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	Julius Kuehn-Institute, Federal Research Centre for Cultivated Plants (JKI), Institute for Epidemiology and Pathogen Diagnostics Messeweg 11-12, 38104 Braunschweig, Germany	
Short description of the test	Detection and identification of pea necrotic yellow dwarf virus by molecular conventional PCR in leaves	
Date, reference of the validation report	2021-03-02 - F0_09_00_01-EPV_A42_03_24 PNYDV	
Validation process according to EPPO Standard PM7/98?	yes	
Is the lab accredited for this test?	yes	
Was the validated data generated in the framework of a project?	no	
Description of the test		
Organism(s)	Nanovirus necropisi (PNYDV0)	
Detection / identification	detection and identification	
Method(s)	Molecular Extraction DNA RNA Molecular Conventional PCR	
Method: Molecular Extraction DNA RNA		
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	Edwards et al. (1991) Nucleic Acids Res.; 19(6): 1349. doi: 10.1093/nar/19.6.1349	
Is the test modified compared to the reference test	yes see SOP A42_03_07	
Kit		
Is a kit used	no	
Other information		

Method: Molecular Conventional PCR		
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?	no	
As or adapted from an IPPC diagnostic protocol	no	
Reference of the test	Gaafar et al., New Disease Reports 35 (2017), 23, http://dx.doi.org/10.5197/j.2044-0588.2017.035.02	
Is the test modified compared to the reference test	yes inclusion of IPC in duplex reaction	
Kit		
Is a kit used	no	
Other information		
Reaction type	Duplex	
Other details on the test	PCR test for detection and identification of pea necrotic yellow dwarf virus including IPC Use of One Taq Quick-Load 2X Master Mix with Standard Buffer from New England Biolabs (NEB)	
Performance Criteria :		
Organism 1.:	Nanovirus necropisi(PNYDV0)	
Organism 1.: Analytical sensitivity	Nanovirus necropisi(PNYDV0)	
Organism 1.: <u>Analytical sensitivity</u> What is smallest amount of target that can be detected reliably?	Nanovirus necropisi(PNYDV0) In serial dilutions of DNA extracts PNYDV was detected in dilutions of 10-3. A PCR inhibition was observed when using undiluted DNA extracts	
Organism 1.: <u>Analytical sensitivity</u> What is smallest amount of target that can be detected reliably? <u>Analytical specificity - inclusivity</u>	Nanovirus necropisi(PNYDV0) In serial dilutions of DNA extracts PNYDV was detected in dilutions of 10-3. A PCR inhibition was observed when using undiluted DNA extracts	
Organism 1.: Analytical sensitivity What is smallest amount of target that can be detected reliably? Analytical specificity - inclusivity Number of strains/populations of target organisms tested	Nanovirus necropisi(PNYDV0) In serial dilutions of DNA extracts PNYDV was detected in dilutions of 10-3. A PCR inhibition was observed when using undiluted DNA extracts 100%	
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Organism 1.: Analytical sensitivity What is smallest amount of target that can be detected reliably? Analytical specificity - inclusivity Number of strains/populations of target organisms tested Specificity value Analytical specificity - exclusivity Number of non-target organisms tested	Nanovirus necropisi(PNYDV0) In serial dilutions of DNA extracts PNYDV was detected in dilutions of 10-3. A PCR inhibition was observed when using undiluted DNA extracts 100% This test detects PNYDV isolates DE15, Holtsee, AT, NL, Denmark The test does not detect other nanoviruses (FBNSV, FBNYV, PYSV, BMLRV, SCSV, MVCDV (isolate G55). In addition, PEMV, BLRV and BYMV were not detected.	
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Organism 1.: Analytical sensitivity What is smallest amount of target that can be detected reliably? Analytical specificity - inclusivity Number of strains/populations of target organisms tested Specificity value Analytical specificity - exclusivity Number of non-target organisms tested Specificity value Specificity value Reproducibility Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	Nanovirus necropisi(PNYDV0) In serial dilutions of DNA extracts PNYDV was detected in dilutions of 10-3. A PCR inhibition was observed when using undiluted DNA extracts 100% This test detects PNYDV isolates DE15, Holtsee, AT, NL, Denmark The test does not detect other nanoviruses (FBNSV, FBNYV, PYSV, BMLRV, SCSV, MVCDV (isolate G55). In addition, PEMV, BLRV and BYMV were not detected. 100% 100%	
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Test performance study		
Test performance study?	no	
Other information		
Any other information considered useful	Inhibition of undiluted DNA extracts were also observed by the co-authors of the original publication. We suggest to use undiluted, 1:10 and 1:100 diluted DNA extracts in each test.	

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