

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.

Target Organism	Erwinia amylovora	
Short description	Lateral flow devices for fire blight testing	
Laboratory contact details	AGES Institute of Sustainable Plant Production Spargelfeldstrasse 191, 1220 Vienna, Austria	
Date and reference of the validation report	2012-12-18 -	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	0 PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora	
Is the test the same as described in the EPPO DP?	Yes	
Is the lab accredited for this test?	No	
Plant species tested (if relevant)		
Matrices tested (if relevant)	Tested on pure bacterial cultures	
List of methods used		
Method for extraction / isolation / baiting of target organism from matrix		
Molecular methods, e.g. hybridization, PCR and real time PCR		
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay	X	Serological lateral flow device tests AgriStrip, Pocket Diagnostics
Plating methods: selective isolation		
Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.		
Pathogenicity test		
Fingerprint methods: protein profiling, fatty acid profiling & DNA profiling		
Morphological and morphometrical methods intended for identification		

Biochemical methods: e.g. enzyme electrophoresis, protein profiling		
Other		
Analytical sensitivity (= limit of detection)		
What is smallest amount of target that can be 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	see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora	
Specify the standard test	see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora	
Analytical specificity		
Specificity value		
Number of strains/populations of target organisms tested	Is routinely being used for testing isolated pure cultures of Erwinia amylovora isolates	
Number of non-target organisms tested	14	
Cross reacts with (specify the species)	Erwinia uzenensis, Erwinia tasmaniensis, Erwinia piriflorinigrans, Erwinia pyrifoliae	
Diagnostic Specificity		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora	
Specify the standard test	see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora	
Reproducibility		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora	
Repeatability		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora	
Test performance study		
Test performance study?	No	
Include brief details of the test performance study and its output.It available, provide a link to published article/report		
Other information		
Any other information considered useful		

e.g. robustness, ease of performing the test, etc.	
The following complementary files are available online:	<ul style="list-style-type: none">• Table on cross reaction of Erwinia amylovora LFDs