

**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.

<b>Target Organism</b>	Erwinia amylovora	
<b>Short description</b>	Detection of Erwinia amylovora from plant material by Commercial lateral flow device Ea Agri-Strip	
<b>Laboratory contact details</b>	Bacteriology. Instituto Valenciano de Investigaciones Agrarias CV-315, km. 10.7, 46113 Moncada, Spain	
<b>Date and reference of the validation report</b>	2012-03 - Not specified	
<b>Validation process according to EPPO Standard PM 7/98:</b>	Yes	
<b>Reference of the test description</b>	PM 7/020(1) For inclusion in the revision	
<b>Is the test the same as described in the EPPO DP?</b>	No For inclusion in the revision	
<b>Is the lab accredited for this test?</b>	No	
<b>Plant species tested (if relevant)</b>	Several plant species from the Rosaceae family	
<b>Matrices tested (if relevant)</b>	Shoots, leaves	
<b>List of methods used</b>		
<b>Method for extraction / isolation / baiting of target organism from matrix</b>		
<b>Molecular methods, e.g. hybridization, PCR and real time PCR</b>		
<b>Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay</b>	X	Commercial lateral flow device
<b>Plating methods: selective isolation</b>		
<b>Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.</b>		
<b>Pathogenicity test</b>		
<b>Fingerprint methods: protein profiling, fatty acid profiling &amp; DNA profiling</b>		
<b>Morphological and morphometrical methods intended for identification</b>		

<b>Biochemical methods: e.g. enzyme electrophoresis, protein profiling</b>		
<b>Other</b>		
<b>Analytical sensitivity (= limit of detection)</b>		
<b>What is smallest amount of target that can be detected reliably?</b>	10 <sup>5</sup> -10 <sup>6</sup> CFU/mL plant extract	
<b>Diagnostic sensitivity</b>		
<b>Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98</b>	Proportion of true positives/total number of samples: 0.13 (in samples from 1 to 10 <sup>6</sup> CFU/mL and healthy samples in ring test in 2010)	
<b>Specify the standard test</b>	-	
<b>Analytical specificity</b>		
<b>Specificity value</b>		
<b>Number of strains/populations of target organisms tested</b>	39 <i>E. amylovora</i> strains all positive	
<b>Number of non-target organisms tested</b>	61 strains all negative	
<b>Cross reacts with (specify the species)</b>	<i>E. tasmaniensis</i> , <i>E. pyrifoliae</i> , <i>E. piriflorinigrans</i>	
<b>Diagnostic Specificity</b>		
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	Proportion of true negatives/total number of samples: 0.93 (in samples from 1 to 10 <sup>6</sup> CFU/mL and healthy samples in ring test in 2010)	
<b>Specify the standard test</b>	-	
<b>Reproducibility</b>		
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	94% when tested with different operators in IVIA assays	
<b>Repeatability</b>		
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	96% In IVIA assays	
<b>Test performance study</b>		
<b>Test performance study?</b>	Yes	
<b>Include brief details of the test performance study and its output. It available, provide a link to published article/report</b>	Yes (14 laboratories from Europe, Morocco, USA and New Zealand) analysed 12 samples each (from 1 to 10 <sup>6</sup> CFU/mL plant extract and healthy samples). Details about ring test protocol available.	
<b>Other information</b>		
<b>Any other information considered useful e.g. robustness, ease of performing the test, etc.</b>	See details in Braun-Kiewnick et al (2011). A rapid lateral-flow immunoassay for phytosanitary detection of <i>Erwinia amylovora</i> and on-site fire blight diagnosis. Journal of Microbiological Methods 987:1-9.	

	Recommended only for symptomatic samples for its low sensitivity but high specificity.
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