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