

**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.

<b>Laboratory contact details</b>	Bavarian State Research Center for Agriculture, Institute for Plant Protection - Phytopathology and Diagnosis Lange Point 10, 85354 Freising, Germany
<b>Short description of the test</b>	Detection of <i>Clavibacter sepedonicus</i> in potato extract by conventional PCR, in a multiplex assay with <i>Ralstonia solanacearum</i>
<b>Date, reference of the validation report</b>	2018-04-16 - Not specified
<b>Validation process according to EPPO Standard PM7/98?</b>	yes
<b>Is the lab accredited for this test?</b>	yes
<b>Was the validated data generated in the framework of a project?</b>	
<b>If yes, please specify</b>	
<b>Description of the test</b>	
<b>Organism(s)</b>	<i>Clavibacter sepedonicus</i> (CORBSE)
<b>Detection / identification</b>	detection
<b>Matrix(ces) tested</b>	Tubers tuber extract
<b>Plant species tested</b>	<i>Solanum tuberosum</i>
<b>Method(s)</b>	Molecular Conventional PCR
<b>Method: Molecular Conventional PCR</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	yes
<b>New test being considered for inclusion in the next version of the EPPO diagnostic protocol?</b>	
<b>EPPO Diagnostic Protocol name</b>	PM 7/059 <i>Clavibacter michiganensis</i> subsp. <i>sepedonicus</i> (version 1)
<b>Name of the test</b>	PCR (Patrik, 2000)
<b>As or adapted from an IPPC diagnostic protocol</b>	
<b>Is the test modified compared to the reference test</b>	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 (Patrik et al., 2002) - IPC after White et al., 1990 (primer NS7, NS8)
<b>Kit</b>	
<b>Is a kit used</b>	
<b>Other information</b>	
<b>Reaction type</b>	
<b>Other details on the test</b>	
<b>Are the performance characteristics included in the EPPO diagnostic protocol?</b>	<b>no</b>
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Clavibacter sepedonicus(CORBSE)</b>
<b>Analytical sensitivity</b>	
<b>What is smallest amount of target that can be detected reliably?</b>	10 <sup>3</sup> cells/ ml tuber extract
<b>Diagnostic sensitivity</b>	
<b>Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98</b>	not done
<b>Standard test(s)</b>	n/a
<b>Analytical specificity - inclusivity</b>	
<b>Number of strains/populations of target organisms tested</b>	LMG 2894 LMG 2889 NCPPB 3898 LMG 6722 NCPPB 2140 LMG 25595
<b>Specificity value</b>	100%
<b>Analytical specificity - exclusivity</b>	
<b>Number of non-target organisms tested</b>	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
<b>Specificity value</b>	100%
<b>Cross reacts with</b>	
<b>Diagnostic Specificity</b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	not done
<b>Specify the test(s)</b>	n/a
<b>Reproducibility</b>	

<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100% for 10 <sup>3</sup> cells/ ml (a total of 56 PCR reactions containing 10 <sup>3</sup> samples (in 24 PCR runs, two different operators, different days), of which 56 were positive)
<b>Repeatability</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100% for 10 <sup>3</sup> cells/ ml (a total of 28 PCR reactions containing 10 <sup>3</sup> samples, in 12 PCR runs, each repeated once - same day, same operator -, of which 28 with the same result)
<b>Test performance study</b>	
<b>Test performance study?</b>	no
<b>Brief details of the test performance study and its output. It available, link to published article/report</b>	
<b>Other information</b>	
<b>Any other information considered useful</b>	

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