

**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>	Detection of <i>E. amylovora</i> by Loop mediated isothermal amplification in shoots and leaves
<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>If yes, please specify</b>	
<b>Description of the test</b>	
<b>Organism(s)</b>	<i>Erwinia amylovora</i> (ERWIAM)
<b>Detection / identification</b>	detection
<b>Matrix(ces) tested</b>	Leaves, Shoots Shoots, leaves
<b>Plant species tested</b>	Rosaceae
<b>Method(s)</b>	Molecular Extraction DNA RNA Molecular LAMP
<b>Method: Molecular Extraction DNA RNA</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	yes
<b>New test being considered for inclusion in the next version of the EPPO diagnostic protocol?</b>	
<b>EPPO Diagnostic Protocol name</b>	PM 7/020 <i>Erwinia amylovora</i> (version 2)
<b>Name of the test</b>	
<b>As or adapted from an IPPC diagnostic protocol</b>	
<b>Is the test modified compared to the reference test</b>	
<b>Kit</b>	

<b>Is a kit used</b>	
<b>Other information</b>	
<b>Other details on the test</b>	Taylor et al. 2001
<b>Method: Molecular LAMP</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	yes
<b>New test being considered for inclusion in the next version of the EPPO diagnostic protocol?</b>	
<b>EPPO Diagnostic Protocol name</b>	PM 7/020 Erwinia amylovora (version 2)
<b>Name of the test</b>	LAMP (Temple et al. 2008 and Temple & Johnson 2011)
<b>As or adapted from an IPPC diagnostic protocol</b>	
<b>Is the test modified compared to the reference test</b>	
<b>Kit</b>	
<b>Is a kit used</b>	
<b>Other information</b>	
<b>Reaction type</b>	
<b>Other details on the test</b>	
<b>Are the performance characteristics included in the EPPO diagnostic protocol?</b>	yes
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Erwinia amylovora(ERWIAM)</b>
<b>Analytical sensitivity</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 after DNA extraction following Taylor et al (2001) (in the ring test 2010)
<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: 0.45 (in samples from 1 to 10 <sup>6</sup> CFU/mL and healthy samples in ring test 2010).
<b>Standard test(s)</b>	
<b>Analytical specificity - inclusivity</b>	
<b>Number of strains/populations of target organisms tested</b>	10 strains: all positive
<b>Specificity value</b>	100%
<b>Analytical specificity - exclusivity</b>	
<b>Number of non-target organisms tested</b>	30 strains: all negative
<b>Specificity value</b>	Cross reactions: None

<b>Cross reacts with</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: 0.83 (in samples from 1 to 10 <sup>6</sup> CFU/mL and healthy samples in ring test 2010).
<b>Specify the test(s)</b>	
<b><u>Reproducibility</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	90% (when tested with different operators in IVIA)
<b><u>Repeatability</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	96% in IVIA assays
<b><u>Test performance study</u></b>	
<b>Test performance study?</b>	yes
<b>Brief details of the test performance study and its output. If available, link to published article/report</b>	Recommended for analysis of symptomatic plants, for the low sensitivity and high specificity. Do not detect pEA29 free strains.
<b><u>Other information</u></b>	
<b>Any other information considered useful</b>	Recommended for analysis of symptomatic plants, for the low sensitivity and high specificity. Do not detect pEA29 free strains.

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