

**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.

<b>Target Organism</b>	Pantoea stewartii subsp. stewartii	
<b>Short description</b>	Conventional PCR (AGES primers) from corn seed macerate	
<b>Laboratory contact details</b>	EUPHRESCO PANTOEAE STEWARTII , , EUPHRESCO	
<b>Date and reference of the validation report</b>	2011-05-31 -	
<b>Validation process according to EPPO Standard PM 7/98:</b>	Yes	
<b>Reference of the test description</b>	PM 7/060 Unpublished test	
<b>Is the test the same as described in the EPPO DP?</b>	Yes	
<b>Is the lab accredited for this test?</b>	No	
<b>Plant species tested (if relevant)</b>	Zea mays	
<b>Matrices tested (if relevant)</b>	PCR can be performed for identification of isolates/strains and symptomatic plant parts; for asymptomatic part or seed detection, in the framework of the test performance study, this PCR was not the most sensitive but the evaluation of this PCR was performed with DNA extraction.	
<b>List of methods used</b>		
<b>Method for extraction / isolation / baiting of target organism from matrix</b>		
<b>Molecular methods, e.g. hybridization, PCR and real time PCR</b>	X	Conventional PCR
<b>Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay</b>		
<b>Plating methods: selective isolation</b>		
<b>Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.</b>		
<b>Pathogenicity test</b>		
<b>Fingerprint methods: protein profiling, fatty acid profiling &amp; DNA</b>		

<b>profiling</b>		
<b>Morphological and morphometrical methods intended for identification</b>		
<b>Biochemical methods: e.g. enzyme electrophoresis, protein profiling</b>		
<b>Other</b>		
<b><u>Analytical sensitivity (= limit of detection)</u></b>		
<b>What is smallest amount of target that can be detected reliably?</b>	10 <sup>2</sup> CFU/mL on pure culture	
<b><u>Diagnostic sensitivity</u></b>		
<b>Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98</b>	Not tested	
<b>Specify the standard test</b>		
<b><u>Analytical specificity</u></b>		
<b>Specificity value</b>	Inclusivity + exclusivity= 96,7% on 30 target and no-target strains	
<b>Number of strains/populations of target organisms tested</b>	Inclusivity tested with 15 target strains: 100% (bacterial suspension concentrations about 10 <sup>7</sup> bact./mL) Pantoea stewartii subsp. stewartii: CFBP 3167/ NCPPB 2295/ICMP 257/ATCC 8199; CFBP 1719/ ICPB SS104; CFBP 2502 / NCPPB 449 CFBP 3157/ NCPPB 1553; CFBP 3166 / ICMP 5930; CFBP 3393/ LMG 2716/ PDDCC 270; CFBP 3394/ LMG 2717/ PDDCC 722; CFBP 3395/ LMG 2718/ ATCC 8200; CFBP 3396/ LMG 2719/ PDDCC 5929; CFBP 3445/ NCPPB 3379; CFBP 3517; CFBP 3168; CFBP 3165; CFBP 3169; NCPPB 3253	
<b>Number of non-target organisms tested</b>	Exclusivity was performed by one lab on a list of 100 non-target strains and obtained 99% with the cross reaction of P indologenes	
<b>Cross reacts with (specify the species)</b>	Yes with Pantoea stewartii subsp. indologenes	
<b><u>Diagnostic Specificity</u></b>		
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	Not tested	
<b>Specify the standard test</b>		
<b><u>Reproducibility</u></b>		
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>		
<b><u>Repeatability</u></b>		
<b>Provide the calculated % of</b>	100%	

<b>agreement for a given level of the pest (see PM 7/98)</b>	
<b><u>Test performance study</u></b>	
<b>Test performance study?</b>	Yes
<b>Include brief details of the test performance study and its output. If available, provide a link to published article/report</b>	<p>Based on the test performance study with 5 laboratories involved, in the framework of EUPH05 Pantoea stewartii ssp. stewartii, EUPHRESCO Final Report 2010-2011</p> <p>Analytical sensitivity: 70% of agreement at <math>7 \times 10^4</math> CFU/mL  Diagnostic sensitivity (10 samples/2repeats/soak/lab): 70 %  Diagnostic specificity (5 samples/2repeats/soak/lab): 76 %  (cross reaction with Pantoea stewartii subsp. indologenes)  Qualitative Repeatability: 95 %  Accuracy: &lt;90%  Qualitative Reproducibility: 58 %</p>
<b><u>Other information</u></b>	
<b>Any other information considered useful e.g. robustness, ease of performing the test, etc.</b>	