

**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>	Council for Agricultural Research and Economics- Research Centre for Plant Protection and Certification Via Carlo Giuseppe Bertero, 22, 00156 Rome, Italy
<b>Short description of the test</b>	Detection of <i>Xylella fastidiosa</i> subsp. <i>pauca</i> ceppo CoDiRo by LAMP-PCR from plant olive crude extracts
<b>Date, reference of the validation report</b>	2021-05-04 - Loreti S., Pucci N., Loconsole G., Modesti V, Lucchesi S.,Potere O., Saponari M 2017. Protocollo Diagnostico per XYLELLA FASTIDIOSA subsp. PAUCA ceppo CoDiRO. In Protocolli Diagnostici - ASPROPI- ISBN 9788899595722.pp. 241-278
<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>	
<b>If yes, please specify</b>	
<b>Description of the test</b>	
<b>Organism(s)</b>	<i>Xylella fastidiosa</i> subsp. <i>pauca</i> (XYLEFP)
<b>Detection / identification</b>	detection
<b>Matrix(ces) tested</b>	Leaves Leaves, petioles
<b>Plant species tested</b>	<i>Olea europaea</i>
<b>Method(s)</b>	Extraction Molecular LAMP
<b>Method: Extraction</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	no
<b>New test being considered for inclusion in the next version of the EPPO diagnostic protocol?</b>	
<b>As or adapted from an IPPC diagnostic protocol</b>	no
<b>Reference of the test</b>	Plant olive crude extract obtained after

	homogenization of leaf tissues following Loconsole et al (2014)
<b>Is the test modified compared to the reference test</b>	
<b>Other information</b>	
<b>Other details on the test</b>	Plant olive crude extract obtained after homogenization of leaf tissues following Loconsole et al (2014)
<b>Method: Molecular LAMP</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	
<b>New test being considered for inclusion in the next version of the EPPO diagnostic protocol?</b>	
<b>As or adapted from an IPPC diagnostic protocol</b>	
<b>Is the test modified compared to the reference test</b>	
<b>Kit</b>	
<b>Is a kit used</b>	yes
<b>Manufacturer name</b>	ENBIOTECH
<b>Specify the kit used</b>	ENBIOTECH Xylella fastidiosa LAMP kit
Kit used following the manufacturer's instructions?	
<b>Other information</b>	
<b>Reaction type</b>	
<b>Other details on the test</b>	LAMP-PCR (manufacturer instructions provided by Enbiotech s.r.l.)
<b>Are the performance characteristics included in the EPPO diagnostic protocol?</b>	yes
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Xylella fastidiosa subsp. pauca(XYLEFP)</b>
<b>Analytical sensitivity</b>	
<b>What is smallest amount of target that can be detected reliably?</b>	10 <sup>3</sup> / 10 <sup>4</sup> CFU/ml
<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>	0,7
<b>Standard test(s)</b>	LAMP-PCR (Enbiotech s.r.l.) from crude extract obtained after homogenization of leaf tissues following Loconsole et al (2014)
<b>Analytical specificity - inclusivity</b>	

<b>Number of strains/populations of target organisms tested</b>	
<b>Specificity value</b>	
<b>Analytical specificity - exclusivity</b>	
<b>Number of non-target organisms tested</b>	
<b>Specificity value</b>	
<b>Cross reacts with</b>	
<b>Diagnostic Specificity</b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	0,97
<b>Specify the test(s)</b>	LAMP-PCR (Enbitech)from crude extract obtained after homogenization of leaf tissues following Loconsole et al (2014)
<b>Reproducibility</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	(Concordance) 63%
<b>Repeatability</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	(Accordance) 68%
<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>	<p>1. Two series of olive extracts spiked with ten fold dilution of Xylella fastidiosa CODiRo strain suspensions from <math>10^7</math> to <math>10^0</math> cfu/ml plus two healthy samples (16 samples in total) were tested in three different laboratories (CREA-PAV; CNR-IPSP; Plant Protection Service Lombardy) (NTC, healthy and infected olive extracts as control) for analytical sensitivity. 2. To check the diagnostic sensitivity and specificity , the accuracy, the repeatability and reproducibility, olive extract samples spiked with Xylella fastidiosa CODiRo strain suspensions at <math>10^6</math> cfu /ml (three repetitions), <math>10^4</math> cfu /ml (three repetitions), <math>10^3</math> cfu /ml (three repetitions), healthy olive extracts (three repetitions) for a total of 12 samples, were tested by the following TPS participants : 1. CREA-DC (N. Pucci; S. Loreti) 2. SELGE/CNR-IPSP/ DiSSPA-Uniba (M. Saponari, G. Loconsole; O. Potere) 3. PPS Piemonte (C. Morone, G. Mason) 4. PPS Friuli Venezia Giulia (G. Bianchi) 5. PPS Lombardia (F. Gaffuri) 6. PPS Emilia Romagna (A. Alessandrini; R. Gozzi) 7. PPS Trentino Alto Adige (V. Gualandri; L. Tessari) 8. PPS Marche (S. Nardi; S. Talevi) 9. PPS Liguria (M. Guelfi) 10. CIHEAM-IAMB (A.M. D'Onghia; M. Digiario) 11. CRSFA (F. Palmisano) 12. Centro di Sperimentazione Agraria e Forestale, Laimburg (A. Gallmetzer;A. Kraus) 13. Uni-MI (P. Casati) 14. Uni-CT (V. Catara) 15. PPS Toscana (D.</p>

	Rizzo) 16. PPS Veneto (A. Saccardi; D. Pasqua di Bisceglie)
<b>Other information</b>	
<b>Any other information considered useful</b>	Relative accuracy: 77%

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