EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION
ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA PROTECTION DES PLANTES
(11-17239)
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.

Target Organism	Erwinia amylovora	
Short description	Detection of Erwinia amylovora in plant extract by Conventional PCR, targeting plasmid pEA29	
Laboratory contact details	Federal State Organization "All-Russian Plant Quarantine Center" Pogranichnaya str.32, Ramensky region, Moscow obl., 140150 Bykovo, Russian Federation	
Date and reference of the validation report	2014 - none	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	PM 7/020(1) Stoger A.A., Schaffer J. & Ruppitsch W. (2006) Rapid and sensitive method for direct detection of Erwinia amylovora in symptomatic and asymptomatic plant tissues by polymerase chain reaction. Journal of Phytopathology 154, 469-473.	
Is the test the same as described in the EPPO DP?	Yes	
Is the lab accredited for this test?	Yes	
Plant species tested (if relevant)	Several plant species from the Rosaceae family, see full report (in Russian)	
Matrices tested (if relevant)	Shoots and leaves	
List of methods used		
Method for extraction / isolation / baiting of target organism from matrix	X	Commercial DNA extraction kit - "Proba-GS" produced by OOO "AgroDiagnostika"
Molecular methods, e.g. hybridization, PCR and real time PCR	X	Conventional PCR (Stoger, 2006)
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay		
Plating methods: selective isolation		
Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.		
Pathogenicity test		

Fingerprint methods: protein profiling, fatty acid profiling & DNA profiling		
Morphological and morphometrical methods intended for identification		
Biochemical methods: e.g. enzyme electrophoresis, protein profiling		
Other		
Analytical sensitivity (= limit of detection)		
What is smallest amount of target that can be detected reliably?	2,6 cfu/µl // 1,2*10^2/ml	
Diagnostic sensitivity		
Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98		
Specify the standard test	FLASH-PCR for Erwinia amylovora	
Analytical specificity		
Specificity value		
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	
Number of non-target organisms tested	92 strains including other Erwinia species	
Cross reacts with (specify the species)	No cross reaction observed	
Diagnostic Specificity		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test		
Specify the standard test		
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	
Include brief details of the test performance study and its output.It		

available, provide a link to published article/report	
Other information	
Any other information considered useful **e.g. robustness, ease of performing the test, etc.**	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