

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

<b>Other information</b>	
<b>Other details on the test</b>	- 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
<b>Are the performance characteristics included in the EPPO diagnostic protocol?</b>	<b>no</b>
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>Xylella fastidiosa(XYLEFA)</b>
<b>Analytical sensitivity</b>	
<b>What is smallest amount of target that can be detected reliably?</b>	up to 10 <sup>2</sup> cfu/ml using dilutions ranging from 10 <sup>7</sup> 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.
<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>	100%
<b>Standard test(s)</b>	33 obtained positive samples/ 33 expected positive samples
<b>Diagnostic Specificity</b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	100%
<b>Specify the test(s)</b>	27 obtained negative samples/ 27 expected negative samples
<b>Reproducibility</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%
<b>Repeatability</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%
<b>Test performance study</b>	
<b>Test performance study?</b>	no
<b>Other information</b>	
<b>Any other information considered useful</b>	Validation of the Lamp-PCR assay was carried out by the Laboratories listed below, under the supervision of the reference laboratory CNR-UNIBA.

	<ul style="list-style-type: none"> <li>• IPSP-CNR: Istituto per la Protezione Sostenibile delle Piante CNR, UOS Bari, (Italy);</li> <li>• DiSSPA-UNIBA: Dipartimento di Scienze del Suolo, della Pianta e degli Alimenti, Università degli Studi Aldo Moro, Bari (Italy);</li> <li>• CRSFA: Centro di Ricerca, Sperimentazione e Formazione in Agricoltura Basile Caramia, Locorotondo (BA) (Italy);</li> <li>• IAMB: Istituto Agronomico Mediterraneo, Valenzano (BA) (Italy);</li> <li>• Enblotech s.r.l. (PA) which provided the kit and the manufacturer instructions</li> </ul>
<p>The following complementary files are available online:</p>	<ul style="list-style-type: none"> <li>• <a href="#">protocols for diagnosis of Xylella fastidiosa</a></li> <li>• <a href="#">Report interlaboratory validation 2015</a></li> </ul>

*Creation date: 2016-01-25 00:00:00 - Last update: 2021-05-03 22:05:29*