

**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 Ea Agri-Strip
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
Kit	
Is a kit used	yes
Manufacturer name	BIOREBA
Specify the kit used	AgriStrip Erwinia amylovora
Kit used following the manufacturer's instructions?	
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 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 I ring test in 2010)
Standard test(s)	-
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	39 E. amylovora strains all positive
Specificity value	100%
Analytical specificity - exclusivity	
Number of non-target organisms tested	61 strains all negative
Specificity value	E. tasmaniensis, E. pyrifoliae, E. piriflorinigrans
Cross reacts with	Erwinia pyrifoliae Erwinia piriflorinigrans
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 in 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	See details in Braun-Kiewnick et al (2011). A rapid lateral-flow immunoassay for phytosanitary detection of Erwinia amylovora and on-site fire blight diagnosis. Journal of Microbiological Methods 987:1-9. Recommended only for symptomatic samples for its low sensitivity but high specificity.