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 E. amylovora by Loop mediated isothermal amplification in shoots and leaves	
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	0 Temple T. and Johnson K. (2011). Evaluation of loop mediated isothermal amplification for rapid detection of E. amylovora on pear and apple fruit flowers. Plant Disease 95:423-430.	
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	X	Loop mediated isothermal amplification
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay		
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?	105-10^6 CFU/mL plant extract after DNA extraction following Taylor et al (2001) (in the ring test 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: 0.45 (in samples from 1 to 10^6 CFU/mL and healthy samples in ring test 2010).	
Specify the standard test		
Analytical specificity		
Specificity value		
Number of strains/populations of target organisms tested	10 strains: all positive	
Number of non-target organisms tested	30 strains: all negative	
Cross reacts with (specify the species)	None	
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: 0.83 (in samples from 1 to 10^6 CFU/mL 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)	90% (when tested with different operators in IVIA)	
Repeatability		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	96% 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	Recommended for analysis of symptomatic plants, for the low sensitivity and high specificity. Do not detect pEA29 free strains.	
Other information		
Any other information considered	Recommended for analysis of symptomatic plants, for the low	

useful **e.g. robustness, ease of performing the test, etc.**	sensitivity and high specificity. Do not detect pEA29 free strains.