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 Erwinia amylovora in plant extract by Conventional PCR, targeting plasmid pEA29
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?	
Description of the test	
Organism(s)	Erwinia amylovora (ERWIAM)
Detection / identification	detection
Method(s)	Molecular Extraction DNA RNA Molecular Conventional PCR
Method: Molecular Extraction DNA RNA	
Reference of the test description	
Kit	
Is a kit used	yes
Manufacturer name	AGRODIAGNOSTICA
Specify the kit used	PREP-GS kit
Kit used following the manufacturer's instructions?	
Other information	
Method: Molecular Conventional PCR	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/020 Erwinia amylovora (version 2)
Name of the test	PCR (Stoger et al. 2006)

Is the test modified compared to the reference test	no
Other information	
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?	2,6 cfu/µl // 1,2*10^2/ml
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
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	for samples with level of infection 10^4 and 10^3 - 100 %, for samples with level of infection 10^2 - 50 %, when tested with different operators
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	for samples with level of infection 10^4 and 10^3 - 100 %, for samples with level of infection 10^2 - 22,2 %
Test performance study	
Test performance study?	no
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:	• 2014. Validation of Conventional PCR (according to Stoeger et al., 2006) for detection of E.a. in plant extract

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