

**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.

<b>Laboratory contact details</b>	Bacteriology. Instituto Valenciano de Investigaciones Agrarias CV-315, km. 10.7, 46113 Moncada, Spain
<b>Short description of the test</b>	Detection of 'Candidatus Liberibacter solanacearum' by real time PCR in different types of plant material using Plant Print diagnostics kit
<b>Date, reference of the validation report</b>	2016-04-28 - Report 2016-04-28; Validation assay October 2012 - Performance study n°1
<b>Validation process according to EPPO Standard PM7/98?</b>	yes
<b>Is the lab accredited for this test?</b>	yes
<b>Was the validated data generated in the framework of a project?</b>	
<b>Description of the test</b>	
<b>Organism(s)</b>	'Candidatus Liberibacter solanacearum'(LIBEPS)
<b>Detection / identification</b>	detection
<b>Method(s)</b>	Extraction Molecular real time PCR
<b>Method: Extraction</b>	
<b>Reference of the test description</b>	
<b>Other information</b>	
<b>Other details on the test</b>	Direct sample preparation without DNA purification (spot procedure)
<b>Method: Molecular real time PCR</b>	
<b>Reference of the test description</b>	
<b>As or adapted from an EPPO diagnostic protocol</b>	yes
<b>EPPO Diagnostic Protocol name</b>	PM 7/143 ' <i>Candidatus</i> Liberibacter solanacearum' (version 1)
<b>Name of the test</b>	Real-time PCR based on 16S rRNA gene (Teresani et al., 2014)
<b>Is the test modified compared to the reference test</b>	yes Use of a kit

<b>Kit</b>	
<b>Is a kit used</b>	yes
<b>Manufacturer name</b>	PLANT PRINT
<b>Specify the kit used</b>	'Candidatus Liberibacter solanacearum' Complete real-time PCR kit for direct screening (Ref: CaLsol/100)
Kit used following the manufacturer's instructions?	
<b>Other information</b>	
<b>Are the performance characteristics included in the EPPO diagnostic protocol?</b>	<b>no</b>
<b>Performance Criteria :</b>	
<b>Organism 1.:</b>	<b>'Candidatus Liberibacter solanacearum'(LIBEPS)</b>
<b>Analytical sensitivity</b>	
<b>What is smallest amount of target that can be detected reliably?</b>	Not calculated for a non-culturable bacterium. The performance study was oriented to receive qualitative results.
<b>Diagnostic sensitivity</b>	
<b>Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98</b>	87% 232 samples agreement / 265 (including replications performed in some labs)
<b>Standard test(s)</b>	Standard test was real time PCR according to Teresani et al. after CTAB extract
<b>Diagnostic Specificity</b>	
<b>Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test</b>	99% 263 samples agreement / 265 (including replications performed in some labs.)
<b>Specify the test(s)</b>	Standard test was real time PCR according to Teresani et al. after CTAB extract
<b>Reproducibility</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	83% (465/530)
<b>Repeatability</b>	
<b>Provide the calculated % of agreement for a given level of the pest (see PM 7/98)</b>	95% The repeatability was calculated in 7 laboratories that performed 3 replications each one and at least in one replication 100% true positives and true negatives according to the standard test (20/21), were detected
<b>Test performance study</b>	
<b>Test performance study?</b>	yes
<b>Brief details of the test performance study and its output.It available, link to published article/report</b>	There were involved 28 laboratories from 15 countries: AGES, Austria; INTA-EEA, Argentina; PROINPA, Bolivia; Agronômica, Brazil; ANSES, France (2 Labs.); FN3PT/RD3PT-UMT INNOPLANT/INRA Paris, France; BPI,Greece; Genlogs Ltd.

	<p>Hungary; Ministry Agricult. and Rural Develop., Israel; University of Catania Italy; NPPO/NRC, The Netherlands; Ministry for Primary Industries, New Zealand; Plant Prot. Central Research Institute, Turkey; SASA, United Kingdom; IFAPA-Sevilla, Spain; INIA-Madrid, Spain; Sanidad Vegetal-Sevilla, Spain; Centro Regional de Diagnostico-Salamanca, Spain; Estación Fitopatologica -Areiro, Spain; Sanidad Vegetal-Huelva, Spain; Lab Regional-Logroño, Spain; IVIA / Bacteriología, Spain; IVIA / Virología e Inmunología, Spain; IVIA / Reference Laboratory MAGRAMA, Spain; USDA/ARS Prosser, WA, USA; USDA-ARS, USA; Experiment Station Rd, Bushland, Texas, USA;</p>
<p><b>Other information</b></p>	
<p><b>Any other information considered useful</b></p>	<p>The diagnostic kit evaluated is simple to use, rapid and accurate. It showed a high robustness in 28 laboratories from 15 countries, and can be applied for rapid testing of plant material of at least the five plant species evaluated. For maximum accuracy a CTAB or other types of DNA extraction is advised.</p>

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