

**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 <i>Erwinia amylovora</i> 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)	<i>Erwinia amylovora</i> (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 <i>Erwinia amylovora</i> (version 2)
Name of the test	Lateral flow devices
Kit	
Is a kit used	yes
Manufacturer name	BIOREBA
Specify the kit used	AgriStrip <i>Erwinia amylovora</i>
Kit used following the manufacturer's instructions?	
Other information	
Are the performance characteristics included in the EPPO diagnostic protocol?	yes
Performance Criteria :	
Organism 1.:	<i>Erwinia amylovora</i>(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.