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 Erwinia amylovora from plant material by immunofluorescence
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)	Erwinia amylovora (ERWIAM)
Detection / identification	detection
Method(s)	Serological IF
Method: Serological IF	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/020 Erwinia amylovora (version 1)
Name of the test	Immunofluorescence (IF)
Is the test modified compared to the reference test	no
Other information	
Other details on the test	Indirect immunofluorescence using specific monoclonal antibody IVIA 7A
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	10^3-10^4 CFU/mL plant extract

detected reliably?	
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: 0.61 (in samples from 1 to 10^7 CFU/mL of plant extract and healthy samples in ring test 2002)
Standard test(s)	Not specified
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	50, all positive
Specificity value	100%
Analytical specificity - exclusivity	
Number of non-target organisms tested	123, 121 negative
Specificity value	two E. amylovora related 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: 0.97 (in samples from 1 to 10^7 CFU/mL of plant extract and healthy samples in ring test 2002)
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	60% when tested with different operators in IVIA assays
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	Ring test in 2002: 10 laboratories from European Union analysed 15 samples each
Other information	
Any other information considered useful	Monoclonal antibody 7A, described in: Gorris et al, 1996. Production and characterization of monoclonal antibodies specific for Erwinia amylovora and their use in different serological techniques. Acta Horticulturae 411, 47-51. Ring test results described in: López et al, 2004. European protocol for diagnosis of Erwinia amylovora. Acta Horticulturae 704:99-103

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