## 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 Commercial lateral flow device Pocket Diagnostics		
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) To be included in the revision Pocket Diagnostics (Forsite Diagnostics, York, UK).		
Is the test the same as described in the EPPO DP?	No Pocket Diagnostics (Forsite Diagnostics, York, UK).		
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		
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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	Х	Commercial lateral flow device	
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 detec	on)		
What is smallest amount of target that can be detected reliably?	10^5-10^6 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: 0.13 (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			
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: 0.93 (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)	4% when tested with different operat	ors, in IVIA assays	
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?	es		
Include brief details of the test performance study and its output.It available, provide a link to published article/report	es (14 laboratories from Europe, Morcealand) analysed 12 samples each (fr lant extract and healthy samples). De rotocol available.	om 1 to 10^6 CFU/mL	
Other information			
Any other information considered	ecommended only for symptomatic s	amples for its low	
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useful	sensitivity but high specificity.
e.g. robustness, ease of performing the test, etc.	