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?	
Description of the test	
Organism(s)	Erwinia amylovora (ERWIAM)
Detection / identification	detection
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
EPPO Diagnostic Protocol name	PM 7/020 Erwinia amylovora (version 2)
Name of the test	Lateral flow devices
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	
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?	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)
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)
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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