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	Bacteriology. Instituto Valenciano de Investigaciones Agrarias CV-315, km. 10.7, 46113 Moncada, Spain	
Short description of the test	Detection of Erwinia amylovora from plant material by Conventional PCR according to Stöger et al (2006)	
Date, reference of the validation report	2012-03-01 - not specified	
Validation process according to EPPO Standard PM7/98?	yes	
Is the lab accredited for this test?	no	
Was the validated data generated in the framework of a project?	no	
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		
As or adapted from an EPPO diagnostic protocol	yes	
EPPO Diagnostic Protocol name	PM 7/020 Erwinia amylovora (version 2)	
Kit		
Is a kit used	yes	
Manufacturer name	SIGMA-ALDRICH	
Specify the kit used	RED-Extract N-Amp T Plant 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)	
As or adapted from an IPPC diagnostic protocol	yes	
IPPC diagnostic Protocol name	ISPM 27 Annex 13 DP 13: Erwinia amylovora (version 2016)	
Name of the test	PCR according to Stöger et al. (2006)	
Kit		
Is a kit used	no	
Other information		
Other details on the test	Reference Stöger et al (2006) for inclusion in PM7/020(2)	
Performance Criteria :		
Organism 1.:	Erwinia amylovora(ERWIAM)	
Analytical sensitivity		
What is smallest amount of target that can be detected reliably?	10^4-10^6 CFU/mL plant extract after DNA extraction using RED-extract-N-Amp T kit (in ring test 2010)	
<u>Diagnostic sensitivity</u>		
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	Proportion of true positives/total number of samples: 0.48 (in samples from 1 to 10^6 CFU/mL and healthy samples in ring test 2010).	
Analytical specificity - inclusivity		
Number of strains/populations of target organisms tested	Contact authors of Stöger et al (2006) Do not detect E. amylovora strains without pEA29.	
Specificity value		
Analytical specificity - exclusivity		
Number of non-target organisms tested	Contact authors of Stöger et al (2006)	
Specificity value		
<u>Diagnostic Specificity</u>		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	Proportion of true negatives/total number of samples: 0.95 (in samples from 1 to 10^6 CFU/mL and healthy samples in ring test 2010).	
Reproducibility		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	80% in IVIA assays when tested with different operators	
Repeatability		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	92% in IVIA assays	
Test performance study		
Test performance study?	yes	

Brief details of the test performance study and its output.It available, link to published article/report	Yes (14 laboratories from Europe, Morocco, USA and New Zealand) analysed 10 samples each (from 1 to 10^6 CFU/mL plant extract and healthy samples). Details about ring test protocol available.	
Other information		
Any other information considered useful	Do not detect E. amylovora strains without pEA29.	

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