

**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	Federal State Organization "All-Russian Plant Quarantine Center" Pogranichnaya str.32, Ramensky region, Moscow obl., 140150 Bykovo, Russia
Short description of the test	Detection of <i>Erwinia amylovora</i> in plant extract by Real-time PCR, targeting chromosomal DNA
Date, reference of the validation report	2014-01-01 - none
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	yes
Was the validated data generated in the framework of a project?	
If yes, please specify	
Description of the test	
Organism(s)	<i>Erwinia amylovora</i> (ERWIAM)
Detection / identification	detection
Matrix(ces) tested	Leaves, Shoots Shoots and leaves
Plant species tested	Rosaceae
Method(s)	Molecular Extraction DNA RNA Molecular real time PCR
Method: Molecular Extraction DNA RNA	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	no
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	
As or adapted from an IPPC diagnostic protocol	no
Reference of the test	
Is the test modified compared to the reference test	
Kit	
Is a kit used	yes

Manufacturer name	AGRODIAGNOSTICA
Specify the kit used	Proba-GS
Kit used following the manufacturer's instructions?	
Other information	
Other details on the test	
Method: Molecular real time PCR	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	
EPPO Diagnostic Protocol name	PM 7/020 Erwinia amylovora (version 2)
Name of the test	Real-time PCR (Gottsberger, 2010)
As or adapted from an IPPC diagnostic protocol	
Is the test modified compared to the reference test	no
Kit	
Is a kit used	
Other information	
Reaction type	
Other details on the test	
Are the performance characteristics included in the EPPO diagnostic protocol?	no
Performance Criteria :	
Organism 1.:	Erwinia amylovora(ERWIAM)
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	24 cfu/μl // 1,2*10 ³ /ml
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	
Standard test(s)	FLASH-PCR for Erwinia amylovora
Analytical specificity - inclusivity	
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	
Analytical specificity - exclusivity	

Number of non-target organisms tested	92 strains including other Erwinia species
Specificity value	No cross reaction observed
Cross reacts with	
<u>Diagnostic Specificity</u>	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	
Specify the test(s)	
<u>Reproducibility</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	for samples with level of infection 10^3 and 10^4 - 100 %, when tested with different operators
<u>Repeatability</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	for samples with level of infection 10^3 and 10^4 - 100 %
Test performance study	
Test performance study?	no
Brief details of the test performance study and its output. It available, link to published article/report	
Other information	
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"> • 2014. Validation of Real-time PCR (according to Gottsberger, 2010) for detection of E.a. in plant extract

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