

**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>	National Institute of Biology, Department of Biotechnology and Systems Biology Vecna pot 111, 1000 Ljubljana, Slovenia
<b>Short description of the test</b>	Detection of <i>Ralstonia solanacearum</i> by egl LAMP in plant material
<b>Date, reference of the validation report</b>	2017-02-09 - Dreo, T., 2017. Summary of validation data on egl LAMP for <i>Ralstonia solanacearum</i> (No. D0004/17), Report on Suitability Testing. National Institute of Biology, Ljubljana.
<b>Validation process according to EPPO Standard PM7/98?</b>	yes
<b>Is the lab accredited for this test?</b>	no
<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>Ralstonia solanacearum</i> species complex(RALSSO)
<b>Detection / identification</b>	detection
<b>Matrix(ces) tested</b>	Shoots, Tubers latent (tuber cores) and symptomatic potato tubers (tuber vascular tissue), symptomatic tomato plants (stems)
<b>Plant species tested</b>	<i>Solanum lycopersicum</i> , <i>Solanum tuberosum</i>
<b>Method(s)</b>	Molecular LAMP
<b>Method: Molecular LAMP</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	
<b>New test being considered for inclusion in the next version of the EPPO diagnostic protocol?</b>	
<b>As or adapted from an IPPC diagnostic protocol</b>	
<b>Is the test modified compared to the reference test</b>	
<b>Kit</b>	

<b>Is a kit used</b>	
<b>Other information</b>	
<b>Reaction type</b>	
<b>Other details on the test</b>	LAMP egl
<b>Are the performance characteristics included in the EPPO diagnostic protocol?</b>	<b>no</b>
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Ralstonia solanacearum species complex(RALSSO)</b>
<b>Analytical sensitivity</b>	
<b>What is smallest amount of target that can be detected reliably?</b>	10E4 cells/mL (25 cells per LAMP reaction) when tested on strains belonging to phylotypes I and III, and a sensitivity limit of 10E5–10E6 cells/mL for strains from phylotypes IIA, IIB and IV; 10E5 cells/mL in potato tubers (cores of 200) as tested on three standard curves.
<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>	100%
<b>Standard test(s)</b>	Potato cores. The official testing scheme (EC 98/57) including screening tests, isolation on media, identification tests and pathogenicity testing with re-isolation and identification for positive samples.
<b>Analytical specificity - inclusivity</b>	
<b>Number of strains/populations of target organisms tested</b>	88 strains of RSSC
<b>Specificity value</b>	99 % (1 false negative, no false positives)
<b>Analytical specificity - exclusivity</b>	
<b>Number of non-target organisms tested</b>	26
<b>Specificity value</b>	no cross-reactions observed
<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>	100%
<b>Specify the test(s)</b>	Immunofluorescence and real-time PCR (Weller et al., 2000) for negative samples.
<b>Reproducibility</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100 % detection for samples with at least 10E4 copies of Rs DNA or more.
<b>Repeatability</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100 % using different machines (SmartCycler, Roche Light Cycler, Genie II).

<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>	The test is proposed as identification test for pure cultures. While the validation data indicates that it may well detect concentrations of <i>R. solanacearum</i> usually seen in latently infected samples there is not sufficient data on the <i>R.s.</i> concentrations encountered in routine testing.
The following complementary files are available online:	<ul style="list-style-type: none"> <li>• <a href="#">Summary of Rs LAMP validation data</a></li> </ul>

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