**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<br>7 rue Jean Dixméras, 49044 Angers, France |
| **Short description of the test** | Detection of Xylella fastidiosa by molecular real time PCR in vectors |
| **Date, reference of the validation report** | 2024-10-23 - Détection de Xylella fastidiosa par PCR en temps réel sur insectes vecteurs MA065ver02 |
| **Validation process according to EPPO Standard PM7/98?** | yes |
| **Is the lab accredited for this test?** | yes |
| **Was the validated data generated in the framework of a project?** | no |
| | |
| **Description of the test** | |
| | |
| **Organism(s)** | Xylella fastidiosa (XYLEFA) |
| **Detection / identification** | detection |
| **Method(s)** | Molecular Extraction DNA RNA<br>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 5) |
| **As or adapted from an IPPC diagnostic protocol** | no |
| **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*** | |
| **Method: Molecular real time PCR** | |
| ***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 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 |
| ***Kit*** | |
| **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 |
| ***Other information*** | |
| **Reaction type** | Duplex |
| **Other details on the test** | Duplex real time Harper et al., 2010 / Ioos et al., 2009 (internal control RNAr 18S) |
| **Performance Criteria :** | |
| **Organism 1.:** | **Xylella fastidiosa(XYLEFA)** |
| **Analytical sensitivity** | |
| **What is smallest amount of target that can be detected reliably?** | 2.10^3 cell./head with a detection rate of 100% |
| **Diagnostic sensitivity** | |
| **Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98** | 100% |
| **Analytical specificity - inclusivity** | |
| **Number of strains/populations of target organisms tested** | 100% |
| **Specificity value** | |
| **Diagnostic Specificity** | |
| **Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test** | 100% |

| **Repeatability** | |
|---|---|
| **Provide the calculated % of agreement for a given level of the pest (see PM 7/98)** | 100% |
| **Test performance study** | |
| **Test performance study?** | no |
| | |
| The following complementary files are available online: | • Validation report |

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