

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 - Nematology Unit Domaine de la Motte au Viconte BP 35327, 35653 Le Rheu, France |
| Short description of the test | Detection of Bursaphelenchus xylophilus using ClearDetections Real-Time PCR Diagnostic kit in extracts from wood chips or on isolated nematodes |
| 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? | no |
| 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 real time PCR |
| 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? | no |
| As or adapted from an IPPC diagnostic protocol | no |
| Reference of the test | Cleardetection kit |
| Is the test modified compared to the reference test | no |
| Kit | |
| Is a kit used | yes |
| Manufacturer name | CLEAR DETECTIONS |
| Specify the kit used | RT-N-D-0401 ClearDetections Real-Time PCR Diagnostic kit: Bursaphelenchus xylophilus |

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| Kit used following the manufacturer's instructions? | yes |
| Other information | |
| Performance Criteria : | |
| Organism 1.: | Bursaphelenchus xylophilus(BURSXY) |
| Analytical sensitivity | |
| What is smallest amount of target that can be detected reliably? | 10 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 | 5 populations of B. xylophilus included (originated from China, Portugal and Canada) |
| Specificity value | 100% |
| Analytical specificity - exclusivity | |
| Number of non-target organisms tested | 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. |
| Specificity value | 100% |
| Diagnostic Specificity | |
| Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test | not applicable |
| Reproducibility | |
| Provide the calculated % of agreement for a given level of the pest (see PM 7/98) | 100% |
| Repeatability | |
| Provide the calculated % of agreement for a given level of the pest (see PM 7/98) | 100% (from 8 replicates of DNA solution) |
| Test performance study | |
| Test performance study? | no |
| Other information | |
| Any other information considered useful | Data obtained in the framework of the VALITEST project, during the preliminary study's phase, prior to the TPS and in a sole laboratory. |
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| The following complementary files are available online: | <ul style="list-style-type: none"> • VALITEST BX1 report |