

**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.

Laboratory contact details	Bacteriology. Instituto Valenciano de Investigaciones Agrarias CV-315, km. 10.7, 46113 Moncada, Spain
Short description of the test	Detection of <i>Erwinia amylovora</i> from plant material by Conventional PCR according to Taylor et al. (2001)
Date, reference of the validation report	2012-03-01 - Not specified
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	no
Was the validated data generated in the framework of a project?	
Description of the test	
Organism(s)	<i>Erwinia amylovora</i> (ERWIAM)
Detection / identification	detection
Method(s)	Molecular Extraction DNA RNA Molecular Extraction DNA RNA (2) Molecular Extraction DNA RNA (3) Molecular Conventional PCR
Method: Molecular Extraction DNA RNA	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/020 <i>Erwinia amylovora</i> (version 2)
Kit	
Is a kit used	yes
Manufacturer name	SIGMA-ALDRICH
Specify the kit used	RED-Extract N-Amp T Plant kit
Kit used following the manufacturer's instructions?	
Other information	
Other details on the test	RED-extract-N-Amp T kit
Method: Molecular Extraction DNA RNA (2)	

Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/020 Erwinia amylovora (version 2)
Other information	
Other details on the test	Llop et al (1999)
Method: Molecular Extraction DNA RNA (3)	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/020 Erwinia amylovora (version 2)
Other information	
Other details on the test	Taylor et al (2001)
Method: Molecular Conventional PCR	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/020 Erwinia amylovora (version 2)
Name of the test	PCR (Taylor et al. 2001)
Other information	
Are the performance characteristics included in the EPPO diagnostic protocol?	yes
Performance Criteria :	
Organism 1.:	Erwinia amylovora(ERWIAM)
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	10 ³ -10 ⁴ CFU/mL plant extract after DNA extraction Llop et al (1999) and DNA extraction using RED-extract-N-Amp T kit and 10 ⁴ -10 ⁵ CFU/mL plant extract following Taylor et al (2001) with small modifications.
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: 0.60; 0.50 and 0.55 after DNA extraction following Llop et al (1999), RED-extract-N-Amp T kit and Taylor et al (2001), respectively (in samples from 1 to 10 ⁶ CFU/mL and healthy samples in ring test 2010)
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	69 strains: all positive. Strains from Rubus sp. were negative
Specificity value	
Analytical specificity - exclusivity	

Number of non-target organisms tested	49 strains: all negative
Specificity value	
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; 0.90 and 0.87 after DNA extraction following Llop et al (1999), RED-extract-N-Amp T kit and Taylor et al (2001), respectively in samples from 1 to 10 ⁶ CFU/mL and healthy samples in ring test 2010).
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% in IVIA assays when tested with different operators
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% in IVIA assays
Test performance study	
Test performance study?	yes
Brief details of the test performance study and its output. It available, link to published article/report	Yes (14 laboratories from Europe, Morocco, USA and New Zealand) analysed 12 samples each (from 1 to 10 ⁶ CFU/mL plant extract and healthy samples). Details about ring test protocol available.

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