EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION
ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA PROTECTION DES PLANTES
(11-17239)
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.

Target Organism	Erwinia amylovora	
Short description	Detection of Erwinia amylovora from plant material by Enrichment-DASI ELISA in King's B or CCT liquid media	
Laboratory contact details	Bacteriology. Instituto Valenciano de Investigaciones Agrarias CV-315, km. 10.7, 46113 Moncada, Spain	
Date and reference of the validation report	2012-03 - Not specified	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	PM 7/020(1)	
Is the test the same as described in the EPPO DP?	Yes	
Is the lab accredited for this test?	No	
Plant species tested (if relevant)	Several plant species from the Rosaceae family	
Matrices tested (if relevant)	Shoots, leaves	
List of methods used		
Method for extraction / isolation / baiting of target organism from matrix		
Molecular methods, e.g. hybridization, PCR and real time PCR		
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay	X	Enrichment (in King's B or CCT liquid media) followed by DASI-ELISA using specific monoclonal antibodies.
Plating methods: selective isolation		
Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.		
Pathogenicity test		
Fingerprint methods: protein profiling, fatty acid profiling & DNA profiling		

Morphological and morphometrical methods intended for identification		
Biochemical methods: e.g. enzyme electrophoresis, protein profiling		
Other		
Analytical sensitivity (= limit of detection)		
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)	
Specify the standard test	Not specified	
Analytical specificity		
Specificity value		
Number of strains/populations of target organisms tested	250 E. amylovora strains, all positive (Gorris et al, 1996 and IVIA assays)	
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)	
Cross reacts with (specify the species)		
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 standard test		
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	
Include brief details of the test performance study and its output.It available, provide a 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 **e.g. robustness, ease of performing the test, etc.**	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