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 Commercial lateral flow device Pocket Diagnostics
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?	
If yes, please specify	
Description of the test	
Organism(s)	Erwinia amylovora(ERWIAM)
Detection / identification	detection
Matrix(ces) tested	Leaves, Shoots Shoots, leaves
Plant species tested	Rosaceae
Method(s)	Serological Lateral Flow Device
Method: Serological Lateral Flow Device	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	
EPPO Diagnostic Protocol name	PM 7/020 Erwinia amylovora (version 2)
Name of the test	Lateral flow devices
As or adapted from an IPPC diagnostic protocol	
Is the test modified compared to the reference test	no
Kit	

Is a kit used	yes
Manufacturer name	POCKET DIAGNOSTIC
Specify the kit used	Pocket Diagnostic® rapid plant disease tests - Erwinia amylovora
Kit used following the manufacturer's instructions?	
Other information	
Reaction type	
Other details on the test	
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?	10^5-10^6 CFU/mL plant extract
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: 0.13 (in samples from 1 to 10^6 CFU/mL and healthy samples in ring test 2010)
Standard test(s)	
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	
Specificity value	-
Analytical specificity - exclusivity	
Number of non-target organisms tested	
Specificity value	
Cross reacts with	
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: 0.93 (in samples from 1 to 10^6 CFU/mL and healthy samples in ring test 2010)
Specify the test(s)	
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	94% when tested with different operators, in IVIA assays
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	Yes (14 laboratories from Europe, Morocco, USA and New Zealand) analysed 12 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	Recommended only for symptomatic samples for its low sensitivity but high specificity.

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