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 Enrichment-DASI ELISA in King's B or CCT liquid media
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 DASI-ELISA
Method: Serological DASI-ELISA	
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	enrichment DASI-ELISA (Gorris et al. 1996)
As or adapted from an IPPC diagnostic protocol	
Is the test modified compared to the reference test	
Kit	

Is a kit used	
Other information	
Reaction type	
Other details on the test	Enrichment (in King’s B or CCT liquid media) followed by DASI-ELISA using specific monoclonal antibodies.
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 CFU/mL plant extract in King’s B and in CCT (Gorris et al, 1996). - 10-10^2 CFU/mL plant extract in King’s B and 10^3-10^4 CFU/mL plant extract in CCT (ring test in 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: 0.73 (in samples from 1 to 10^6 CFU/mL of plant extract and healthy samples in ring test 2010)
Standard test(s)	Not specified
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	250 E. amylovora strains, all positive (Gorris et al, 1996 and IVIA assays)
Specificity value	100%
Analytical specificity - exclusivity	
Number of non-target organisms tested	258 unidentified strains from fire blight hosts and 45 strains of plant pathogens, all negative (Gorris et al, 1996)
Specificity value	100%
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: 0.90 (in samples from 1 to 10^6 CFU/mL of plant extract 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)	95% 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)	100% 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	14 laboratories from Europe, Morocco, USA and New Zealand analysed 12 samples each (from 1 to 106 CFU/mL plant extract and healthy samples). Details about ring test protocol available.
Other information	
Any other information considered useful	See details in: Gorris et al, 1996. A sensitive and specific detection of E. amylovora, based on the ELISA-DASI enrichment method with monoclonal antibodies. Acta Horticulturae 411, 41-45

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