

**EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION  
ORGANISATION EUROPÉENNE ET MEDITERRANÉENNE POUR LA PROTECTION DES PLANTES**

(11-17239)

**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>Target Organism</b>	Xylella fastidiosa	
<b>Short description</b>	Détection de Xylella fastidiosa par PCR en temps réel sur végétal	
<b>Laboratory contact details</b>	Anses Plant Health Laboratory - Bacteriology, Virology and GMO Unit 7 rue Jean Dixméras, 49044 Angers, France	
<b>Date and reference of the validation report</b>	2019-1 - MA039 version 4	
<b>Validation process according to EPPO Standard PM 7/98:</b>	Yes	
<b>Reference of the test description</b>	PM 7/024 CTAB-based DNA extraction QuickPick SML Plant DNA kit-based DNA extraction Real-time PCR Harper et al., 2010	
<b>Is the test the same as described in the EPPO DP?</b>	Modified Insertion of a step of sonication of the macerate prior to DNA extraction in order to break the <i>X. fastidiosa</i> biofilms Real-time PCR Harper et al., 2010: DNA extract added to the PCR mix doubled (4 µL instead of 2 µL)	
<b>Is the lab accredited for this test?</b>	Yes	
<b>Plant species tested (if relevant)</b>	Olea europaea; Quercus ilex	
<b>Matrices tested (if relevant)</b>	Petioles	
<b>List of methods used</b>		
<b>Method for extraction / isolation / baiting of target organism from matrix</b>		
<b>Molecular methods, e.g. hybridization, PCR and real time PCR</b>	X	CTAB-based DNA extraction QuickPick SML Plant DNA kit-based DNA extraction Real-time PCR Harper et al., 2010
<b>Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay</b>		
<b>Plating methods: selective isolation</b>		
<b>Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.</b>		
<b>Pathogenicity test</b>		

<b>Fingerprint methods: protein profiling, fatty acid profiling &amp; DNA profiling</b>		
<b>Morphological and morphometrical methods intended for identification</b>		
<b>Biochemical methods: e.g. enzyme electrophoresis, protein profiling</b>		
<b>Other</b>		
<b><u>Analytical sensitivity (= limit of detection)</u></b>		
<b>What is smallest amount of target that can be detected reliably?</b>	Olea europaea: 1.10 <sup>5</sup> bact./mL of macerate (detection rate = 100%) Quercus ilex: 1.10 <sup>4</sup> bact./mL of macerate (detection rate = 100%)	
<b><u>Diagnostic sensitivity</u></b>		
<b>Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98</b>		
<b>Specify the standard test</b>		
<b><u>Analytical specificity</u></b>		
<b>Specificity value</b>	100%	
<b>Number of strains/populations of target organisms tested</b>	74 X. fastidiosa strains belonging to X. f. subsp fastidiosa, morus, sandyi, pauca and multiplex	
<b>Number of non-target organisms tested</b>	29 non-target organism: - 1 Xylophilus ampelinus (CFBP2098) - 2 Xanthomonas arboricola pv. pruni (LSV2574/LSV 2573) - 1 Xanthomonas arboricola pv. juglandis (LSV0862) - 1 Xanthomonas axonopodis pv. citri (LSV2647) - 1 Xanthomonas axonopodis pv. aurantifolia (LSV2680) - 2 Xanthomonas axonopodis pv. phaseoli (LSV1014/LSV3161) - 1 Xanthomonas axonopodis pv. fragariae (LSV3151) - 1 Xanthomonas fragariae (LSV2553) - 1 Xanthomonas hortorum pv. carotae (LSV1776) - 1 Xanthomonas campestris pv. campestris (LSV0455) - 1 Xanthomonas campestris pv. juglandis (LSV1158) - 1 Xanthomonas hortorum pv. hedera (LSV2303) - 1 Xanthomonas translucens pv. graminis (LSV0628) - 1 Xanthomonas translucens pv. hordei (LSV0629) - 1 Xanthomonas oryzae pv. oryzae (LSV0865) - 1 Ca. Liberibacter asiaticus - 1 Ca. L. africanus - 6 bactéries saprophytes isolées de Coffea spp. - 4 bactéries saprophytes isolées de Citrus sinensis	
<b>Cross reacts with (specify the species)</b>	No cross reaction	
<b><u>Diagnostic Specificity</u></b>		
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a</b>		

<b>standard test</b>	
<b>Specify the standard test</b>	
<b><u>Reproducibility</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%
<b><u>Repeatability</u></b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	100%
<b><u>Test performance study</u></b>	
<b>Test performance study?</b>	No
<b>Include brief details of the test performance study and its output. If available, provide a link to published article/report</b>	
<b><u>Other information</u></b>	
<b>Any other information considered useful e.g. robustness, ease of performing the test, etc.</b>	
The following complementary files are available online:	<ul style="list-style-type: none"> <li>• <a href="#">Rapport de caractérisation et de validation d'une méthode d'analyse MA0039 version 4</a></li> </ul>