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	Council for Agricultural Research and Economics–Research Centre for Plant Protection and Certification Via Carlo Giuseppe Bertero, 22, 00156 Rome, Italy
Short description of the test	Detection of Clavibacter michiganensis Clavibacter michiganensis by Molecular Conventional PCR in Tomato Seeds
Date, reference of the validation report	2025-09-29 - Detection of Clavibacter michiganensis by molecular assay from tomato seedsed
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?	Other_project
If yes, please specify	ASPROPI (MIPAAF funded project)
Description of the test	
Organism(s)	Clavibacter michiganensis (CORBMI)
Detection / identification	detection
Method(s)	Molecular Conventional PCR
Method: Molecular Conventional PCR	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	yes
EPPO Diagnostic Protocol name	PM 7/042 Clavibacter michiganensis subsp. michiganensis (version 3)
Name of the test	Conventional PCR test (adapted from Pastrik & Rainey, 1999)
Is the test modified compared to the reference test	yes The test was adapted for detection of CORBMI from tomato seeds
Kit	
Is a kit used	no

Other information	
Reaction type	Simplex
Other details on the test	Evaluation performed using the Taq DNA polimerase "Hot start" Immolase TM
Performance Criteria :	
Organism 1.:	**Clavibacter michiganensis(CORBMI)**
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	81%
Standard test(s)	Comparison with samples of known status
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	12 different C. michiganensis strains covering different Italian geographic areas
Specificity value	100%
Analytical specificity - exclusivity	
Number of non-target organisms tested	11 strains of which: 3 strains of other genera (Pseudomonas corrugata, P. mediterranea, Ralstonia solanacearum), 4 C. michiganensis look-alikes isolates, 3 Clavibacter strains from different host plants (C. tessellarius, C. nebraskensis and C. sepedonicus).
Specificity value	100%
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	86.1%
Specify the test(s)	Comparison with samples of known status
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	70.5%- Evaluated following Langton et al., 2002 (Langton, S.D.; Chevennement, R.; Nagelkerke, N.; Lombard, B. Analysis collaborative trials for qualitative microbiological methods. Int. J. Food Microbiol. 2002, 79, 175–181)
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	79.8% - Evaluated following Langton et al., 2002 (Langton, S.D.; Chevennement, R.; Nagelkerke, N.; Lombard, B. Analysis collaborative trials for qualitative microbiological methods. Int. J. Food Microbiol. 2002, 79, 175–181)
Test performance study	
Test performance study?	yes
Brief details of the test performance study and its output.It available, link to published article/report	Performance criteria was obtained by involving nine Italian laboratories in a national test performance study. Each laboratory tested 11

	tomato seed samples, each consisting of 5,000 seeds. The infected samples included: 2 samples with 1 infected seed, 2 samples with 3 infected seeds, and 2 samples with 5 infected seeds. Non-target samples were also evaluated, specifically: 2 samples of 5,000 non-infected seeds and 2 samples of 5,000 seeds contaminated with 5 seeds of Pseudomonas corrugata.
The following complementary files are available online:	• TPS CMM Pastrick and Raney 1999

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