EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION
ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA PROTECTION DES PLANTES
(11-17239)
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.

Target Organism	Ralstonia solanacearum	
Short description	Detection of Ralstonia solanacearum by egl LAMP in plant material	
Laboratory contact details	National Institiute of Biology, Department of Biotechnology and Systems Biology Vecna pot 121, 1000 Ljubljana, Slovenia	
Date and reference of the validation report	2017-02-09 - Dreo, T., 2017. Summary of validation data on egl LAMP for Ralstonia solanacearum (No. D0004/17), Report on Suitability Testing. National Institute of Biology, Ljubljana.	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	N/R	
Is the test the same as described in the EPPO DP?		
Is the lab accredited for this test?	No	
Plant species tested (if relevant)	Solanum tuberosum, Solanum lycopersicon	
Matrices tested (if relevant)	latent (tuber cores) and symptomatic potato tubers (tuber vascular tissue), symptomatic tomato plants (stems)	
List of methods used		
Method for extraction / isolation / baiting of target organism from matrix		
Molecular methods, e.g. hybridization, PCR and real time PCR	X	LAMP egl
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay		
Plating methods: selective isolation		
Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.		
Pathogenicity test		
Fingerprint methods: protein profiling, fatty acid profiling & DNA		

profiling		
Morphological and morphometrical methods intended for identification		
Biochemical methods: e.g. enzyme electrophoresis, protein profiling		
Other		
Analytical sensitivity (= limit of detection)		
What is smallest amount of target that can be detected reliably?	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.	
Diagnostic sensitivity		
Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98	100 %	
Specify the standard test	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.	
Analytical specificity		
Specificity value	99 % (1 false negative, no false positives)	
Number of strains/populations of target organisms tested	88 strains of RSSC	
Number of non-target organisms tested	26	
Cross reacts with (specify the species)	no cross-reactions observed	
Diagnostic Specificity		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	100 %	
Specify the standard test	Immunofluorescence and real-time PCR (Weller et al., 2000) for negative samples.	
Reproducibility		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100 % detection for samples with at least 10E4 copies of Rs DNA or more.	
Repeatability		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100 % using different machines (SmartCycler, Roche Light Cycler, Genie II).	
Test performance study		
Test performance study?	No	

Include brief details of the test performance study and its output.It available, provide a link to published article/report	
Other information	
Any other information considered useful **e.g. robustness, ease of performing the test, etc.**	The test is proposed as identification test for pure cultures. While the validation data indicates that it may well detect concentrations of R. solanacearum usually seen in latently infected samples there is not sufficient data on the R.s. concentrations encountered in routine testing.
The following complementary files are available online:	• Summary of Rs LAMP validation data