

**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.

<b>Target Organism</b>	Clavibacter michiganensis subsp. michiganensis	
<b>Short description</b>	Detection of Clavibacter michiganensis subsp. michiganensis from seed by plating	
<b>Laboratory contact details</b>	Netherlands Institute for Vectors, Invasive plants and Plant health P.O. Box 9102, 6700 HC Wageningen, Netherlands	
<b>Date and reference of the validation report</b>	2010-02-02 - Validation Report of the isolation method for Clavibacter michiganensis michiganensis (Naktuinbouw version: 1.0)	
<b>Validation process according to EPPO Standard PM 7/98:</b>	Yes	
<b>Reference of the test description</b>	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.	
<b>Is the test the same as described in the EPPO DP?</b>	No May be included in the revision of PM 7/042	
<b>Is the lab accredited for this test?</b>	No	
<b>Plant species tested (if relevant)</b>	Solanum lycopersicum	
<b>Matrices tested (if relevant)</b>	Seed (seed lots with both a high and a low saprophytic background were included in the validation)	
<b>List of methods used</b>		
<b>Method for extraction / isolation / baiting of target organism from matrix</b>		
<b>Molecular methods, e.g. hybridization, PCR and real time PCR</b>		
<b>Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay</b>		
<b>Plating methods: selective isolation</b>	X	Isolation plating on two semi-selective media : FSCM and CMM1
<b>Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.</b>		

<b>Pathogenicity test</b>		
<b>Fingerprint methods: protein profiling, fatty acid profiling &amp; DNA profiling</b>		
<b>Morphological and morphometrical methods intended for identification</b>		
<b>Biochemical methods: e.g. enzyme electrophoresis, protein profiling</b>		
<b>Other</b>		
<b><u>Analytical sensitivity (= limit of detection)</u></b>		
<b>What is smallest amount of target that can be detected reliably?</b>	25 cfu*ml-1	
<b><u>Diagnostic sensitivity</u></b>		
<b>Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98</b>	100%	
<b>Specify the standard test</b>	Isolation on the conventional media SCM and D2ANX	
<b><u>Analytical specificity</u></b>		
<b>Specificity value</b>		
<b>Number of strains/populations of target organisms tested</b>	20 cmm strains (see details in the full validation report)	
<b>Number of non-target organisms tested</b>	20 related strains (see details in the full validation report)	
<b>Cross reacts with (specify the species)</b>	No cross reaction, growth performance of cmm strains is higher than the growth performance of the related bacteria	
<b><u>Diagnostic Specificity</u></b>		
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	100%	
<b>Specify the standard test</b>	Isolation on the conventional media SCM and D2ANX	
<b><u>Reproducibility</u></b>		
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	93.8%	
<b><u>Repeatability</u></b>		
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%	
<b><u>Test performance study</u></b>		
<b>Test performance study?</b>	No	
<b>Include brief details of the test performance study and its output.It</b>		

available, provide a link to published article/report	
<b>Other information</b>	
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"> <li>• <a href="#">Validation report of the isolation method for <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i>. Naktuinbouw 2010-02</a></li> </ul>