

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	Anses Plant Health Laboratory - Mycology Unit Mycology Unit Domaine de Pixérécourt, Bât. E, 54220 Malzéville, France
Short description of the test	Detection of <i>Monilia fructicola</i> by PCR in plant material
Date, reference of the validation report	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.
Validation process according to EPPO Standard PM7/98?	no
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)	Monilinia fructicola (MONIFC)
Detection / identification	detection
Method(s)	Molecular Conventional PCR
Method: Molecular Conventional PCR	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	no
As or adapted from an IPPC diagnostic protocol	no
Reference of the test	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.
Other information	
Other details on the test	end point PCR
Are the performance characteristics included in the EPPO diagnostic protocol?	no
Performance Criteria :	

Organism 1.:	Monilinia fructicola(MONIFC)
<u>Analytical sensitivity</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%
Standard test(s)	Use of standard samples of known status (artificially spiked with the target)
<u>Analytical specificity - inclusivity</u>	
Number of strains/populations of target organisms tested	6
Specificity value	
<u>Analytical specificity - exclusivity</u>	
Number of non-target organisms tested	M. fructigena (16 strains) M. laxa (17 strains)
Specificity value	
<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)	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%
Test performance study	
Test performance study?	no
Other information	
Any other information considered useful	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.

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