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 - Nematology Unit Domaine de la Motte au Viconte BP 35327, 35653 Le Rheu, France |
| :---: | :---: |
| Short description of the test | Detection of Bursaphelenchus xylophilus using real time PCR for direct detection on wood extracts (Anses-LSV, FR) adapted from François et al. (2007). |
| Date, reference of the validation report | 2019-12-10-Bx1 |
| 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? | Other_project |
| If yes, please specify | VALITEST |
| Description of the test |  |
| Organism(s) | Bursaphelenchus xylophilus(BURSXY) |
| Detection / identification | detection |
| 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 7/004 Bursaphelenchus xylophilus (version 3) |
| 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 | QIAGEN |


| Specify the kit used | QIAamp DNA Mini Kit |
| :---: | :---: |
| 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 7/004 Bursaphelenchus xylophilus (version 3) |
| Name of the test | Real time PCR protocol for direct detection on wood extracts (Anses-LSV, FR) |
| Kit |  |
| Is a kit used | no |
| Other information |  |
| Reaction type | Duplex |
| Performance Criteria : |  |
| Organism 1.: | Bursaphelenchus xylophilus(BURSXY) |
| Analytical sensitivity |  |
| What is smallest amount of target that can be detected reliably? | 5 individuals |
| Diagnostic sensitivity |  |
| Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98 | 100\% |
| Standard test(s) | Comparison with samples of known status |
| Analytical specificity - inclusivity |  |
| Number of strains/populations of target organisms tested | 2 populations of Bursaphelenchus xylophilus either from China or Portugal |
| Specificity value | 100\% |
| Analytical specificity - exclusivity |  |
| Number of non-target organisms tested | One population for each of the following species: B. macromucronatus, B. doui, B. hoffmani, B. kolymensis, B. mucronatus, B. sexdentati |
| Specificity value | 100\% |
| Diagnostic Specificity |  |
| Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test | 100\% |
| Specify the test(s) | Comparison with samples of known status |
| Test performance study |  |


| Test performance study? | yes |  |
| :--- | :--- | :---: |
| Brief details of the test performance study <br> and its output.It available, link to published <br> article/report | Test performance study organised in the <br> framework of the VALITEST project in 2019, <br> including 16 participating laboratories from 14 <br> countries. Only 14 sets of data were considered for <br> the analysis and calculation of performance <br> criteria. |  |
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| The following complementary files are available <br> online: | • VALITEST BX1 report |  |

