detection of <i>Monilia fructicola</i> by PCR in plant material
<b>Date, reference of the validation report</b>	2008-01-01 - 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 PM7/98?</b>	no
<b>Is the lab accredited for this test?</b>	yes
<b>Was the validated data generated in the framework of a project?</b>	
<b>Description of the test</b>	
<b>Organism(s)</b>	<i>Monilinia fructicola</i> (MONIFC)
<b>Detection / identification</b>	detection
<b>Method(s)</b>	Molecular Conventional PCR
<b>Method: Molecular Conventional PCR</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	no
<b>As or adapted from an IPPC diagnostic protocol</b>	no
<b>Reference of the test</b>	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>Other information</b>	
<b>Other details on the test</b>	end point PCR
<b>Are the performance characteristics included in the EPPO diagnostic protocol?</b>	<b>no</b>
<b>Performance Criteria :</b>	

<b>Organism 1.:</b>	<b>Monilinia fructicola(MONIFC)</b>
<b>Analytical sensitivity</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>Standard test(s)</b>	Use of standard samples of known status (artificially spiked with the target)
<b>Analytical specificity - inclusivity</b>	
<b>Number of strains/populations of target organisms tested</b>	6
<b>Specificity value</b>	
<b>Analytical specificity - exclusivity</b>	
<b>Number of non-target organisms tested</b>	M. fructigena (16 strains) M. laxa (17 strains)
<b>Specificity value</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 test(s)</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>Other information</b>	
<b>Any other information considered useful</b>	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 M. laxa or M. fructigena.

Creation date: 2012-11-13 00:00:00 - Last update: 2021-05-10 14:56:30