

**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 121, 1000 Ljubljana, Slovenia
<b>Short description of the test</b>	Detection and identification of tomato spotted wilt tospovirus by ELISA Bioreba in symptomatic tomato leaves (TPS)
<b>Date, reference of the validation report</b>	2020-12-14 - TSWV V1.0
<b>Link to other validation data</b>	- TSWV V1.0 Detection and identification of tomato spotted wilt tospovirus by ELISA Bioreba in symptomatic tomato leaves (prevalidation study) - TSWV V1.0 Detection and identification of tomato spotted wilt tospovirus by ELISA Agdia in symptomatic tomato leaves (prevalidation study) - TSWV V1.0 Detection and identification of tomato spotted wilt tospovirus by ELISA Agdia in symptomatic tomato leaves (TPS)
<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>	Other_project
<b>If yes, please specify</b>	VALITEST
<b>Description of the test</b>	
<b>Organism(s)</b>	Tomato spotted wilt virus / Orthotospovirus tomatomaculae (TSWV00)
<b>Detection / identification</b>	detection and identification
<b>Method(s)</b>	Serological DAS-ELISA
<b>Method: Serological DAS-ELISA</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	yes
<b>EPPO Diagnostic Protocol name</b>	PM 7/139 Tospoviruses (genus Orthotospovirus) (version 1)
<b>Name of the test</b>	DAS ELISA Generic or Specific antisera (Appendix 2)
<b>Is the test modified compared to the reference test</b>	no

<b>Kit</b>	
<b>Is a kit used</b>	yes
<b>Manufacturer name</b>	BIOREBA
<b>Specify the kit used</b>	ELISA Tomato spotted wilt virus
Kit used following the manufacturer's instructions?	yes
<b>Other information</b>	
<b>Other details on the test</b>	ELISA TSWV Complete kit
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Orthotospovirus tomatomaculae(TSWV00)</b>
<b>Analytical sensitivity</b>	
<b>What is smallest amount of target that can be detected reliably?</b>	10,000x dilution of isolate TSWV-PV-1175 (level of agreement between experiments: 82.2%)
<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>	96.40%
<b>Standard test(s)</b>	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, 100x diluted TSWV-PV-0182 isolate and 10,000x diluted TSWV-PV-0389 isolate have been used as medium and as low concentrated TSWV positive sample, respectively.
<b>Analytical specificity - inclusivity</b>	
<b>Number of strains/populations of target organisms tested</b>	3 TSWV isolates from DSMZ collection (PV-1175, PV-0182, PV-0389)
<b>Specificity value</b>	/
<b>Analytical specificity - exclusivity</b>	
<b>Number of non-target organisms tested</b>	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)
<b>Specificity value</b>	/
<b>Cross reacts with</b>	Alstroemeria necrotic streak virus Groundnut ringspot orthotospovirus Chrysanthemum stem necrosis orthotospovirus Tomato chlorotic spot orthotospovirus
<b>Diagnostic Specificity</b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared</b>	71.30%

<b>to results from a standard test</b>	
<b>Specify the test(s)</b>	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.
<b><u>Reproducibility</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	95.50%
<b><u>Repeatability</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	97.60%
<b>Test performance study</b>	
<b>Test performance study?</b>	yes
<b>Brief details of the test performance study and its output. It available, link to published article/report</b>	Test performance study organized in the framework of the VALITEST project involving 14 laboratories from 11 countries. Full validation report is available on request (send the e-mail to: niblabfito@nib.si and natasa.mehle@nib.si).

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