

**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>	Federal State Organization "All-Russian Plant Quarantine Center" Pogranichnaya str.32, Ramensky region, Moscow obl., 140150 Bykovo, Russian Federation
<b>Short description of the test</b>	Detection of <i>Erwinia amylovora</i> in plant extract by Real-time PCR, targeting chromosomal DNA
<b>Date, reference of the validation report</b>	2014-01-01 - none
<b>Validation process according to EPPO Standard PM7/98?</b>	yes
<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>Erwinia amylovora</i> (ERWIAM)
<b>Detection / identification</b>	detection
<b>Matrix(ces) tested</b>	Leaves, Shoots Shoots and leaves
<b>Plant species tested</b>	Rosaceae
<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>	no
<b>As or adapted from an IPPC diagnostic protocol</b>	no
<b>Kit</b>	
<b>Is a kit used</b>	yes
<b>Manufacturer name</b>	AGRODIAGNOSTICA
<b>Specify the kit used</b>	PREP-GS kit
<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 Erwinia amylovora (version 2)
<b>Name of the test</b>	Real-time PCR (Gottsberger, 2010)
<b>Is the test modified compared to the reference test</b>	no
<b>Other information</b>	
<b>Are the performance characteristics included in the EPPO diagnostic protocol?</b>	no
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Erwinia amylovora(ERWIAM)</b>
<b>Analytical sensitivity</b>	
<b>What is the smallest amount of target that can be detected reliably?</b>	24 cfu/μl // 1,2*10 <sup>3</sup> /ml
<b>Analytical specificity - inclusivity</b>	
<b>Number of strains/populations of target organisms tested</b>	126 strains: 1 strain of Erwinia amylovora CFBP 1430 + 99 strains isolated in different regions of Russian Federation + 26 strains isolated in Kazakhstan, Kyrgyzstan, Poland and Moldova
<b>Specificity value</b>	
<b>Analytical specificity - exclusivity</b>	
<b>Number of non-target organisms tested</b>	92 strains including other Erwinia species
<b>Specificity value</b>	No cross reaction observed
<b>Reproducibility</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	for samples with level of infection 10 <sup>3</sup> and 10 <sup>4</sup> - 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>	for samples with level of infection 10 <sup>3</sup> and 10 <sup>4</sup> - 100 %
<b>Test performance study</b>	
<b>Test performance study?</b>	no
<b>Other information</b>	
<b>Any other information considered useful</b>	Primers, probe, MasterMix and Internal control were made by Russian companies. You can find attached full validation report in Russian
The following complementary files are available online:	
	<ul style="list-style-type: none"> <li>• <a href="#">2014. Validation of Real-time PCR (according to Gottsberger, 2010) for detection of E.a. in plant extract</a></li> </ul>