

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 Enrichment-DASI ELISA in King's B or CCT liquid media |
| 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 DASI-ELISA |
| Method: Serological DASI-ELISA | |
| 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 | enrichment DASI-ELISA (Gorris et al. 1996) |
| Other information | |
| Other details on the test | Enrichment (in King's B or CCT liquid media) followed by DASI-ELISA using specific monoclonal antibodies. |
| Are the performance characteristics included in the EPPO diagnostic protocol? | yes |
| Performance Criteria : | |
| Organism 1.: | <i>Erwinia amylovora</i>(ERWIAM) |
| Analytical sensitivity | |
| What is smallest amount of target that can be detected reliably? | - 10 CFU/mL plant extract in King's B and in CCT (Gorris et al, 1996). - 10-10 ² CFU/mL plant |

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| | extract in King's B and 10 ³ -10 ⁴ CFU/mL plant extract in CCT (ring test in 2010) |
| 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: 0.73 (in samples from 1 to 10 ⁶ CFU/mL of plant extract and healthy samples in ring test 2010) |
| Standard test(s) | Not specified |
| Analytical specificity - inclusivity | |
| Number of strains/populations of target organisms tested | 250 E. amylovora strains, all positive (Gorris et al, 1996 and IVIA assays) |
| Specificity value | 100% |
| Analytical specificity - exclusivity | |
| Number of non-target organisms tested | 258 unidentified strains from fire blight hosts and 45 strains of plant pathogens, all negative (Gorris et al, 1996) |
| Specificity value | 100% |
| 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: 0.90 (in samples from 1 to 10 ⁶ CFU/mL of plant extract and healthy samples in ring test 2010) |
| Reproducibility | |
| Provide the calculated % of agreement for a given level of the pest (see PM 7/98) | 95% 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) | 100% 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 | 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: Gorris et al, 1996. A sensitive and specific detection of E. amylovora, based on the ELISA-DASI enrichment method with monoclonal antibodies. Acta Horticulturae 411, 41-45 |

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