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	Institute for Sustainable Plant Protection via Amendola, 122/D, 70126 Bari, Italy
Short description of the test	Detection of Xylella fastidiosa in perennial host species by LAMP-PCR
Date, reference of the validation report	2015-07-01 - Maria Saponari, Giuliana Loconsole, Oriana Potere, Donato Boscia, 2015. DETECTION OF XYLELLA FASTIDIOSA, INTERLABORATORY VALIDATION - MOLECULAR AND SEROLOGICAL METHODS
Validation process according to EPPO Standard PM7/98?	no
Is the lab accredited for this test?	yes
Was the validated data generated in the framework of a project?	
Description of the test	
Organism(s)	Xylella fastidiosa (XYLEFA)
Detection / identification	detection
Matrix(ces) tested	Leaves leaf petioles
Plant species tested	Nerium oleander, Olea europaea
Method(s)	Extraction Molecular LAMP
Method: Extraction	
Reference of the test description	
Other information	
Other details on the test	- T. YASEEN, S. DRAGO, F. VALENTINI, T. ELBEAINO, G. STAMPONE, M. DIGIARO and A.M. D'ONGHIA. Onsite detection of Xylella fastidiosa in host plants and in "spy insects" using the real-time loopmediated isothermal amplification method, 2015. Phytopathologia Mediterranea 54: 488−496. - manufacturer instructions provided by Enbiotech s.r.l. - Maria Saponari, Giuliana Loconsole, Oriana Potere, Donato Boscia, 2015. DETECTION OF XYLELLA FASTIDIOSA, INTERLABORATORY VALIDATION - MOLECULAR AND SEROLOGICAL METHODS.

Method: Molecular LAMP	
Reference of the test description	
Other information	
Other details on the test	- T. YASEEN, S. DRAGO, F. VALENTINI, T. ELBEAINO, G. STAMPONE, M. DIGIARO and A.M. D'ONGHIA. Onsite detection of Xylella fastidiosa in host plants and in "spy insects" using the real-time loopmediated isothermal amplification method, 2015. Phytopathologia Mediterranea 54: 488−496. - manufacturer instructions provided by Enbiotech s.r.l. - Maria Saponari, Giuliana Loconsole, Oriana Potere, Donato Boscia, 2015. DETECTION OF XYLELLA FASTIDIOSA, INTERLABORATORY VALIDATION - MOLECULAR AND SEROLOGICAL METHODS
Are the performance characteristics included in the EPPO diagnostic protocol?	**no**
Performance Criteria :	
Organism 1.:	**Xylella fastidiosa(XYLEFA)**
Analytical sensitivity	
What is the smallest amount of target that can be detected reliably?	up to 10^2 cfu/ml using dilutions ranging from 10^7 to 10 CFU/ml, prepared by adding to the extraction buffer the proper aliquots of bacterial suspension after the incubation with a piece of healthy olive stem.
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)	33 obtained positive samples/ 33 expected positive samples
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	100%
Specify the test(s)	27 obtained negative samples/ 27 expected negative samples
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%
Test performance study	
Test performance study?	no
Other information	

Any other information considered useful	Validation of the Lamp-PCR assay was carried out by the Laboratories listed below, under the supervision of the reference laboratory CNR-UNIBA. • IPSP-CNR: Istituto per la Protezione Sostenibile delle Piante CNR, UOS Bari, (Italy); • DiSSPA-UNIBA: Dipartimento di Scienze del Suolo, della Pianta e degli Alimenti, Università degli Studi Aldo Moro, Bari (Italy); • CRSFA: Centro di Ricerca, Sperimentazione e Formazione in Agricoltura Basile Caramia, Locorotondo (BA) (Italy); • IAMB: Istituto Agronomico Mediterraneo, Valenzano (BA) (Italy); • Enblotech s.r.l. (PA) which provided the kit and the manufacturer instructions
The following complementary files are available online:	• protocols for diagnosis of Xylella fastidiosa • Report interlaboratory validation 2015

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