

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.

| | | |
|---|--|--|
| Target Organism | Erwinia amylovora | |
| Short description | Lateral flow devices for fire blight testing | |
| Laboratory contact details | AGES Institute of Sustainable Plant Production Spargelfeldstrasse 191, 1220 Vienna, Austria | |
| Date and reference of the validation report | 2012-12-18 - | |
| Validation process according to EPPO Standard PM 7/98: | Yes | |
| Reference of the test description | 0 PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora | |
| 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) | | |
| Matrices tested (if relevant) | Tested on pure bacterial cultures | |
| List of methods used | | |
| Method for extraction / isolation / baiting of target organism from matrix | | |
| Molecular methods, e.g. hybridization, PCR and real time PCR | | |
| Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay | X | Serological lateral flow device tests AgriStrip, Pocket Diagnostics |
| 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 profiling | | |
| Morphological and morphometrical methods intended for identification | | |

| | | |
|---|--|--|
| Biochemical methods: e.g. enzyme electrophoresis, protein profiling | | |
| Other | | |
| <u>Analytical sensitivity (= limit of detection)</u> | | |
| What is smallest amount of target that can be detected reliably? | | |
| <u>Diagnostic sensitivity</u> | | |
| Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98 | see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora | |
| Specify the standard test | see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora | |
| <u>Analytical specificity</u> | | |
| Specificity value | | |
| Number of strains/populations of target organisms tested | Is routinely being used for testing isolated pure cultures of Erwinia amylovora isolates | |
| Number of non-target organisms tested | 14 | |
| Cross reacts with (specify the species) | Erwinia uzenensis, Erwinia tasmaniensis, Erwinia piriflorinigrans, Erwinia pyrifoliae | |
| <u>Diagnostic Specificity</u> | | |
| Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test | see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora | |
| Specify the standard test | see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora | |
| <u>Reproducibility</u> | | |
| Provide the calculated % of agreement for a given level of the pest (see PM 7/98) | see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora | |
| <u>Repeatability</u> | | |
| Provide the calculated % of agreement for a given level of the pest (see PM 7/98) | see PM 7/020(2) - EPPO Diagnostic Protocol for Erwinia amylovora | |
| <u>Test performance study</u> | | |
| Test performance study? | No | |
| Include brief details of the test performance study and its output.It available, provide a link to published article/report | | |
| <u>Other information</u> | | |
| Any other information considered useful | | |

| | |
|---|---|
| e.g. robustness, ease of performing the test, etc. | |
| | |
| The following complementary files are available online: | <ul style="list-style-type: none"> • Table on cross reaction of Erwinia amylovora LFDs |