**EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION**
**ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA PROTECTION DES PLANTES**
(11-17239)
**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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| **Target Organism** | Erwinia amylovora | |
| **Short description** | Real-time PCR assay targeting chromosomal DNA of Erwinia amylovora. | |
| **Laboratory contact details** | AGES Institute of Sustainable Plant Production<br>Spargelfeldstrasse 191, 1220 Vienna, Austria | |
| **Date and reference of the validation report** | 2010 - none | |
| **Validation process according to EPPO Standard PM 7/98:** | Yes | |
| **Reference of the test description** | PM 7/020(1)<br>New test approved for inclusion in PM 7/020(2) approval 2012<br>Gottsberger RA (2010) Development and evaluation of a real-time PCR assay targeting chromosomal DNA of Erwinia amylovora. Letters in Applied Microbiology 51, 285–292. | |
| **Is the test the same as described in the EPPO DP?** | Yes | |
| **Is the lab accredited for this test?** | No | |
| **Plant species tested (if relevant)** | Several plant species from the Rosaceae family | |
| **Matrices tested (if relevant)** | Shoots, leaves, blossoms, roots, honey bees | |
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| ***List of methods used*** | | |
| **Method for extraction / isolation / baiting of target organism from matrix** | | |
| **Molecular methods, e.g. hybridization, PCR and real time PCR** | X | Real-time PCR (Gottsberger 2010) |
| **Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay** | | |
| **Plating methods: selective isolation** | | |
| **Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.** | | |
| **Pathogenicity test** | | |
| **Fingerprint methods: protein profiling, fatty acid profiling & DNA** | | |

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| **profiling** | | |
| **Morphological and morphometrical methods intended for identification** | | |
| **Biochemical methods: e.g. enzyme electrophoresis, protein profiling** | | |
| **Other** | | |
| **Analytical sensitivity (= limit of detection)** | | |
| **What is smallest amount of target that can be detected reliably?** | 2 cfu/µl | |
| **Diagnostic sensitivity** | | |
| **Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98** | Contact the lab | |
| **Specify the standard test** | | |
| **Analytical specificity** | | |
| **Specificity value** | | |
| **Number of strains/populations of target organisms tested** | 71 (in Gottsberger 2010) | |
| **Number of non-target organisms tested** | 41 (in Gottsberger 2010) | |
| **Cross reacts with (specify the species)** | No cross reaction | |
| **Diagnostic Specificity** | | |
| **Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test** | Contact the lab | |
| **Specify the standard test** | Bereswill et al. (1992) | |
| **Reproducibility** | | |
| **Provide the calculated % of agreement for a given level of the pest (see PM 7/98)** | 100%, when tested with different operators | |
| **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 | |
| **Include brief details of the test performance study and its output.It available, provide a link to published article/report** | | |
| **Other information** | | |

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| **Any other information considered useful**<br>**e.g. robustness, ease of performing the test, etc.** | Test can be used for quantification. A dilution series of a target bacteria suspension with determined concentration can be used as standards. |