

**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 | Bacteriology. Instituto Valenciano de Investigaciones Agrarias CV-315, km. 10.7, 46113 Moncada, Spain |
| Short description of the test | Detection of <i>Erwinia amylovora</i> from plant material by Commercial lateral flow device Ea Agri-Strip |
| Date, reference of the validation report | 2012-03-01 - Not specified |
| 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? | |
| Description of the test | |
| Organism(s) | <i>Erwinia amylovora</i> (ERWIAM) |
| Detection / identification | detection |
| Method(s) | Serological Lateral Flow Device |
| Method: Serological Lateral Flow Device | |
| Reference of the test description | |
| As or adapted from an EPPO diagnostic protocol | yes |
| EPPO Diagnostic Protocol name | PM 7/020 <i>Erwinia amylovora</i> (version 2) |
| Name of the test | Lateral flow devices |
| Kit | |
| Is a kit used | yes |
| Manufacturer name | BIOREBA |
| Specify the kit used | AgriStrip <i>Erwinia amylovora</i> |
| Kit used following the manufacturer's instructions? | |
| Other information | |
| Are the performance characteristics included in the EPPO diagnostic protocol? | yes |
| Performance Criteria : | |
| Organism 1.: | <i>Erwinia amylovora</i>(ERWIAM) |

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| Analytical sensitivity | |
| What is smallest amount of target that can be detected reliably? | 10 ⁵ -10 ⁶ CFU/mL plant extract |
| Diagnostic sensitivity | |
| Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98 | Proportion of true positives/total number of samples: 0.13 (in samples from 1 to 10 ⁶ CFU/mL and healthy samples I ring test in 2010) |
| Standard test(s) | - |
| Analytical specificity - inclusivity | |
| Number of strains/populations of target organisms tested | 39 E. amylovora strains all positive |
| Specificity value | 100% |
| Analytical specificity - exclusivity | |
| Number of non-target organisms tested | 61 strains all negative |
| Specificity value | E. tasmaniensis, E. pyrifoliae, E. piriflorinigrans |
| Cross reacts with | Erwinia pyrifoliae Erwinia piriflorinigrans |
| Diagnostic Specificity | |
| Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test | Proportion of true negatives/total number of samples: 0.93 (in samples from 1 to 10 ⁶ CFU/mL and healthy samples in ring test in 2010) |
| Specify the test(s) | - |
| Reproducibility | |
| Provide the calculated % of agreement for a given level of the pest (see PM 7/98) | 94% when tested with different operators in IVIA assays |
| Repeatability | |
| Provide the calculated % of agreement for a given level of the pest (see PM 7/98) | 96% In IVIA assays |
| Test performance study | |
| Test performance study? | yes |
| Brief details of the test performance study and its output. It available, link to published article/report | Yes (14 laboratories from Europe, Morocco, USA and New Zealand) analysed 12 samples each (from 1 to 10 ⁶ CFU/mL plant extract and healthy samples). Details about ring test protocol available. |
| Other information | |
| Any other information considered useful | See details in Braun-Kiewnick et al (2011). A rapid lateral-flow immunoassay for phytosanitary detection of Erwinia amylovora and on-site fire blight diagnosis. Journal of Microbiological Methods 987:1-9. Recommended only for symptomatic samples for its low sensitivity but high specificity. |