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 Gotsberger, adapted from Obradovic et al. (2007)
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?	
Description of the test	
Organism(s)	Erwinia amylovora (ERWIAM)
Detection / identification	detection
Method(s)	Molecular Extraction DNA RNA Molecular Extraction DNA RNA (2) Molecular Extraction DNA RNA (3) 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)
Other information	
Other details on the test	Llop et al (1999)
Method: Molecular Extraction DNA RNA (2)	
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)
Other information	
Other details on the test	Taylor et al (2001)

Method: Molecular Extraction DNA RNA (3)	
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	
Other details on the test	RED-extract-N-Amp T kit
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 (Gottsberger adapted from Obradovic et al. 2007)
Other information	
Are the performance characteristics included in the EPPO diagnostic protocol?	**yes**
Performance Criteria :	
Organism 1.:	**Erwinia amylovora(ERWIAM)**
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	10^3-10^4 CFU/mL plant extract after DNA extraction following Llop et al (1999). 10^4-10^5 CFU/mL plant extract following Taylor et al (2001) and RED-extract-N-Amp T kit
Diagnostic sensitivity	
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: 0.67; 0.57 and 0.56 after DNA extraction following Llop et al (1999), Taylor et al (2001) and RED-extract-N-Amp T kit, respectively (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	30 strains all negative
Specificity value	44 strains all positive
Diagnostic Specificity	

Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	Proportion of true negatives/total number of samples: 0.90; 0.87 and 0.82 after DNA extraction following Llop et al (1999), Taylor et al (2001) and RED-extract-N-Amp T kit, respectively (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)	90% 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 12 samples each (from 1 to 106 CFU/mL plant extract and healthy samples). Details about ring test protocol available.

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