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 and identification of tomato spotted wilt tospovirus by ImmunoStrip LFD Agdia in symptomatic tomato leaves (TPS)
Date, reference of the validation report	2020-12-14 - TSWV V1.0
Link to other validation data	- TSWV V1.0 Detection and identification of tomato spotted wilt tospovirus by ImmunoStrip LFD Agdia in symptomatic tomato leaves (prevalidation study) - TSWV V1.0 Detection and identification of tomato spotted wilt tospovirus by AgriStrip LFD Bioreba in symptomatic tomato leaves (TPS) - TSWV V1.0 Detection and identification of tomato spotted wilt tospovirus by AgriStrip LFD Bioreba in symptomatic tomato leaves (prevalidation study)
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?	Other_project
If yes, please specify	VALITEST
Description of the test	
Organism(s)	Tomato spotted wilt virus / Orthotospovirus tomatomaculae (TSWV00)
Detection / identification	detection and identification
Method(s)	Serological Lateral Flow Device
Method: Serological Lateral Flow Device	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	yes
EPPO Diagnostic Protocol name	PM 7/139 Tospoviruses (genus Orthotospovirus) (version 1)
Name of the test	Lateral flow devices
As or adapted from an IPPC diagnostic protocol	no

Is the test modified compared to the reference test	no
Kit	
Is a kit used	yes
Manufacturer name	AGDIA
Specify the kit used	ImmunoStrip® for Tomato spotted wilt virus (TSWV) (ISK 39300)
Kit used following the manufacturer's instructions?	yes
Other information	
Performance Criteria :	
Organism 1.:	**Orthotospovirus tomatomaculae(TSWV00)**
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	10,000x dilution of isolate TSWV-PV-1175 (level of agreement between experiments: 76.9%)
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	96.10%
Standard test(s)	Calculation was done on the basis of expected results which for some samples differ from the health status of the samples. Expected results for isolate TSWV-PV-1175 which was tested in the 5 serial dilutions were determined based on the results of preliminary studies: for last two dilutions of 1,000,000x and 100,000x expected result was negative. Additionally, in the TPS study, 10x diluted TSWV-PV-0182 isolate and 1000x diluted TSWV-PV-0389 isolate have been used as medium and as low concentrated TSWV positive sample, respectively.
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	3 TSWV isolates from DSMZ collection (PV-1175, PV-0182, PV-0389)
Specificity value	/
Analytical specificity - exclusivity	
Number of non-target organisms tested	3 healthy tomato samples, 5 other tospovirus species (ANSV00 isolate PV-1027; CSNV00 isolate PV-0529; GRSV00 isolate PV-0205; INSV00 isolate PV-0281; TCSV00 isolate PV-0390)
Specificity value	/
Cross reacts with	Alstroemeria necrotic streak virus Groundnut ringspot orthotospovirus Tomato chlorotic spot orthotospovirus
Diagnostic Specificity	

Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	75.00%
Specify the test(s)	Calculation was done based on the results of samples listed in sections inclusivity and exclusivity. For one TSWV isolate that has been included in testing as several dilutions, expected results (as explained in the section diagnostic sensitivity) were used for calculation of diagnostic specificity.
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	96.50%
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	98.30%
Test performance study	
Test performance study?	yes
Brief details of the test performance study and its output.It available, link to published article/report	Test performance study organized in the framework of the VALITEST project involving 13 laboratories from 10 countries. Full validation report is available on request (send the e-mail to: niblabfito@nib.si and natasa.mehle@nib.si).

Creation date: 2020-12-31 21:20:00 - Last update: 2021-09-13 18:16:58