

**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	Anses Plant Health Laboratory - Bacteriology, Virology and GMO Unit 7 rue Jean Dixm�ras, 49044 Angers, France
Short description of the test	Detection and Identification of Xylella fastidiosa subspecies on plant extracts by real time PCR Dupas et al., 2019
Date, reference of the validation report	2021-09-16 - Dupas et al., 2019 report version 01
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	no
Was the validated data generated in the framework of a project?	no
If yes, please specify	
Description of the test	
Organism(s)	Xylella fastidiosa(XYLEFA)
Detection / identification	detection and identification
Matrix(ces) tested	Leaves, Shoots Naturally contaminated plants are issued from French national official survey and healthy plants from nurseries
Plant species tested	Helichrysum italicum, Lavandula sp., Polygala myrtifolia
Method(s)	Molecular Extraction DNA RNA Molecular real time PCR
Method: Molecular Extraction DNA RNA	
Reference of the test description	
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 4)
Name of the test	
As or adapted from an IPPC diagnostic protocol	yes

IPPC diagnostic Protocol name	ISPM 27 Annex 25 DP 25: Xylella fastidiosa (version 2018)
Name of the test	QuickPick SML Plant DNA kit (Bio-Nobile)
Is the test modified compared to the reference test	no
Kit	
Is a kit used	yes
Manufacturer name	BIONOBILE
Specify the kit used	QuickPick™ SML Plant DNA
Kit used following the manufacturer's instructions?	yes
Other information	
Other details on the test	
Method: Molecular real time 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?	yes
As or adapted from an IPPC diagnostic protocol	no
Reference of the test	Dupas et al., 2019
Is the test modified compared to the reference test	no
Kit	
Is a kit used	no
Other information	
Reaction type	Multiplex (>3)
Other details on the test	A cut-off value of 38 is applied
Are the performance characteristics included in the EPPO diagnostic protocol?	
Performance Criteria :	
Organism 1.:	Xylella fastidiosa(XYLEFA)
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	XF Harper with set N°5 (on Polygala myrtifolia, Lavandula sp. and Helichrysum italicum) : 10 ⁵ cells/mL XFFSL with set N°5 (on Polygala myrtifolia, Lavandula sp. and Helichrysum italicum) : 10 ⁵ cells/mL XFM with set N°5 : Not evaluated XFP with set N°5 : not evaluated
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the	XF Harper with set N°5 : 92% (on pure DNA extract) - 100% (on 10 fold diluted DNA for 1 sample. /12)

standard test, see appendix 2 of PM 7/98	XFM with set N°5 : 89% XFP with set N°5 : 100% XFFSL with set N°5 : 100%
Standard test(s)	MLST based on the conventional PCR Yuan et al., 2010
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	Cf. attached file "Rapport de validation Dupas et al"
Specificity value	100% Cf. attached file "Rapport de validation Dupas et al"
Analytical specificity - exclusivity	
Number of non-target organisms tested	Cf. attached file "Eclusivity"
Specificity value	100% except for primers / probe XFF for the set N° 2 (non-specific amplification observed with the strain of Xanthomonas hortorum pv. carotae LNPV 17.76) Cf. details in attached file "Eclusivity"
Cross reacts with	Xanthomonas hortorum pv. carotae
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	XF Harper with set N°5 : 100% XFM with set N°5 : 100% XFP with set N°5 : 100% XFFSL with set N°5 : 100%
Specify the test(s)	MLST based on the conventional PCR Yuan et al., 2010
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	Not evaluated
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	XF Harper with set N°5 : 97% XFM with set N°5 : 98% XFP with set N°5 : 100% XFFSL with set N°5 : 100%
Test performance study	
Test performance study?	no
Brief details of the test performance study and its output. If available, link to published article/report	
Other information	
Any other information considered useful	

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