

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.

Laboratory contact details	Netherlands Institute for Vectors, Invasive plants and Plant health P.O. Box 9102, 6700 HC Wageningen, Netherlands
Short description of the test	Identification of <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> by IF
Date, reference of the validation report	2011-02-01 - BAC-2010-10 Methodevalidatie Immunofluorescentie (IF) toets voor identificatie van <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> isolaten
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	no
Was the validated data generated in the framework of a project?	
Description of the test	
Organism(s)	<i>Clavibacter michiganensis</i> (CORBMI)
Detection / identification	identification
Method(s)	Serological IF
Method: Serological IF	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/042 <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> (version 1)
Name of the test	Immunofluorescence test
Is the test modified compared to the reference test	no
Other information	
Other details on the test	IF test for identification purposes of cmm isolates (IPO antiserum 69101)
Performance Criteria :	
Organism 1.:	<i>Clavibacter michiganensis</i>(CORBMI)
<u>Analytical sensitivity</u>	

What is smallest amount of target that can be detected reliably?	4.7*10 ⁴ cfu/ml
Diagnostic sensitivity	
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)
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	20 cmm strains (see details in the full validation report)
Specificity value	100%
Analytical specificity - exclusivity	
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.
Diagnostic Specificity	
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)
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%
Test performance study	
Test performance study?	no
The following complementary files are available online:	<ul style="list-style-type: none"> • BAC-2010-10 Method validation of the immunofluorescence (IF) test for identification of Clavibacter michiganensis subsp. michiganensis, Plant Protection Service (in Dutch)

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