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.

Target Organism	Clavibacter michiganensis subsp. michiganensis
Short description	Identification of Clavibacter michiganensis subsp. michiganensis by IF
Laboratory contact details	Netherlands Institute for Vectors, Invasive plants and Plant health P.O. Box 9102, 6700 HC Wageningen, Netherlands
Date and reference of the validation report	2011-02 - BAC-2010-10 Methodevalidatie Immunofluorescentie (IF) toets voor identificatie van Clavibacter michiganensis subsp. michiganensis isolaten
Validation process according to EPPO Standard PM 7/98:	Yes
Reference of the test description	PM 7/042(1)
Is the test the same as described in the EPPO DP?	Yes
Is the lab accredited for this test?	No
Plant species tested (if relevant)	
Matrices tested (if relevant)	

List of methods used		
Method for extraction / isolation / baiting of target organism from matrix		
Molecular methods, e.g. hybridization, PCR and real time PCR		
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay	X	IF test for identification purposes of cmm isolates (IPO antiserum 69101)
Plating methods: selective isolation		
Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.		
Pathogenicity test		
Fingerprint methods: protein profiling, fatty acid profiling & DNA profiling		

Morphological and morphometrical methods intended for identification		
Biochemical methods: e.g. enzyme electrophoresis, protein profiling		
Other		

Analytical sensitivity (= limit of detection)

What is smallest amount of target that can be detected reliably?	4.7*10^4 cfu*ml-1

Diagnostic sensitivity

Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98	100%
Specify the standard test	IF test for identification purposes of cmm isolates (IPO antiserum 69101)

Analytical specificity

Specificity value	
Number of strains/populations of target organisms tested	20 cmm strains (see details in the full validation report)
Number of non-target organisms tested	21 related strains (see details in the full validation report)
Cross reacts with (specify the species)	cross reaction observed from 10 out the 12 look-a-like isolates included in the validation

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 standard test	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
Include brief details of the test performance study and its output.It available, provide a link to published article/report	

Other information

Any other information considered useful **e.g. robustness, ease of performing the test, etc.**	
The following complementary files are available online:	• [BAC-2010-10 Method validation of the immunofluorescence (IF) test for identification of Clavibacter michiganensis subsp. michiganensis, Plant Protection Service (in Dutch)](#)