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	National Instituite of Biology, Department of Biotechnology and Systems Biology Vecna pot 121, 1000 Ljubljana, Slovenia
Short description of the test	Detection of Ralstonia solanacearum by egl LAMP in plant material
Date, 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 PM7/98?	yes
Is the lab accredited for this test?	no
Was the validated data generated in the framework of a project?	
Description of the test	
Organism(s)	Ralstonia solanacearum species complex (RALSSO)
Detection / identification	detection
Method(s)	Molecular LAMP
Method: Molecular LAMP	
Reference of the test description	
Other information	
Other details on the test	LAMP egl
Are the performance characteristics included in the EPPO diagnostic protocol?	**no**
Performance Criteria :	
Organism 1.:	**Ralstonia solanacearum species complex(RALSSO)**
Analytical sensitivity	
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%
Standard test(s)	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 - inclusivity	
Number of strains/populations of target organisms tested	88 strains of RSSC
Specificity value	99 % (1 false negative, no false positives)
Analytical specificity - exclusivity	
Number of non-target organisms tested	26
Specificity value	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 test(s)	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
Other information	
Any other information considered useful	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

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