

**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.

<b>Laboratory contact details</b>	Netherlands Institute for Vectors, Invasive plants and Plant health P.O. Box 9102, 6700 HC Wageningen, Netherlands
<b>Short description of the test</b>	Identification of <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> by real-time PCR
<b>Date, reference of the validation report</b>	2011-03-28 - Validation report of <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> PTSSK primers and probe, Rijk Zwaan
<b>Validation process according to EPPO Standard PM7/98?</b>	yes
<b>Is the lab accredited for this test?</b>	no
<b>Was the validated data generated in the framework of a project?</b>	
<b>Description of the test</b>	
<b>Organism(s)</b>	<i>Clavibacter michiganensis</i> (CORBMI)
<b>Detection / identification</b>	identification
<b>Method(s)</b>	Molecular real time PCR
<b>Method: Molecular real time PCR</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	yes
<b>EPPO Diagnostic Protocol name</b>	PM 7/042 <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> (version 2)
<b>Name of the test</b>	TaqMan real-time PCR test (Oosterhof & Berendsen, 2011)
<b>As or adapted from an IPPC diagnostic protocol</b>	no
<b>Other information</b>	
<b>Other details on the test</b>	Real-time PCR for identification of <i>cmm</i> isolates based on the PTSSK putative two-component system sensor kinase using sequence data acquired from <i>cmm</i> strain NCPPB 382
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b><i>Clavibacter michiganensis</i>(CORBMI)</b>

<b>Analytical sensitivity</b>	
<b>What is smallest amount of target that can be detected reliably?</b>	2x10 <sup>3</sup> cfu/ml
<b>Diagnostic sensitivity</b>	
<b>Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98</b>	97.6%
<b>Standard test(s)</b>	Pastrik & Rainey (1999)
<b>Analytical specificity - inclusivity</b>	
<b>Number of strains/populations of target organisms tested</b>	41 cmm strains covering different geographical origins, which were all positive in pathogenicity on tomato (see details in the full validation report)
<b>Specificity value</b>	97,6%
<b>Analytical specificity - exclusivity</b>	
<b>Number of non-target organisms tested</b>	26 related strains (look-a-likes and others) which were all negative in pathogenicity on tomato (see details in the full validation report)
<b>Specificity value</b>	97,6%
<b>Diagnostic Specificity</b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	96.15%
<b>Specify the test(s)</b>	Pastrik & Rainey (1999)
<b>Reproducibility</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%
<b>Repeatability</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%
<b>Test performance study</b>	
<b>Test performance study?</b>	no
<b>Other information</b>	
<b>Any other information considered useful</b>	Results from this PCR correlate very well with the pathogenicity results after inoculation on tomato plants.
The following complementary files are available online:	
	<ul style="list-style-type: none"> <li>• <a href="#">Poster: The development of a specific Real-Time TagMan for the detection of <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i>.</a></li> <li>• <a href="#">Validation report of <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> PTSSK primers and probe, Rijk Zwaan</a></li> </ul>