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 E. amylovora by Loop mediated isothermal amplification in shoots and leaves
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 LAMP
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	Taylor et al. 2001
Method: Molecular LAMP	
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	LAMP (Temple et al. 2008 and Temple & Johnson 2011)
Other information	
Are the performance characteristics included	**yes**

in the EPPO diagnostic protocol?	
Performance Criteria :	
Organism 1.:	**Erwinia amylovora(ERWIAM)**
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	105-10^6 CFU/mL plant extract after DNA extraction following Taylor et al (2001) (in the ring test 2010)
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: 0.45 (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	10 strains: all positive
Specificity value	100%
Analytical specificity - exclusivity	
Number of non-target organisms tested	30 strains: all negative
Specificity value	Cross reactions: None
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: 0.83 (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% (when tested with different operators in IVIA)
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	96% 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	Recommended for analysis of symptomatic plants, for the low sensitivity and high specificity. Do not detect pEA29 free strains.
Other information	
Any other information considered useful	Recommended for analysis of symptomatic plants, for the low sensitivity and high specificity. Do not detect pEA29 free strains.

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