

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 | Clavibacter michiganensis subsp. michiganensis | |
| Short description | Detection of Clavibacter michiganensis subsp. michiganensis from seed by plating | |
| Laboratory contact details | Netherlands Institute for Vectors, Invasive plants and Plant health P.O. Box 9102, 6700 HC Wageningen, Netherlands | |
| Date and reference of the validation report | 2010-02-02 - Validation Report of the isolation method for Clavibacter michiganensis michiganensis (Naktuinbouw version: 1.0) | |
| Validation process according to EPPO Standard PM 7/98: | Yes | |
| Reference of the test description | 0 Koenraad, H., van Vliet, A., Neijndorff, N., and Woudt, B. 2009. Improvement of semi-selective media for the detection of Clavibacter michiganensis subsp. michiganensis in seeds of tomato. (Abstr.) Phytopathology 99:S66. | |
| Is the test the same as described in the EPPO DP? | No May be included in the revision of PM 7/042 | |
| Is the lab accredited for this test? | No | |
| Plant species tested (if relevant) | Solanum lycopersicum | |
| Matrices tested (if relevant) | Seed (seed lots with both a high and a low saprophytic background were included in the validation) | |
| 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 | | |
| Plating methods: selective isolation | X | Isolation plating on two semi-selective media : FSCM and CMM1 |
| Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting. | | |

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| 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? | 25 cfu*ml-1 | |
| <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 | 100% | |
| Specify the standard test | Isolation on the conventional media SCM and D2ANX | |
| <u>Analytical specificity</u> | | |
| Specificity value | | |
| Number of strains/populations of target organisms tested | 20 cmm strains (see details in the full validation report) | |
| Number of non-target organisms tested | 20 related strains (see details in the full validation report) | |
| Cross reacts with (specify the species) | No cross reaction, growth performance of cmm strains is higher than the growth performance of the related bacteria | |
| <u>Diagnostic Specificity</u> | | |
| Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test | 100% | |
| Specify the standard test | Isolation on the conventional media SCM and D2ANX | |
| <u>Reproducibility</u> | | |
| Provide the calculated % of agreement for a given level of the pest (see PM 7/98) | 93.8% | |
| <u>Repeatability</u> | | |
| Provide the calculated % of agreement for a given level of the pest (see PM 7/98) | 100% | |
| <u>Test performance study</u> | | |
| Test performance study? | No | |
| Include brief details of the test performance study and its output.It | | |

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| available, provide a link to published article/report | |
| Other information | |
| Any other information considered useful e.g. robustness, ease of performing the test, etc. | |
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| The following complementary files are available online: | <ul style="list-style-type: none"> • Validation report of the isolation method for <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i>. Naktuinbouw 2010-02 |