

**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>	National Reference Centre, National Plant Protection Organization 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>If yes, please specify</b>	
<b>Description of the test</b>	
<b>Organism(s)</b>	<i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> (CORBMI)
<b>Detection / identification</b>	identification
<b>Matrix(ces) tested</b>	Pure culture
<b>Plant species tested</b>	
<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>New test being considered for inclusion in the next version of the EPPO diagnostic protocol?</b>	
<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>As or adapted from an IPPC diagnostic protocol</b>	

Is the test modified compared to the reference test	no
<b>Kit</b>	
Is a kit used	
<b>Other information</b>	
Reaction type	
Other details on the test	IF test for identification purposes of cmm isolates (IPO antiserum 69101)
Are the performance characteristics included in the EPPO diagnostic protocol?	
<b>Performance Criteria :</b>	
Organism 1.:	<b>Clavibacter michiganensis subsp. michiganensis(CORBMI)</b>
<b>Analytical sensitivity</b>	
What is smallest amount of target that can be detected reliably?	4.7*10 <sup>4</sup> cfu/ml
<b>Diagnostic sensitivity</b>	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	100%
Standard test(s)	IF test for identification purposes of cmm isolates (IPO antiserum 69101)
<b>Analytical specificity - inclusivity</b>	
Number of strains/populations of target organisms tested	20 cmm strains (see details in the full validation report)
Specificity value	100%
<b>Analytical specificity - exclusivity</b>	
Number of non-target organisms tested	21 related strains (see details in the full validation report)
Specificity value	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.
Cross reacts with	
<b>Diagnostic Specificity</b>	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	52,4% (this low diagnostic specificity is due to the false positive results acquired from the look-a-likes)
Specify the test(s)	IF test for identification purposes of cmm isolates (IPO antiserum 69101)
<b>Reproducibility</b>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	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>Brief details of the test performance study and its output. If available, link to published article/report</b>	
<b>Other information</b>	
<b>Any other information considered useful</b>	
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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