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 LAMP test developped by Kikuchi et al. in extracts from wood chips or on isolated nematodes Date, reference of the validation report Validation process according to EPPO standard PM7/98? Is the lab accredited for this test? No Was the validated data generated in the framework of a project? If yes, please specify VALITEST Description of the test Organism(s) Bursaphelenchus xylophilus (BURSXY) Detection / identification Method(s) Molecular LAMP Reference of the test description As or adapted from an EPPO diagnostic protocol? As or adapted from an IPPC diagnostic protocol? As or adapted from an IPPC diagnostic protocol? PPC diagnostic Protocol name ISPM 27 Annex 10 DP 10: Bursaphelenchus xylophilus (version 2016) Name of the test Visuanie al. 2009 Is the test modified compared to the reference test Kit Leich and Molecular used (FAM dye) for the detection of the reference test Kit Leich and Molecular publication | | | | |
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| | • | of the reaction insted of color changes in the | | |
| | Kit | | | |
| Is a kit used no | Is a kit used | no | | |

| Other information | | | | |
|---|--|--|--|--|
| Other details on the test | LAMP amplification performed with the following kit; OPTIGENE - Isothermal master mix ISO-004. | | | |
| Performance Criteria : | | | | |
| Organism 1.: | Bursaphelenchus xylophilus(BURSXY) | | | |
| Analytical sensitivity | | | | |
| What is smallest amount of target that can be detected reliably? | 1 individual | | | |
| 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: | VALITEST BX1 report | | | |

| Creation date: 2020-06-21 14:30:23 - I | Last update: 2023-02-14 11:12:49 | |
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