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 Clavibacter michiganensis subsp. michiganensis by real-time PCR
Date, reference of the validation report	2011-03-28 - Validation report of Clavibacter michiganensis subsp. michiganensis PTSSK primers and probe, Rijk Zwaan
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)	Clavibacter michiganensis (CORBMI)
Detection / identification	identification
Method(s)	Molecular real time PCR
Method: Molecular real time PCR	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/042 Clavibacter michiganensis subsp. michiganensis (version 2)
Name of the test	TaqMan real-time PCR test (Oosterhof & Berendsen, 2011)
As or adapted from an IPPC diagnostic protocol	no
Other information	
Other details on the test	Real-time PCR for identification of cmm isolates based on the PTSSK putative two-component system sensor kinase using sequence data acquired from cmm strain NCPPB 382
Performance Criteria :	
Organism 1.:	**Clavibacter michiganensis(CORBMI)**

Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	2x10^3 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	97.6%
Standard test(s)	Pastrik & Rainey (1999)
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	41 cmm strains covering different geographical origins, which were all positive in pathogenicity on tomato (see details in the full validation report)
Specificity value	97,6%
Analytical specificity - exclusivity	
Number of non-target organisms tested	26 related strains (look-a-likes and others) which were all negative in pathogenicity on tomato (see details in the full validation report)
Specificity value	97,6%
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	96.15%
Specify the test(s)	Pastrik & Rainey (1999)
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
Other information	
Any other information considered useful	Results from this PCR correlate very well with the pathogenicity results after inoculation on tomato plants.
The following complementary files are available online:	• Poster: The development of a specific Real-Time TaqMan for the detection of Clavibacter michiganensis subsp. michiganensis • Validation report of Clavibacter michiganensis subsp. michiganensis PTSSK primers and probe, Rijk Zwaan

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