

Food and Agriculture Organization of the United Nations



International Plant Protection Convention

Department for Environment Food & Rural Affairs

Quality assurance and validation in diagnostics: Why is it important?



Context

Global and increasing trade of plant and plant products **Diversity of products** Quick evolution of sectors Critical challenges for plant production and plant health Facilitate safe trade Secure food supply Avoid loss of productions Avoid dissemination of pests Avoid environmental impacts Need for rapid and reliable plant pests diagnostic



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Context

Quality assurance and validation support the reliability of diagnostics



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How quality assurance support the reliability of diagnostic

Quality assurance implies in the laboratory:

- Written and standardized testing procedures
 - Reproducibility of testing
 - Traceability

Mutual / multi-lateral recognition of diagnostic

- Staff competence monitoring
- Confidence in testing and tests results Mutual / multi-lateral recognition





How quality assurance support the reliability of diagnostic

Quality assurance implies :

- Standardization of diagnostic protocol
 - IPPC diagnostic standards (31 protocols available)

https://www.ippc.int/fr/core-activities/standards-setting/ispms/

regional standards (e.g. 150 EPPO diagnostic standards available at EPPO website)

https://www.eppo.int/RESOURCES/eppo_standards/pm7_diagnostics

- Cooperation at international / regional levels (e.g European cooperation for Accreditation)
- Standardization of implementation of ISO standards and validation procedure
 - EPPO PM 7/98 EPPO PM7/122

PM 7/98 (5) Specific requirements for 1	aboratories preparing
accreditation for a plant post diagnostic	activity
accreditation for a plant pest diagnostic	activity
Bulletin OEPP/EPPO Bulletin (2014) 44 (3), 390–399	ISSN 0250-8052. DOI: 10.1111/epp.121
Furnnean and Mediterranean Plant Protection Organization	
Organisation Européenne et Méditerranéenne pour la Protection des Plantes	PM 7/122
Diagnostics	



Validation is a complex process:

Development of sampling and testing program

Expression of needs From risk manager's perspective From laboratory's perspective



Test fit for purpose

Performance of test Performance study Standardized process Appropriate metrics



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Validation is a complex process:

Expression of needs From risk manager's perspective From laboratory's perspective

Misunderstandings Ambiguities

Which common acceptable risk for false positive / negative result?



London, 21 – 23 September 2022 | International Plant Health Conference

Harrison et al. 2022 – PhytoFrontiers https://doi.org/10.1094/PHYTOFR-03-22-0027-FI

Validation is a complex process:

Expression of needs From risk manager's perspective From laboratory's perspective Need for consensus tool to assist the design of **optimal sampling and testing program** for early detection of an invasive pest

➡ VALITEST (EU funded project)

developed a prototype mathematical / statistical framework To be further refined and evaluated

Harrison et al. 2022 - Phytofrontiers https://doi.org/10.1094/PHYTOFR-03-22-0027-FI

https://www.valitest.eu



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 773139





Validation is a complex process:

Performance of test Performance study Standardized process Appropriate metrics

Standardized process Dedicated documentation Shared data International cooperation



FIGURE 2 Validation process

EPPO 2021 PM 7/98 (5) Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity DOI: 10-1111/epp.12780



Validation is a complex process:

Performance of test Performance study Standardized process Appropriate metrics Need for validation data and update of diagnostic protocols

➡ VALITEST (EU funded project) produced validation data 11 pests concerned



VALITEST test performance studies

Pests concerned by the test performance studies:

11 pests from different groups

bacteria

fungi

nematodes

viruses

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Pest	TPS organizer	Tests	Number of participants	Number of samples prepared
Erwinia amylovora	NIB	6 tests (real-time PCR, LFDs and LAMP)	32 (from 20 countries)	~900
Pantoea stewartii subsp. stewartii	NIB	6 tests (real-time PCR, PCR)	23 (from 16 countries)	~450
Citrus tristeza virus	ANSES	11 tests (ELISA, TPIA, Conventional RT-PCR, Real-time RT-PCR, RT-LAMP and ImmunoStrip)	17 (from 11 countries)	~1650
Bursaphelenchus xylophilus	ANSES	5 tests (conventional PCR, real-time PCR, LAMP)	21 (from 18 countries)	~430 DNA extracts ~280 spiked wood extracts
Plum pox virus	NVWA	8 tests selected (RT-PCR, real-time RT-PCR, DAS-ELISA)	17 (from 12 countries)	~700
Fusarium circinatum	FERA	6 tests (plating, PCR, real-time PCR)	20 (from 15 countries)	~640
Pest	TPS organizer	Tests	Number of participants	Number of samples prepared
Tomato spotted wilt tospovirus	NIB	8 tests (DAS-ELISA, on-site tests, conventional and real-time RT- PCR)	21 (from 12 countries)	~1540
Xylophilus ampelinus	FERA	9 tests (ELISA, IF, conventional and real-time RT-PCR)	12 (from 11 countries)	~570
Cryphonectria parasitica	UNITO	3 tests (conventional and real-time PCR)	11 (from 8 countries)	~220
Plum pox virus	ANSES	3 tests (LFD RPA, LFD)	15 (from 12 countries)	~640
Tomato brown rugose fruit virus	CREA	5 tests (conventional and real-time RT-PCR)	34 (from 18 countries)	~850
Xanthomonas citri pv. citri	ANSES	13 tests (conventional and real-time PCR, LAMP and direct molecular tests performed from Immunostrips or Whatman [™] FTA cards)	19 (from 14 countries)	~960



Validation is a complex process:

Performance of test Performance study Standardized process Appropriate metrics Need for validation data and update of diagnostic protocols

⇒ VALITEST (EU funded project) produced validation data

11 pests concerned 12 test performance studies conducted 80 diagnostic tests evaluated (ELISA, IF, PCR...) More details at <u>https://www.valitest.eu</u>

Revision of 13 EPPO standards Validation data available at EPPO diagnostic data base (<u>https://dc.eppo_int/</u>)



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Validation is a complex process:

Performance of test Performance study Standardized process Appropriate metrics Need for validation data and update of diagnostic protocols

⇒ VALITEST (EU funded project)

Development of the European Plant Diagnostic Industry Association (EPDIA)



ABOUT US QUALITY CHARTER DIAGNOSTIC KITS IN ACTION RESOURCES HOME





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POTECTING



VALITEST webinar series and training activities

Quick links

THE CONCEPT OF TEST VALIDATION IN PLANT HEALTH

TEST PERFORMANCE STUDIES ORGANISATION

THE USE AND VALIDATION OF HIGH THROUGHPUT SEQUENCING (HTS) TESTS FOR DIAGNOSTICS OF PLANT PESTS.

Follow Us On



Three series of webinars and training activities were organised in the framework of VALITEST:

- One on the concept of test validation in Plant Health
- One on the organisation of Test Performance Studies (TPS)
- One on the guidelines for the development, validation and routine use of High Throughput Sequencing (HTS) tests for diagnostics of plant pests.

The concept of test validation in Plant Health

Objective of the series and activities

The objectives of this webinar series and activities were:

- To introduce the concept of validation and present the state of the art in terms of choice of a test and analysis of the results of performance evaluation
- To train experts on the use of kits (including on-site and field tests)





Validation is a complex process:

Performance of test Performance study Standardized process Appropriate metrics Need for standardized process for test validation

➡ VALITEST (EU funded project) developed dedicated documentation and ressources

- Recorded webinars
- Projects deliverables

More details at https://www.valitest.eu

- Booklet (Springer eds. – open access)

Critical Points for the Organisation of Test Performance Studies in Microbiology



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 773139

Plant Pathology in the 21st Century

Quality assurance and validation in diagnostics: why is it important?

Ana Vučurović · Nataša Mehle Géraldine Anthoine · Tanja Dreo Maja Ravnikar *Editors*

Critical Points for the Organisation of Test Performance Studies in Microbiology

Plant Pathogens as a Case Study



EN ACCESS



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Need for standardized process for test validation

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Critical Points for the Organisation of Test Performance Studies in Microbiology

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Health Conference

Current challenges

Improve communication between stakeholders, define a common langage

Co-design the sampling and testing programs

Improved validation process standard

Share validation data (e.g EPPO diagnostic database)

Harmonize diagnostic standards (IPPC ISPM n°27 annexes)







Food and Agriculture Organization of the United Nations



Department for Environment Food & Rural Affairs

Thank you

London, 21 – 23 September 2022

International Plant Health Conference

Geraldine ANTHOINE Deputy head – Plant Health Laboratory - ANSES

