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	Bavarian State Research Center for Agriculture, Institute for Plant Protection - Phytopathology and Diagnosis Lange Point 10, 85354 Freising, Germany
Short description of the test	Detection of Clavibacter sepedonicus in potato extract by conventional PCR, in a multiplex assay with Ralstonia solanacearum
Date, reference of the validation report	2018-04-16 - Not specified
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	yes
Was the validated data generated in the framework of a project?	
Description of the test	
Organism(s)	Clavibacter sepedonicus (CORBSE)
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
EPPO Diagnostic Protocol name	PM 7/059 Clavibacter michiganensis subsp. sepedonicus (version 1)
Name of the test	PCR (Pastrik, 2000)
Is the test modified compared to the reference test	yes Modified - PCR mastermix (Qiagen Multiplex PCR Plus Kit) - DNA extraction: MasterPure Complete DNA Purification kit (Lucigen) - Multiplex setup with primers Rs 1 F/R for Rs (Pastrik et al., 2002) - IPC after White et al., 1990 (primer NS7, NS8)
Other information	
Are the performance characteristics included in the EPPO diagnostic protocol?	**no**
Performance Criteria :	

Organism 1.:	**Clavibacter sepedonicus(CORBSE)**
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	10^3 cells/ ml tuber extract
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	not done
Standard test(s)	n/a
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	LMG 2894 LMG 2889 NCPPB 3898 LMG 6722 NCPPB 2140 LMG 25595
Specificity value	100%
Analytical specificity - exclusivity	
Number of non-target organisms tested	Clavibacter michiganensis subsp. michiganensis LMG 3687 Clavibacter michiganensis subsp. insidiosus LMG 7268 Pseudomonas syringae pv. striafaciens GSPB 2570 Pectobacterium atrosepticum SCRI 1039 Pectobacterium carotovorum subsp. carotovorum LMG 2401 Pectobacterium wasabiae DSM 18074 Pectobacterium carotovorum subsp. brasiliensis LMG 21371 Pectobacterium carotovorum subsp. odoriferum LMG 6688 Pectobacterium betavasculorum LMG 2466 Dickeya solani JKI
Specificity value	100%
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	not done
Specify the test(s)	n/a
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% for 10^3 cells/ ml (a total of 56 PCR reactions containing 10^3 samples (in 24 PCR runs, two different operators, different days), of which 56 were positive)
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100% for 10^3 cells/ ml (a total of 28 PCR reactions containing 10^3 samples, in 12 PCR runs, each repeated once - same day, same operator -, of which 28 with the same result)
Test performance study	
Test performance study?	no

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