

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.

Laboratory contact details	Bacteriology. Instituto Valenciano de Investigaciones Agrarias CV-315, km. 10.7, 46113 Moncada, Spain
Short description of the test	detection of 'Candidatus Liberibacter asiaticus', 'Candidatus Liberibacter africanus', 'Candidatus Liberibacter americanus' 'Candidatus Liberibacter americanus' by Molecular real time PCR in DNA samples
Date, reference of the validation report	2021-03-08 - TPS 2020 HLB
Validation process according to EPPO Standard PM7/98?	yes
Is the lab accredited for this test?	no
Was the validated data generated in the framework of a project?	EURL
If yes, please specify	Test Performance Study for the molecular detection of regulated 'Candidatus Liberibacter' species in Citrus sinensis and Citrus reticulata using conventional and real-time PCR tests
Description of the test	
Organism(s)	'Candidatus Liberibacter asiaticus'(LIBEAS) 'Candidatus Liberibacter africanus'(LIBEAF) 'Candidatus Liberibacter americanus'(LIBEAM)
Detection / identification	detection
Matrix(ces) tested	Other DNA samples
Plant species tested	Citrus reticulata, Citrus sinensis
Method(s)	Molecular Conventional PCR Molecular real time PCR
Method: Molecular Conventional PCR	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	
As or adapted from an IPPC diagnostic protocol	

Is the test modified compared to the reference test	
Kit	
Is a kit used	
Other information	
Other details on the test	
Method: Molecular real time PCR	
Reference of the test description	
As or adapted from an EPPO diagnostic protocol	
New test being considered for inclusion in the next version of the EPPO diagnostic protocol?	
As or adapted from an IPPC diagnostic protocol	
Is the test modified compared to the reference test	
Kit	
Is a kit used	
Other information	
Other details on the test	
Are the performance characteristics included in the EPPO diagnostic protocol?	
Performance Criteria :	
Organism 1.:	'Candidatus Liberibacter asiaticus'(LIBEAS)
Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	
Standard test(s)	
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	
Specificity value	
Analytical specificity - exclusivity	
Number of non-target organisms tested	
Specificity value	
Cross reacts with	

<u>Diagnostic Specificity</u>	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	
Specify the test(s)	
<u>Reproducibility</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	
<u>Repeatability</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	
Organism 2.:	'Candidatus Liberibacter africanus'(LIBEAF)
<u>Analytical sensitivity</u>	
What is smallest amount of target that can be detected reliably?	
<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	
Standard test(s)	
<u>Analytical specificity - inclusivity</u>	
Number of strains/populations of target organisms tested	
Specificity value	
<u>Analytical specificity - exclusivity</u>	
Number of non-target organisms tested	
Specificity value	
Cross reacts with	
<u>Diagnostic Specificity</u>	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	
Specify the test(s)	
<u>Reproducibility</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	
<u>Repeatability</u>	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	
Organism 3.:	'Candidatus Liberibacter americanus'(LIBEAM)

Analytical sensitivity	
What is smallest amount of target that can be detected reliably?	
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 2 of PM 7/98	
Standard test(s)	
Analytical specificity - inclusivity	
Number of strains/populations of target organisms tested	
Specificity value	
Analytical specificity - exclusivity	
Number of non-target organisms tested	
Specificity value	
Cross reacts with	
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	
Specify the test(s)	
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	
Test performance study	
Test performance study?	no
Brief details of the test performance study and its output. If available, link to published article/report	
Other information	
Any other information considered useful	Test Performance Study for the molecular detection of regulated 'Candidatus Liberibacter' species in Citrus sinensis and Citrus reticulata using conventional and real-time PCR tests

Creation date: 2021-03-08 08:15:55 - Last update: 2021-03-08 08:19:57