

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

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

<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>	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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