

**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	AGES Institute of Sustainable Plant Production Spargelfeldstrasse 191, 1220 Vienna, Austria
Short description of the test	Real-time PCR assay targeting chromosomal DNA of <i>Erwinia amylovora</i> .
Date, reference of the validation report	2010-01-01 - none
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	no
Was the validated data generated in the framework of a project?	no
Description of the test	
Organism(s)	<i>Erwinia amylovora</i> (ERWIAM)
Detection / identification	detection and identification
Method(s)	Molecular Extraction DNA RNA Molecular real time PCR
Method: Molecular Extraction DNA RNA	
<i>Reference of the test description</i>	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/020 <i>Erwinia amylovora</i> (version 2)
Kit	
Is a kit used	yes
Manufacturer name	
Specify the kit used	
Kit used following the manufacturer's instructions?	
Other information	
Method: Molecular real time PCR	
<i>Reference of the test description</i>	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/020 <i>Erwinia amylovora</i> (version 2)

Name of the test	Real-time PCR (Gottsberger, 2010)
As or adapted from an IPPC diagnostic protocol	yes
IPPC diagnostic Protocol name	ISPM 27 Annex 13 DP 13: Erwinia amylovora (version 2016)
Name of the test	Real-time PCR according to Gottsberger (2010)
Is the test modified compared to the reference test	no
Kit	
Is a kit used	no
Other information	
Other details on the test	New test approved for inclusion in PM 7/020(2) approval 2012 Gottsberger RA (2010) Development and evaluation of a realtime PCR assay targeting chromosomal DNA of Erwinia amylovora. Letters in Applied Microbiology 51, 285-292.
Are the performance characteristics included in the EPPO diagnostic protocol?	yes
Performance Criteria :	
Organism 1.:	Erwinia amylovora(ERWIAM)
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	2 cfu/μl
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	Contact the lab
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	71 (in Gottsberger 2010)
Specificity value	
Analytical specificity - exclusivity	
Number of non-target organisms tested	41 (in Gottsberger 2010)
Specificity value	100%
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	Contact the lab
Specify the test(s)	Bereswill et al. (1992)
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%, when tested with different operators

Repeatability	
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	Test can be used for quantification. A dilution series of a target bacteria suspension with determined concentration can be used as standards.

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