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	Extraction of Erwinia amylovora from plant material followed by isolation in CCT medium	
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	X	Extraction in antioxidant buffer followed by isolation in CCT medium
Molecular methods, e.g. hybridization, PCR and real time PCR		
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay		
Plating methods: selective isolation	X	isolation in CCT medium
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?	10-10^2 CFU/mL plant extract after isolation in CCT	
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: 0.90 (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	Not relevant	
Number of non-target organisms tested		
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: 1.00 (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)	100% when tested with different operators 100% 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 10^6 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.**	The antioxidant buffer allows multiplication of E. amylovora in presence of cellular compounds of the host plant, that are toxic to the bacteria (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).