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	Real-time PCR assay targeting chromosomal DNA of Erwinia amylovora.	
Laboratory contact details	AGES Institute of Sustainable Plant Production Spargelfeldstrasse 191, 1220 Vienna, Austria	
Date and reference of the validation report	2010 - none	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	PM 7/020(1) New test approved for inclusion in PM 7/020(2) approval 2012 Gottsberger RA (2010) Development and evaluation of a real-time PCR assay targeting chromosomal DNA of Erwinia amylovora. Letters in Applied Microbiology 51, 285–292.	
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)	Several plant species from the Rosaceae family	
Matrices tested (if relevant)	Shoots, leaves, blossoms, roots, honey bees	
List of methods used		
Method for extraction / isolation / baiting of target organism from matrix		
Molecular methods, e.g. hybridization, PCR and real time PCR	X	Real-time PCR (Gottsberger 2010)
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay		
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?	2 cfu/µl	
Diagnostic sensitivity		
Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98	Contact the lab	
Specify the standard test		
Analytical specificity		
Specificity value		
Number of strains/populations of target organisms tested	71 (in Gottsberger 2010)	
Number of non-target organisms tested	41 (in Gottsberger 2010)	
Cross reacts with (specify the species)	No cross reaction	
Diagnostic Specificity		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	Contact the lab	
Specify the standard test	Bereswill et al. (1992)	
Reproducibility		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%, when tested with different operators	
Repeatability		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%	
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.**	Test can be used for quantification. A dilution series of a target bacteria suspension with determined concentration can be used as standards.