

**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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| <b>Laboratory contact details</b>   | Anses Plant Health Laboratory - Nematology Unit<br>Domaine de la Motte au Viconte BP 35327, 35653<br>Le Rheu, France    |
| <b>Short description of the test</b>  | Identification of <i>Bursaphelenchus xylophilus</i> by conventional PCR in extracts from cultures performed on mycelium |
| <b>Date, reference of the validation report</b>   | 2019-12-10 - Bx1  |
| <b>Validation process according to EPPO Standard PM7/98?</b>  | yes   |
| <b>Is the lab accredited for this test?</b>   | yes   |
| <b>Was the validated data generated in the framework of a project?</b>                              | Other_project   |
| <b>If yes, please specify</b>   | VALITEST  |
| <b>Description of the test</b>  |   |
| <b>Organism(s)</b>  | <i>Bursaphelenchus xylophilus</i> (BURSXY)  |
| <b>Detection / identification</b>   | identification  |
| <b>Method(s)</b>  | Molecular Conventional PCR  |
| <b>Method: Molecular Conventional PCR</b>   |   |
| <b>Reference of the test description</b>  |   |
| <b>As or adapted from an EPPO diagnostic protocol</b>   | no  |
| <b>New test being considered for inclusion in the next version of the EPPO diagnostic protocol?</b> | yes   |
| <b>As or adapted from an IPPC diagnostic protocol</b>   | yes   |
| <b>IPPC diagnostic Protocol name</b>  | ISPM 27 Annex 10 DP 10: <i>Bursaphelenchus xylophilus</i> (version 2016)  |
| <b>Name of the test</b>   | Matsunaga et al. 2004   |
| <b>Is the test modified compared to the reference test</b>  | no  |
| <b>Kit</b>  |   |
| <b>Is a kit used</b>  | no  |
| <b>Other information</b>  |   |

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| <b>Reaction type</b>   | Simplex  |
| <b>Other details on the test</b>   | Taq DNA polymerase from MP Biomedicals (ref. EPTQD925)   |
| <b>Performance Criteria :</b>  |  |
| <b>Organism 1.:</b>  | <b>Bursaphelenchus xylophilus(BURSXY)</b>  |
| <b>Analytical sensitivity</b>  |  |
| <b>What is smallest amount of target that can be detected reliably?</b>  | 1 individual   |
| <b>Diagnostic sensitivity</b>  |  |
| <b>Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98</b> | not applicable   |
| <b>Analytical specificity - inclusivity</b>  |  |
| <b>Number of strains/populations of target organisms tested</b>  | 5 populations of B. xylophilus included (originated from China, Portugal and Canada)   |
| <b>Specificity value</b>   | 100%   |
| <b>Analytical specificity - exclusivity</b>  |  |
| <b>Number of non-target organisms tested</b>   | 19 populations of the following species included: B. macromucronatus, B. doui, B. hoffmani, B. kolymensis, B. mucronatus, B. sexdentati, B. vallesianus, B. willibaldi, B. sp. |
| <b>Specificity value</b>   | 100%   |
| <b>Diagnostic Specificity</b>  |  |
| <b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>        | not applicable   |
| <b>Reproducibility</b>   |  |
| <b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>   | 100%   |
| <b>Repeatability</b>   |  |
| <b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>   | 100% (from 8 replicates of DNA solution)   |
| <b>Test performance study</b>  |  |
| <b>Test performance study?</b>   | no   |
| <b>Other information</b>   |  |
| <b>Any other information considered useful</b>   | Data obtained in the framework of the VALITEST project, during the preliminary study's phase, prior to the TPS and in a sole laboratory.                                       |
| The following complementary files are available online:  |  |
|  | <ul style="list-style-type: none"> <li>• <a href="#">VALITEST BX1 report</a></li> </ul>  |