

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.

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| Laboratory contact details | Anses Plant Health Laboratory - Bacteriology, Virology and GMO Unit 7 rue Jean Dixméras, 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 |
| Description of the test | |
| Organism(s) | Xylella fastidiosa(XYLEFA) |
| Detection / identification | detection and identification |
| 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) |
| 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 |

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| Manufacturer name | BIONOBILE |
| Specify the kit used | QuickPick™ SML Plant DNA |
| Kit used following the manufacturer's instructions? | yes |
| Other information | |
| 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 |
| 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 standard test, see appendix 2 of PM 7/98 | XF Harper with set N°5 : 92% (on pure DNA extract) - 100% (on 10 fold diluted DNA for 1 sample. /12) 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 | |

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| 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 |
| <u>Diagnostic Specificity</u> | |
| 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 |
| <u>Reproducibility</u> | |
| Provide the calculated % of agreement for a given level of the pest (see PM 7/98) | Not evaluated |
| <u>Repeatability</u> | |
| 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% |
| <u>Test performance study</u> | |
| Test performance study? | no |

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