

**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 IF
<b>Date, reference of the validation report</b>	2011-02-01 - BAC-2010-10 Methodevalidatie Immunofluorescentie (IF) toets voor identificatie van <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> isolaten
<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>	Serological IF
<b>Method: Serological IF</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 1)
<b>Name of the test</b>	Immunofluorescence test
<b>Is the test modified compared to the reference test</b>	no
<b>Other information</b>	
<b>Other details on the test</b>	IF test for identification purposes of cmm isolates (IPO antiserum 69101)
<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>	4.7*10 <sup>4</sup> cfu/ml
<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>Standard test(s)</b>	IF test for identification purposes of cmm isolates (IPO antiserum 69101)
<b><u>Analytical specificity - inclusivity</u></b>	
<b>Number of strains/populations of target organisms tested</b>	20 cmm strains (see details in the full validation report)
<b>Specificity value</b>	100%
<b><u>Analytical specificity - exclusivity</u></b>	
<b>Number of non-target organisms tested</b>	21 related strains (see details in the full validation report)
<b>Specificity value</b>	Cross reaction observed from 10 out the 12 look-a-like isolates included in the validation. The look-a-likes are of an unknown species.
<b><u>Diagnostic Specificity</u></b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	52,4% (this low diagnostic specificity is due to the false positive results acquired from the look-a-likes)
<b>Specify the test(s)</b>	IF test for identification purposes of cmm isolates (IPO antiserum 69101)
<b><u>Reproducibility</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%
<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
The following complementary files are available online:	
	<ul style="list-style-type: none"> <li>• <a href="#">BAC-2010-10 Method validation of the immunofluorescence (IF) test for identification of Clavibacter michiganensis subsp. michiganensis, Plant Protection Service (in Dutch)</a></li> </ul>

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