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 Instiitute of Biology, Department of Biotechnology and Systems Biology Vecna pot 121, 1000 Ljubljana, Slovenia
Short description of the test	Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests
Date, reference of the validation report	2024-09-17 - Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests.
Link to other validation data	- Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests. Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests - Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests. Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests - Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests. Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests - Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests. Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests - Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests. Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests - Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests. Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests - Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests. Report on the results of the test performance study

	on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests - Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests. Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests - Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests. Report on the results of the test performance study on detection and identification of tomato mottle mosaic virus (ToMMV) using molecular tests
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?	Euphresco
If yes, please specify	Euphresco project 2022-A-394 (Validation of molecular diagnostic methods for the detection and identification of tomato mottle mosaic virus (ToMMV-detect))
Description of the test	
Organism(s)	Tomato mottle mosaic virus / Tobamovirus maculatessellati (TOMMV0)
Detection / identification	detection and identification
Method(s)	Molecular LAMP
Method: Molecular LAMP	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	no
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	yes
As or adapted from an IPPC diagnostic protocol	no
Reference of the test	Kimura et al. 2023
Is the test modified compared to the reference test	yes Different master mix was used, because of unavailability of the master mix from the publication on the market in the country organizing TPS.
Kit	
Is a kit used	yes

Manufacturer name	OPTIGENE
Specify the kit used	Isothermal Master Mix
Kit used following the manufacturer's instructions?	yes
Other information	
Reaction type	Simplex
Performance Criteria :	
Organism 1.:	**Tobamovirus maculatessellati(TOMMV0)**
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	at least to 2.5 x 10^4 dilution of isolate ToMMV NIB V 373 (level of agreement between experiments: 100%).
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	58%
Standard test(s)	Calculation was done on the basis of health status of the samples. Isolates used: ToMMV NIB V 373 dilutions 2.5 x 10^1 to 2.5 x 10^8 of isolate ToMMV NIB V 414 dilutions 2x and 2x 10^1.
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	two ToMMV isolates (NIB V 373 and NIB V 414).
Specificity value	/
Analytical specificity - exclusivity	
Number of non-target organisms tested	3 healthy tomato samples (two seeds, one leaves), 11 isolates of 9 other tobamovirus species (CGMMV isolate NIB V 403, ObPV isolate NIB V 364, ORSV isolate NIB V 365, PaMMV isolate NIB V 366, PMMoV isolate NIB V 408, TMGMV isolate NIB V 404, TMV isolates: NIB V 405 and 413, ToBRFV isolate NIB V 331, ToMV isolate NIB V 410, ToMV isolates NIB V 406).
Specificity value	/
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	92.9%
Specify the test(s)	/
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	87%
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	/

Test performance study	
Test performance study?	yes
Brief details of the test performance study and its output.It available, link to published article/report	Preparation for test performance study organized in the framework of the Euphresco project 2022-A-394.
Other information	
Any other information considered useful	Test performance study organized in the framework of the Euphresco project 2022-A-394 involving 5 laboratories from 5 countries. The results of one laboratory were excluded from calculation of diagnostic parameters because of more false negative (FN) results compared to other laboratories. Full validation report is available: https://drop.euphresco.net/data/af730655-4022-4e87-a952-b94cfda3a971/

Creation date: 2024-10-08 17:49:20 - Last update: 2024-10-23 17:32:54