EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION
ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA PROTECTION DES PLANTES

20-25700

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.

Basic information regarding the validation report:	
Laboratory contact details	Field filled automatically when connected
Short description of the test	Indicate whether the test is used for detection or identification or both, target pest, method and matrix(ces). The description should be short. Details will be asked when entering the validation data. *For example: Detection of Acidovorax citrulli by real time PCR in seeds*
Date and reference of the validation report	Date of signature of the report and name or code given to the report to ensure traceability.
Validation process according to EPPO Standard PM7/98?	Were the validation data be generated according to the recommendations of PM7/98 (in particular appendix 5)? ☐ Yes ☐ No
Is the lab accredited for this test?	☐ Yes ☐ No
Was the validated data generated in the framework of a project or in the framework of an EURL activity?	☐ No ☐ Yes, EURL activity ☐ Yes, Euphresco project ☐ Yes, other project
(if Yes: please specify)	Specify the name of the project
Description of the test	
Organism(s)	You can enter EPPO code or scientific name; only preferred scientific name will be kept. This field is restricted to existing EPPO codes. If a new EPPO code is needed, a query to EPPO Secretariat should be submitted.
Detection / identification	Precise whether the test is used for detection or identification of the pest or for both. ☐ detection ☐ identification ☐ detection and identification
Matrix(ces) tested	Select the type of matrice(s) tested during the validation process Leaves, Shoots, Fruits, Seeds, Roots, Herbaceous cuttings, Woody cuttings, Wood, Bark, Tubers, Bulbs, Pure culture, Soil, Water, Specimen, Other
Specify the matrix(ces)	Give any additional details regarding the matrix(ces). For example specify where the matrix was obtained from (collection, reference of the material).
Plant species tested	Specify the plant species tested during the validation process. You can enter EPPO code or scientific name; only preferred scientific name will be kept. This field is restricted to existing EPPO codes. If a new EPPO code is needed, a query to EPPO Secretariat should be submitted.
Method(s)	Select one or several method(s) among the one proposed. Extraction, Molecular (Molecular Extraction DNA RNA, Molecular Conventional PCR, Molecular Conventional RT PCR, Molecular real time PCR, Molecular real time RT PCR, Molecular PCR-RFLP,

		Molecular LAMP, Molecular other) Serological (Serological IF, Serological ELISA, Serological DAS-ELISA, Serological DASI-ELISA, Serological PTA ELISA, Serological Tissue print-ELISA or Direct tissue blot immunoassay, Serological Lateral Flow Device, Serological other) Isolation, Bioassay, Pathogenicity, Fingerprint, Morphological, Biochemical, Other
Method: Extraction [same questions are asked for methods other than Molecular / Serological (see below)]		
As in (or adapted from) an EPPO diagnostic protocol ?		Is the test as or adapted from an EPPO diagnostic protocol? ☐ Yes ☐ No
If yes	**EPPO diagnostic protocol name**	Select the EPPO diagnostic protocol from a list of selection based on the organisms indicated in the previous section.
	Name of the test	Select the test used from a list of selection corresponding to the tests described in the annex of the indicated EPPO DP.
As in (or adapted from) an IPPC diagnostic protocol ?		Is the test as or adapted from an IPPC diagnostic protocol? ☐ Yes ☐ No
If yes	**IPPC diagnostic Protocol name**	Select the IPPC diagnostic protocol from a list of selection based on the organisms indicated in the previous section.
If neither EPPO nor IPPC protocols was used, please provide the reference of the test		Please indicate the scientific publication on which is based the diagnostic test.
Is the test modified compared to the reference test		☐ Yes ☐ No
If yes	**Specify the modifications:**	Specify the modifications compared to the reference test
Other details on the test		Specify any other details on the test (example: reagents used)
Are the performance characteristics included in the EPPO diagnostic protocol?		EPPO secretariat to fill
Method: Molecular / Serological		
As in (or adapted from) an EPPO diagnostic protocol ?		Is the test as or adapted from an EPPO diagnostic protocol? ☐ Yes ☐ No
If yes	**EPPO diagnostic protocol reference**	Select the EPPO diagnostic protocol from a list of selection based on the organisms indicated in the previous section.
	Name of the test	Select the test used from a list of selection corresponding to the tests described in the annex of the indicated EPPO DP.
As in (or adapted from) an IPPC diagnostic protocol ?		Is the test as or adapted from an IPPC diagnostic protocol? ☐ Yes ☐ No
If yes	**IPPC diagnostic Protocol name:**	Select the IPPC diagnostic protocol from a list of selection based on the organisms indicated in the previous section.
If neither EPPO nor IPPC protocols was used, please provide the reference of the test		Please indicate the scientific publication on which is based the diagnostic test.
Is the test modified compared to the reference		☐ Yes ☐ No
If yes	**Specify the modifications:**	Specify the modifications compared to the reference test
Is a kit used		☐ Yes ☐ No
If yes	**Manufacturer name**	Please indicated the manufacturer of the kit (example: QIAGEN, CLEAR DETECTION…) from a list of selection
	Name of the kit	Please indicated the name of the kit (example: DNA easy mini kit…) from a list of selection
	Did you use the kit following the manufacturer's instructions?	☐ Yes ☐ No
	Please specify	Please specify the modification that were made compared to manufacturer's instructions
Reaction type (to add for molecular and serological)		Select from a list of selection the type of molecular amplification (simplex, duplex, triplex, multiplex, nested) and whether a probe is used.
Other details on the test		Specify any other detail on the test (example: reagents used)

Are the performance characteristics included in the EPPO diagnostic protocol?	EPPO secretariat to fill
Performance Criteria :	
Organism 1.: (same for other organisms)	
Analytical sensitivity	
What is smallest amount of target that can be detected reliably (specify the level of agreement between experiments see PM 7/98 Appendix 5)?	*e.g. nb of specimen, cfu/mL, cell/mL, copy numbers, quantity of DNA/RNA….*
Diagnostic sensitivity	
Proportion of infected/infested samples tested positive compared to results from the standard test, see appendix 6 of PM 7/98	*e.g. 100%*
Standard test(s)	Specify the standard test used or indicate if this is a comparison with samples of known status.

Analytical specificity - inclusivity	
Strains/populations/specimen of target organisms tested	Provide the number and the list of strains/populations of target organism evaluated.
Inclusivity value	*e.g. 100% (10 strains/populations/specimens of the target organism could be detected/identified out of the 10 tested)*
Strains/populations/specimen of the target not detected/identified	Specify the strains/population which cross react.
Analytical specificity - exclusivity	
Non-target organisms tested	Provide the number and the list of species evaluated.
Exclusivity value	*e.g. 100% (10 non-target species (or strains/populations/specimens of non-target species) could be excluded out of the 10 tested)*
Cross reacts with	Specify the species which cross react. You can enter EPPO code or scientific name; only preferred scientific name will be kept. This field is restricted to existing EPPO codes. If a new EPPO code is needed, a query to EPPO Secretariat should be submitted.
Diagnostic Specificity	
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	*e.g. 99%*
Specify the test(s)	Specify the standard test used or indicate if this is a comparison with samples of known status.
Reproducibility	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	*e.g. 100% (e.g. evaluated with3 replicates at 10^3 cfu/mL by 2 operators on 3 different days and with 2 different PCR equipment) Data for more than one concentration level may be provided*
Repeatability	
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	*e.g. 100% (e.g. evaluated on 3 replicates at 10^3 cfu/mL). Data for more than one concentration level may be provided.*
Test performance study	
Test performance study?	Have the results been produced as part of a Test Performance Study (TPS)?
Brief details of the test performance study and its output. It available, link to published article/report	*e.g. Test performance study organized in the framework of the Euphresco project XX involving 12 laboratories from 8 countries*
Other information	
Any other information considered useful	