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	Х	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				
Analytical sensitivity (= limit of detection)				
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).			
Diagnostic sensitivity				
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				
Analytical specificity				
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.			
Diagnostic Specificity				
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	Not evaluated			
Specify the standard test				
Reproducibility				
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	NSA and k CCT: 1009	King'B: 100% for a concentration of 10 ² cells/mL % for a concentration of 10 ³ cells/mL		
Repeatability				
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	NSA and k CCT: 1009	King'B: 100% for a concentration of 10^2 cells/mL % for a concentration of 10^3 cells/mL		
Test performance study				
Test performance study?	No			
Include brief details of the test performance study and its output.It available, provide a link to published article/report				

Other information	
Any other information considered useful e.g. robustness, ease of performing the test, etc.	
The following complementary files are available online:	• VALIDAREA Ea Izolare pe mediu de cultura