**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<br>CV-315, km. 10.7, 46113 Moncada, Spain |
| **Short description of the test** | Detection of Erwinia amylovora 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)** | Erwinia amylovora (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 Erwinia amylovora (version 2) |
| **Name of the test** | Lateral flow devices |
| ***Kit*** | |
| **Is a kit used** | yes |
| **Manufacturer name** | BIOREBA |
| **Specify the kit used** | AgriStrip Erwinia amylovora |
| Kit used following the manufacturer's instructions? | |
| ***Other information*** | |
| **Are the performance characteristics included in the EPPO diagnostic protocol?** | **yes** |
| **Performance Criteria :** | |
| **Organism 1.:** | **Erwinia amylovora(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<br>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. |

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