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 immunofluorescence	
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	Indirect immunofluorescence using specific monoclonal antibody IVIA 7A
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?	10^3-10^4 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: 0.61 (in samples from 1 to 10^7 CFU/mL of plant extract and healthy samples in ring test 2002)	
Specify the standard test	Not specified	
Analytical specificity		
Specificity value		
Number of strains/populations of target organisms tested	50, all positive	
Number of non-target organisms tested	123, 121 negative	
Cross reacts with (specify the species)	two E. amylovora related 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: 0.97 (in samples from 1 to 10^7 CFU/mL of plant extract and healthy samples in ring test 2002)	
Specify the standard test		
Reproducibility		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	60% 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	Ring test in 2002: 10 laboratories from European Union analysed 15 samples each	
Other information		
Any other information considered useful **e.g. robustness, ease of performing the test, etc.**	Monoclonal antibody 7A, described in: Gorris et al, 1996. Production and characterization of monoclonal antibodies specific for Erwinia amylovora and their use in different serological techniques. Acta Horticulturae 411, 47-51.	

	Ring test results described in: López et al, 2004. European protocol for diagnosis of Erwinia amylovora. Acta Horticulturae 704:99-103