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?	
Description of the test	
Organism(s)	Erwinia amylovora (ERWIAM)
Detection / identification	detection
Method(s)	Serological DASI-ELISA
Method: Serological DASI-ELISA	
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	enrichment DASI-ELISA (Gorris et al. 1996)
Other information	
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%
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)
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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