

**EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION**  
**ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA PROTECTION DES PLANTES**  
**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>Laboratory contact details</b>	Bacteriology. Instituto Valenciano de Investigaciones Agrarias CV-315, km. 10.7, 46113 Moncada, Spain
<b>Short description of the test</b>	Extraction of Erwinia amylovora from plant material followed by isolation in CCT medium
<b>Date, reference of the validation report</b>	2012-03-01 - Not specified
<b>Validation process according to EPPO Standard PM7/98?</b>	yes
<b>Is the lab accredited for this test?</b>	no
<b>Was the validated data generated in the framework of a project?</b>	
<b>Description of the test</b>	
<b>Organism(s)</b>	Erwinia amylovora (ERWIAM)
<b>Detection / identification</b>	detection
<b>Method(s)</b>	Extraction Isolation
<b>Method: Extraction</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	yes
<b>EPPO Diagnostic Protocol name</b>	PM 7/020 Erwinia amylovora (version 1)
<b>Name of the test</b>	Antioxidant maceration buffer (Gorris et al., 1996)
<b>Is the test modified compared to the reference test</b>	no
<b>Other information</b>	
<b>Other details on the test</b>	Extraction in antioxidant buffer followed by isolation in CCT medium
<b>Method: Isolation</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	yes
<b>EPPO Diagnostic Protocol name</b>	PM 7/020 Erwinia amylovora (version 1)

<b>Name of the test</b>	Isolation on CCT medium (Ishimaru & Klos, 1984)
<b>As or adapted from an IPPC diagnostic protocol</b>	no
<b>Is the test modified compared to the reference test</b>	no
<b><i>Other information</i></b>	
<b>Other details on the test</b>	isolation in CCT medium
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Erwinia amylovora(ERWIAM)</b>
<b><u>Analytical sensitivity</u></b>	
<b>What is smallest amount of target that can be detected reliably?</b>	10-10 <sup>2</sup> CFU/mL plant extract after isolation in CCT
<b><u>Diagnostic sensitivity</u></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: 0.90 (in samples from 1 to 10 <sup>6</sup> CFU/mL of plant extract and healthy samples in ring test 2010)
<b>Standard test(s)</b>	Not specified
<b><u>Analytical specificity - inclusivity</u></b>	
<b>Number of strains/populations of target organisms tested</b>	Not relevant
<b>Specificity value</b>	
<b><u>Diagnostic Specificity</u></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: 1.00 (in samples from 1 to 10 <sup>6</sup> CFU/mL of plant extract and healthy samples in ring test 2010)
<b><u>Reproducibility</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100% when tested with different operators 100% in IVIA assays
<b><u>Repeatability</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100% in IVIA assays
<b>Test performance study</b>	
<b>Test performance study?</b>	yes
<b>Brief details of the test performance study and its output.It available, link to published article/report</b>	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</b>	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).
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