

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	detection of Erwinia amylovora by isolation on culture medium	
Laboratory contact details	National Phytosanitary Laboratory 11 BLVD Voluntari, 077190 Voluntari, Romania	
Date and reference of the validation report	2015-07 - Cod: F 6 PS BA 2, Vers. 1 / rev. 0 / 07/2015	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	PM 7/020	
Is the test the same as described in the EPPO DP?	Modified For CCT and KingB medium the recipe used is the same as in PM 7/20. For NSA medium a different recipe was used (1 g beef extract, 2 g yeast extract, 5 g Peptone, 5 g NaCl, 50 g sucroza 5%, 15 g agar)	
Is the lab accredited for this test?	Yes	
Plant species tested (if relevant)		
Matrices tested (if relevant)		
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	OEPP PM 7/20 (2) media: NSA (modified from standardized protocol), CCT, King B
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?	10 ² cells/mL for NSA and King'B media and 10 ³ cells/mL for CCT media (100% of the 6 tests positive).	
<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	Not evaluated	
Specify the standard test		
<u>Analytical specificity</u>		
Specificity value		
Number of strains/populations of target organisms tested	1: Erwinia amylovora (E.a.) PD 4072	
Number of non-target organisms tested	1: Pseudomonas syringae pv. syringae (P.s.s.) NCPPB 2778	
Cross reacts with (specify the species)	NSA and King'B media are not specific of Erwinia amylovora. Pseudomonas syringae pv. syringae can be isolated on those media.	
<u>Diagnostic Specificity</u>		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	Not evaluated	
Specify the standard test		
<u>Reproducibility</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	NSA and King'B: 100% for a concentration of 10 ² cells/mL CCT: 100% for a concentration of 10 ³ cells/mL	
<u>Repeatability</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	NSA and King'B: 100% for a concentration of 10 ² cells/mL CCT: 100% for a concentration of 10 ³ cells/mL	
<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"> • VALIDAREA Ea Izolare pe mediu de cultura