

**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>	Anses Plant Health Laboratory - Bacteriology, Virology and GMO Unit 7 rue Jean Dixméras, 49044 Angers, France
<b>Short description of the test</b>	Detection of Xylella fastidiosa by molecular real time PCR in vectors
<b>Date, reference of the validation report</b>	2024-10-23 - Détection de Xylella fastidiosa par PCR en temps réel sur insectes vecteurs MA065ver02
<b>Validation process according to EPPO Standard PM7/98?</b>	yes
<b>Is the lab accredited for this test?</b>	yes
<b>Was the validated data generated in the framework of a project?</b>	no
<b>Description of the test</b>	
<b>Organism(s)</b>	Xylella fastidiosa (XYLEFA)
<b>Detection / identification</b>	detection
<b>Method(s)</b>	Molecular Extraction DNA RNA Molecular real time PCR
<b>Method: Molecular Extraction DNA RNA</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	yes
<b>New test being considered for inclusion in the next version of the EPPO diagnostic protocol?</b>	no
<b>EPPO Diagnostic Protocol name</b>	PM 7/024 Xylella fastidiosa (version 5)
<b>As or adapted from an IPPC diagnostic protocol</b>	no
<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>	BIONOBILE
<b>Specify the kit used</b>	QuickPick™ SML Plant DNA

Kit used following the manufacturer's instructions?	yes
<b>Other information</b>	
<b>Method: Molecular real time PCR</b>	
<b>Reference of the test description</b>	
As or adapted from an EPPO diagnostic protocol	yes
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	no
EPPO Diagnostic Protocol name	PM 7/024 Xylella fastidiosa (version 5)
Name of the test	Real-time PCR (Harper et al., 2010; erratum 2013)
As or adapted from an IPPC diagnostic protocol	no
Is the test modified compared to the reference test	no
<b>Kit</b>	
Is a kit used	yes
Manufacturer name	Applied Biosystems
Specify the kit used	TaqMan™ Fast Universal Master Mix (2X), no AmpErase™ UNG
Kit used following the manufacturer's instructions?	yes
<b>Other information</b>	
Reaction type	Duplex
Other details on the test	Duplex real time Harper et al., 2010 / loos et al., 2009 (internal control RNAr 18S)
<b>Performance Criteria :</b>	
Organism 1.:	<b>Xylella fastidiosa(XYLEFA)</b>
<b>Analytical sensitivity</b>	
What is smallest amount of target that can be detected reliably?	2.10 <sup>3</sup> cell./head with a detection rate of 100%
<b>Diagnostic sensitivity</b>	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	100%
<b>Analytical specificity - inclusivity</b>	
Number of strains/populations of target organisms tested	100%
Specificity value	
<b>Diagnostic Specificity</b>	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	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
The following complementary files are available online:	<ul style="list-style-type: none"> <li>• <a href="#">Validation report</a></li> </ul>

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