

**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, Russia
<b>Short description of the test</b>	Detection of <i>Erwinia amylovora</i> in plant extract by Conventional PCR, targeting plasmid pEA29
<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>Method(s)</b>	Molecular Extraction DNA RNA Molecular Conventional PCR
<b>Method: Molecular Extraction DNA RNA</b>	
<b>Reference of the test description</b>	
<b>Kit</b>	
<b>Is a kit used</b>	yes
<b>Manufacturer name</b>	AGRODIAGNOSTICA
<b>Specify the kit used</b>	PREP-GS kit
Kit used following the manufacturer's instructions?	
<b>Other information</b>	
<b>Method: Molecular Conventional 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>	PCR (Stoger et al. 2006)

Is the test modified compared to the reference test	no
<b>Other information</b>	
Are the performance characteristics included in the EPPO diagnostic protocol?	no
<b>Performance Criteria :</b>	
Organism 1.:	<b>Erwinia amylovora(ERWIAM)</b>
<b>Analytical sensitivity</b>	
What is smallest amount of target that can be detected reliably?	2,6 cfu/μl // 1,2*10 <sup>2</sup> /ml
<b>Analytical specificity - inclusivity</b>	
Number of strains/populations of target organisms tested	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
Specificity value	
<b>Analytical specificity - exclusivity</b>	
Number of non-target organisms tested	92 strains including other Erwinia species
Specificity value	No cross reaction observed
<b>Reproducibility</b>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	for samples with level of infection 10 <sup>4</sup> and 10 <sup>3</sup> - 100 %, for samples with level of infection 10 <sup>2</sup> - 50 %, when tested with different operators
<b>Repeatability</b>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	for samples with level of infection 10 <sup>4</sup> and 10 <sup>3</sup> - 100 %, for samples with level of infection 10 <sup>2</sup> - 22,2 %
<b>Test performance study</b>	
Test performance study?	no
<b>Other information</b>	
Any other information considered useful	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 Conventional PCR (according to Stoeger et al., 2006) for detection of E.a. in plant extract</a></li> </ul>

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