

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	Clavibacter michiganensis subsp. michiganensis	
Short description	Detection of Clavibacter michiganensis subsp. michiganensis from seed by plating	
Laboratory contact details	National Reference Centre, National Plant Protection Organization P.O. Box 9102, 6700 HC Wageningen, Netherlands	
Date and reference of the validation report	2010-02-02 - Validation Report of the isolation method for Clavibacter michiganensis michiganensis (Naktuinbouw version: 1.0)	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	0 Koenraad, H., van Vliet, A., Neijndorff, N., and Woudt, B. 2009. Improvement of semi-selective media for the detection of Clavibacter michiganensis subsp. michiganensis in seeds of tomato. (Abstr.) Phytopathology 99:S66.	
Is the test the same as described in the EPPO DP?	No May be included in the revision of PM 7/042	
Is the lab accredited for this test?	No	
Plant species tested (if relevant)	Solanum lycopersicum	
Matrices tested (if relevant)	Seed (seed lots with both a high and a low saprophytic background were included in the validation)	
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		
Plating methods: selective isolation	X	Isolation plating on two semi-selective media : FSCM and CMM1
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		
<u>Analytical sensitivity (= limit of detection)</u>		
What is smallest amount of target that can be detected reliably?	25 cfu*ml-1	
<u>Diagnostic sensitivity</u>		
Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98	100%	
Specify the standard test	Isolation on the conventional media SCM and D2ANX	
<u>Analytical specificity</u>		
Specificity value		
Number of strains/populations of target organisms tested	20 cmm strains (see details in the full validation report)	
Number of non-target organisms tested	20 related strains (see details in the full validation report)	
Cross reacts with (specify the species)	No cross reaction, growth performance of cmm strains is higher than the growth performance of the related bacteria	
<u>Diagnostic Specificity</u>		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	100%	
Specify the standard test	Isolation on the conventional media SCM and D2ANX	
<u>Reproducibility</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	93.8%	
<u>Repeatability</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%	
<u>Test performance study</u>		
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">• Validation report of the isolation method for Clavibacter michiganensis subsp. michiganensis, Naktuinbouw 2010-02