

Introduction of the webinar and training activities

The concept of test validation in Plant Health

Webinar 1	What is test validation and why it matters for reliable diagnostics?	Monday 11 th January, 2 pm
Webinar 2	How to adopt a new test in your laboratory?	Friday 15 th January, 2pm
Webinar 3	The use and validation of on-site tests	Wednesday 20 th January, 2pm
Practical training session 1	Analysis of performance characteristics	Tuesday 26 th of January, 2pm to 4:30 pm
Webinar 4	How do companies handle quality control and validation of products and how will the EPDIA charter help in improving this task?	Monday 1st of February, 2pm
Webinar 5	Why is communication on test selection between risk managers and diagnostic laboratories important ?	Monday 15 th of February, 2pm
Practical training session 2	The use of kits: training and demonstration	Thursday 22 nd of April, 2pm

How do companies handle quality control and validation of products and how will the EPDIA charter help in improving this task?

February 1st, 2021

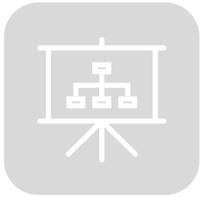
Caroline Freye, LOEWE

Marta Santos, ClearDetections

Camilo Gianinazzi, IpadLab



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



Outlines

LOEWE®

Caroline FREYE

THE CONTEXT

- What is the definition of quality and validation?
- How companies handle with product development and validation?



Marta SANTOS

THE EUROPEAN QUALITY CHARTER

- Why the market needs a Quality Charter?
- What is the aims of the Charter?



Camilo GIANINAZZI

THE EUROPEAN ASSOCIATION

- Establishment reasons of an European Association
- What will be the role of the European Association?



VALITEST WP7 goals



WP7 GOALS

To lay the foundations for structuring the quality and commercial offers for plant health diagnostic tools



PMI Partners

The worldwide largest expertise in products development and manufacturing for plant health





Poll 1

What is your organisation main activity?

select one answer

- Laboratory performing plant pests analysis
- Company manufacturing kits
- Research institute
- Plant Protection service
- Accreditation service

VALITEST

Context of Quality and Validation

Caroline Freye

LOEWE®



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Poll 2

What do you think is quality?

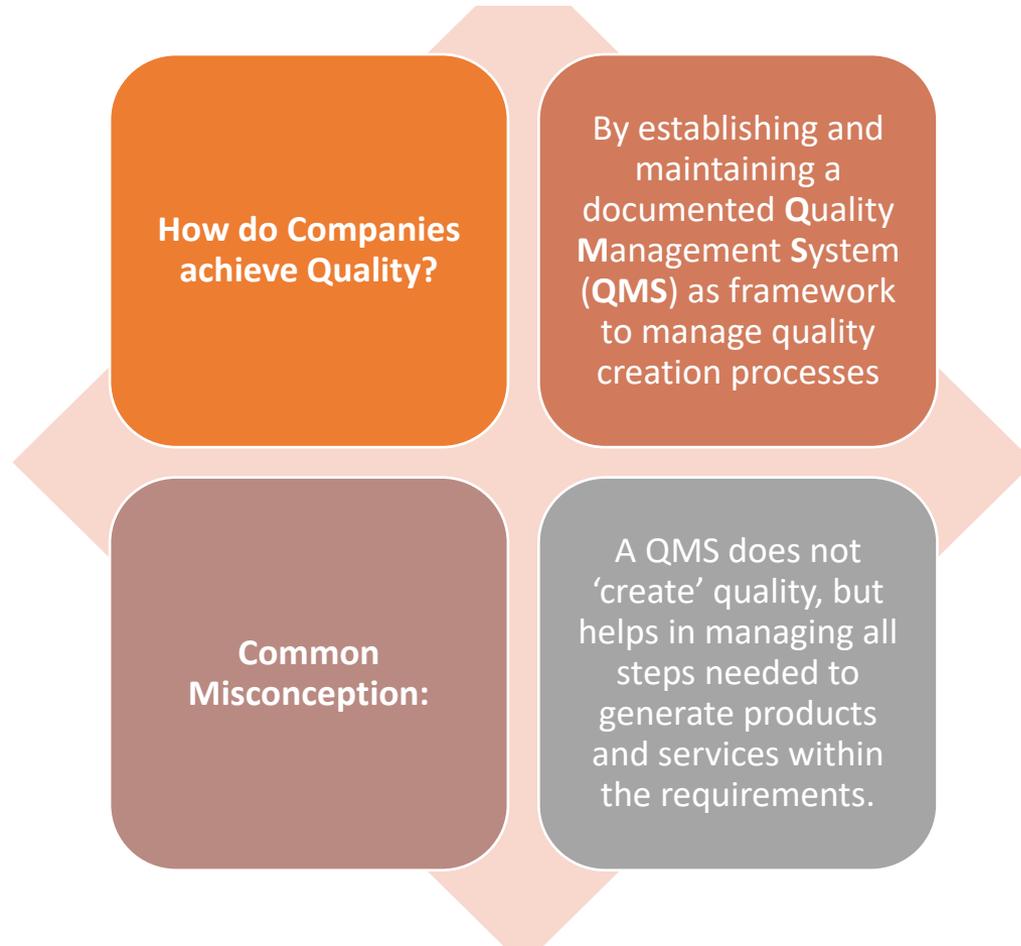
select one answer

- Quality standards used by companies for VALIDATION
- Degree of excellence
- Conformance to requirements
- Fitness for purpose
- Freedom from defects



What is Quality?

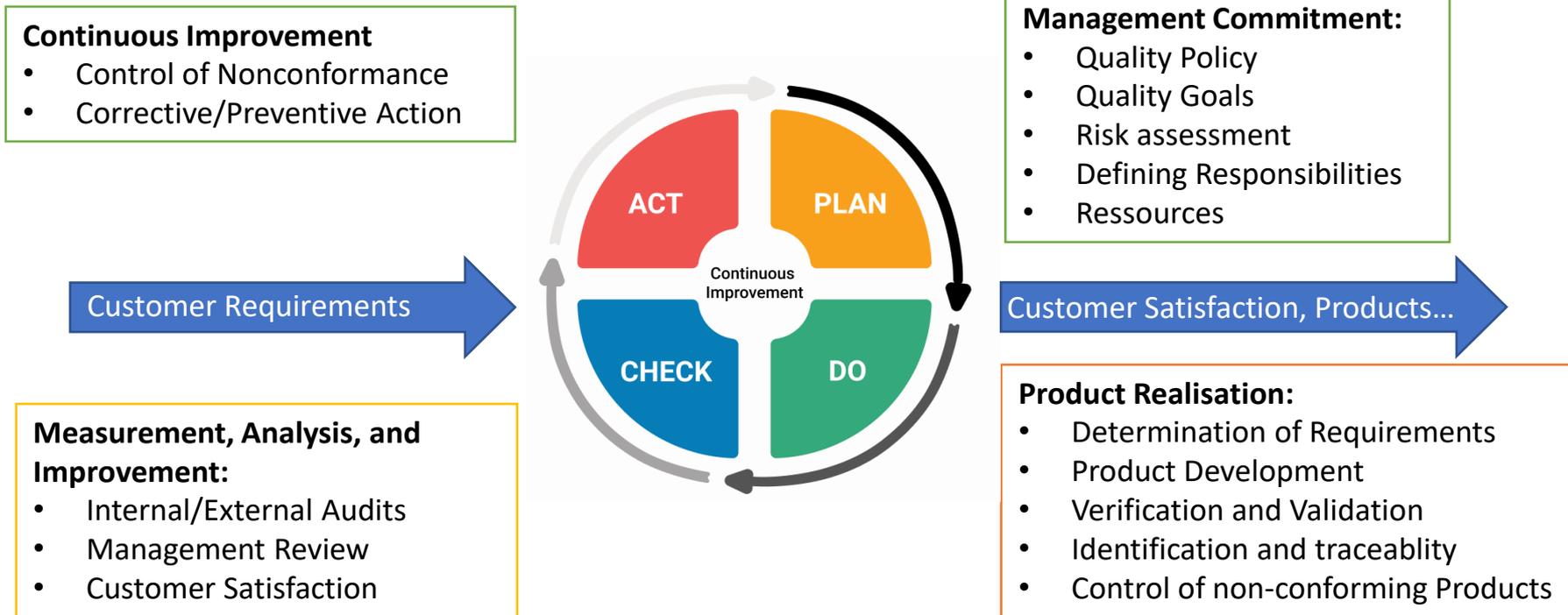
Quality refers to the inherent properties of an object that allow to satisfy stated or implied needs... It is the perception that a customer has about it.





What does a QMS do?

A Quality Management System is a set of documented **business processes** which are implemented to help an organization deliver products which consistently achieve **customer satisfaction**.





Certification - Accreditation

Certification

- Organisation demonstrates that specified requirements of a system, products or personnel are met
- Requirements usually based on international standards



Organizations receive accreditation for specific activities whereas certification relates to the company as a whole

- Formal recognition on the competency towards a specified standard by an authoritative body
- Includes all principles of a QMS

Accreditation



ISO9001: Any Industry
 ISO13458: Medical Devices
 IAF 6949: Automotive Industry
 AS9100: Aerospace Industry

Plant Health Diagnostic Industry:
 Certified QMS with strong focus on the requirements for QC and Validation

ISO17025: Test- and Calibration Laboratories
 ISO17065: Certifying Bodies
 ISO17043: Organizers of Ringtests
 ISO17034: Manufacturer's of Reference Material



Verification - Validation

VERIFICATION

... testing that your product meets the specifications / requirements you have written...

"Did I build what I said I would?"

VALIDATION

..tests how well the product meets the market needs...

"Did I build what is needed?"

Verification and validation are independent procedures that are used together for checking that a product, service, or system meets requirements and specifications and that it fulfills its intended purpose.



Development of a Commercial RNA-PCR Kit for the Detection of ToBRFV

Identification of market needs

Customer needs:

1. Report of ToBRFV in a Greenhouse in Germany in Dec. 2018



© S. Davino, University of Palermo

Identification of Requirements

- ✓ Procurement of infected material
- ✓ Fulfilment of legal requirements: Application for permission and LOA

Planning and Design

- ✓ Definition of product specifications (scope): Sensitive and Specific Detection of ToBRFV in Tomato plants
- ✓ Project assignment to suitable personnel
- ✓ Literature Research, Primer Design, Assay Setup
- ✓ Verification of infected material (Sequencing)

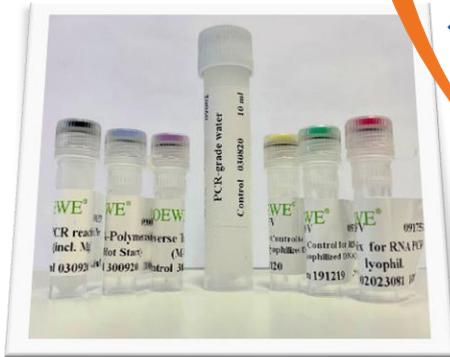
Prototyping

- ✓ Verification: Optimization to meet scope
- ✓ In-house Validation of performance criteria: LOD, Matrix effects, Specificity, Repeatability

Standardization and Production

- ✓ Production release with documentation (SOPs)
- ✓ Routine Quality Control (Lifecycle stability tests)

New requirements





Product validation and Quality control

How much is detected:

- Analytical Sensitivity – Limit of Detection
- Internal standards as reference
- Matrix influence – Healthy plants

What is detected:

- Analytical Specificity – different isolates, non-target pathogens (cross reactions)
- Isolates from internal collection, collaborations, strain collections (DSMZ, ATCC, etc.)

Repeatability/Robustness

- New method validation / Reagent Change
- Technical replicates
- Lot-to-lot Consistency

LOEWE®

Premix Tomato Brown Rugose Fruit Virus

Pathogen Tomato Brown Rugose Fruit Virus

Cat. No. 09175
Control No.: 02023081

Premix (Mixture of forward and reverse primer and dNTPs) 1 x 100 tests (red cap)

Best before once opened use within 6 months
Storage below - 20°C

Analytical Data

Size of expected fragment: 475 bp

Analytical Data

1 2 3 4 5 6 7 1kb plus DNA Ladder
1: Positive control C191219 (DNA based)

No cross reactions were observed for:

CGMMV Cucumber green mottle mosaic virus	PVY Potato virus Y
KGMMV Kyuri green mottle mosaic virus	PVX Potato virus X
ORSV Odontoglossum ringspot virus	ToLCNDV Tomato leaf curl New Delhi virus
PaMMV Paprika mild mottle virus	TSWV Tomato spotted wilt virus
PMMoV Pepper mild mottle virus	TYLCV tomato yellow leaf curl virus
RMV Ribgrass mosaic virus	ToCV Tomato chlorosis virus
TMGMV Tobacco mild green mosaic virus	TRV Tobacco rattle virus
TMV Tobacco mosaic virus	TAV Tomato aspermy virus
ToMV Tomato mosaic virus	TCSV Tomato chlorotic soot orthotospovirus
YMoV Youcai mosaic virus	CYSDV Cucurbit yellow stunting disorder virus
ZGMMV Zucchini green mottle mosaic virus	TBRV Tomato black ring virus
BPeMV Bell pepper mottle virus	TBSV Tomato bushy stunt virus
SFBV Streptocarpus flower break virus	CMV Cucumber mosaic virus
TVCV Turnip vein clearing virus	

ToBRFV isolates tested and detected:

ToBRFV PV-1236 (Tomato, Germany)	ToBRFV PV-1244 (Germany)
ToBRFV PV-1241 (Tomato, Israel)	

Quality Manager: *C. Apollinis*

Best-Before: September 2021
Date released: 25.03.2020



Validation and Validation data

Always:

In-house Validation

- Product specifications
- Certificates of Analysis
- Manuals



Frequently:

by an External Party
(Reference Laboratories,
Research Groups)

- Publications
- EPPO Database

No Common Source on
Complete Validation Data
(up to now...)



Rarely:

Ringtests/TPS (NPPOs)

- Valitest
- PoNTE
- Euphresco...
- EPPO Diagnostic Protocol



Sometimes:

Cooperation with external
partner

- Publications
- Product specifications

VALITEST

Presentation of the EU Plant Health Diagnostics Charter for Industry

Marta Santos Paiva and Marieke Beltman



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





You need info on a diagnostic method what do you do?

You can be

- Laboratory performing official plant pests analyses
- Plant pest private laboratory
- Plant Protection service

You might need

- Choose a new test
- Check if a certain diagnostic is fit for your purpose
- Validation data for your Quality control

You will look

- EPPO database expertise
- Colleagues
- Literature
- Company websites

I just want to use a commercial kit! And not spend time and resources on finding information!



How do you find info about commercial diagnostic kits?

If you're looking for info on a ready to use commercial kit for your diagnostic purpose, what will you do?

- Where will you look for it?
- What guarantee will you have about its performance?
- How do you know if it fits your purpose?
- How can you evaluate its quality?
- How can you trust the IP behind it?

What if there is a way to present you all this information on a structured and systematic way, accessible for everyone and including many of the commercial kits produced in EU?



**Plant Health Diagnostics
Charter for Industry**



Plant Health Diagnostics Charter for Industry - Aims

Quality Guidelines

Defines quality standards used by companies in **VALIDATION**

Defines quality standards used by companies in **PRODUCTION**

Promotes the use of **QUALITY MANAGEMENT SYSTEM**

Standardization & visibility of Information

Make visible **MARKET OPTIONS** for kits

Implements **STANDARDISED DOCUMENTS** by manufacturers to see all information about the kits

Facilitate the **SHARING OF INFORMATION** available about kit



Poll 3

According to you, which are the most important aim of the charter?

select maximum 2 answers

- Quality guidelines for kits VALIDATION
- Quality guidelines for kits PRODUCTION
- Make visible MARKET OPTIONS
- Implementation of STANDARDIZED DOCUMENTATION
- Information Sharing



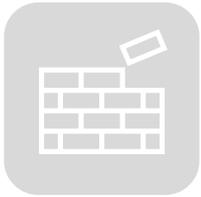
Plant Health Diagnostics Charter for Industry - Scope

Quality Charter provisions are addressed to all the companies **developing, manufacturing and selling** plant pests' detection tests.

Quality Charter scope covers the general **competence requirements** for carrying out high quality kits' development, production and sale.

Each manufacturer shall establish and maintain a **Quality System** that is appropriate for the plant pests' detection kits' design, validation and/or production, and that meets the requirements of the Quality Charter

The commitment to Quality Charter shall ensure the final user that the kits are designed, validated, produced and sold through **high quality standards**



The 6 pillars of the Quality Charter

PILLAR 1

LEGAL FRAMEWORK

All EPDIA members undertake to carry out their own professional activities in accordance with the national and UE laws and regulations

PILLAR 2

QUALITY SYSTEM

All EPDIA members establish QMS including planification, procedures, instructions and resources needed

PILLAR 3

QUALITY PROCEDURES FOR PRODUCTS DEVELOPMENT AND VALIDATION

All EPDIA members undertake to develop and validate new products following high quality standards

PILLAR 4

QUALITY PROCEDURES FOR PRODUCTS MANUFACTURING

All EPDIA members undertake to put in place control procedures to guarantee the quality of the production

PILLAR 5

COMMUNICATION AND MARKETING ETHICS

All EPDIA members commit to providing clear, honest and ethical marketing messages

PILLAR 6

SUSTAINABILITY AND SOCIAL IMPACT

All EPDIA members manufacturer shall act as a responsible citizen company



How will the implementation of the charter look like

QUALITY PROCEDURES FOR PRODUCTS DEVELOPMENT AND VALIDATION

Creation and implementation of Validation Datasheet for industry

General information	Test information	Validation data	Kit information	Other information
<ul style="list-style-type: none">• Organism• Taxonomic group• Manufacturer• Country of production	<ul style="list-style-type: none">• Type of test• Type of detection• Type of sample• Number of targets• Targets• Available extraction method• Scope	<ul style="list-style-type: none">• Validation performance characteristics• Reference material• Manufacturers' validation report• References (such EPPO, article)	<ul style="list-style-type: none">• Product code• Available kit format• Components• Other information	<ul style="list-style-type: none">• User guidelines• MSDS sheet• Other useful information (e.g., product video's)



How will the implementation of the charter look like

QUALITY PROCEDURES FOR PRODUCTS DEVELOPMENT AND VALIDATION

Creation and implementation of Validation Datasheet for industry



This validation data sheet has been produced following the recommendation of EPDIA quality Charter. For more information, please, visit EPDIA website (www.epdia.eu)

KIT CODE	qPCR/CIV-1000-1q (indicate the kit's code)
Kit description	One-step Real-Time RT-PCR for the detection of <i>Citrus tristeza virus</i>
MANUFACTURER	International Plant Analysis and Diagnostics srl Via Euzelica, SNC - 26000 Lodi - Italy www.ipadlab.eu - info@ipadlab.eu

GENERAL INFORMATION

Target Organism	<i>Citrus tristeza virus</i> (indicate the pest's name: http://www.ncbi.nlm.nih.gov/Genbank/)
Method	One-Step Real-Time RT-PCR based on the detection of a fluorescent dye (Taq man) http://www.ncbi.nlm.nih.gov/Genbank/ (indicate the primer sequence of a fluorescent dye) or "ELISA"
References	VALITEST project - TPS round 1 results (European Union's Horizon 2020 research and innovation program - grant agreement N° 773139) (indicate the article title, http://www.ncbi.nlm.nih.gov/pubmed/ , journal name, day, month, year, PPS, EPPO standards...)

SCOPE

Scope	Identification of <i>Citrus tristeza virus</i> by Real-Time PCR (Taq man) http://www.ncbi.nlm.nih.gov/Genbank/ (indicate the primer sequence of a fluorescent dye) or real-time PCR)
Matrix	Leaves
Tested species	Citrus (indicate the plant species tested if relevant)

VALIDATION PERFORMANCE CHARACTERISTICS

Analytical specificity (ability of the method to distinguish the target organism from other organisms and the degree to which the method can distinguish between variants of the organism)	100% http://www.ncbi.nlm.nih.gov/Genbank/ (URL, list of target and non-target organism tested)
Cross reaction with (specify the species)	-
Diagnostic specificity (ability of the kit to detect a validated control sample (that requires testing negative compared to results from another test)	100% (no data available, not applicable)
Analytical sensitivity (level of detection)	-
Diagnostic sensitivity (ability of the kit to detect a validated control sample (that requires testing negative compared to results from another test)	100% (no data available, not applicable)

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www.epdia.eu



Reproducibility (ability of the kit to provide consistent results when applied to aliquots of the same sample tested under different conditions)	- (no data available, not applicable)
Repeatability (the level of agreement between replicates of a sample tested under the same conditions)	- (no data available, not applicable)



REFERENCE MATERIAL

Parameter	Description
Type of reference material	Frozen and fresh Citrus leaves infected and not infected by <i>Citrus tristeza virus</i> (indicate the most information available on the type of positive control used for validation: http://www.ncbi.nlm.nih.gov/Genbank/ (issues of plant), nutrient suspension, greenhouse material, strain collection)
Reference material control	MANUFACTURER INTERNAL CONTROL PROCEDURE WITH: • RT real-time PCR test based on Olmos et al., 1999 (Hacker: Actis Research, 72-1564-1565) • ELISA test - BIOREBA (indicate how the reference material was controlled and by whom (e.g. control with alternative method, strain collection http://www.ncbi.nlm.nih.gov/Genbank/))

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How will the implementation of the charter look like

QUALITY PROCEDURES FOR PRODUCTS MANUFACTURING

Standardization of a quality production certificate

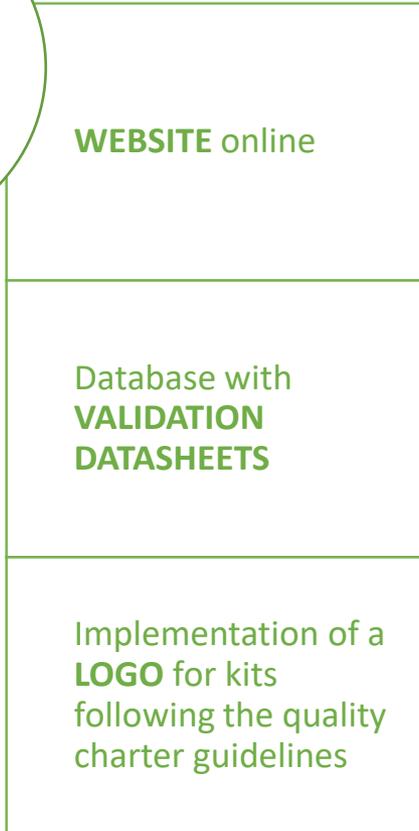
Certificate identification	Product identification	Product conditioning	Quality control results including
<ul style="list-style-type: none">• Number and date of the certificate	<ul style="list-style-type: none">• Name of the product• Catalog reference• Method• Format• Batch number	<ul style="list-style-type: none">• Expiration date• Storage conditions	<ul style="list-style-type: none">• Testing of a positive control• Negative control• Water/buffer control• Other parameters



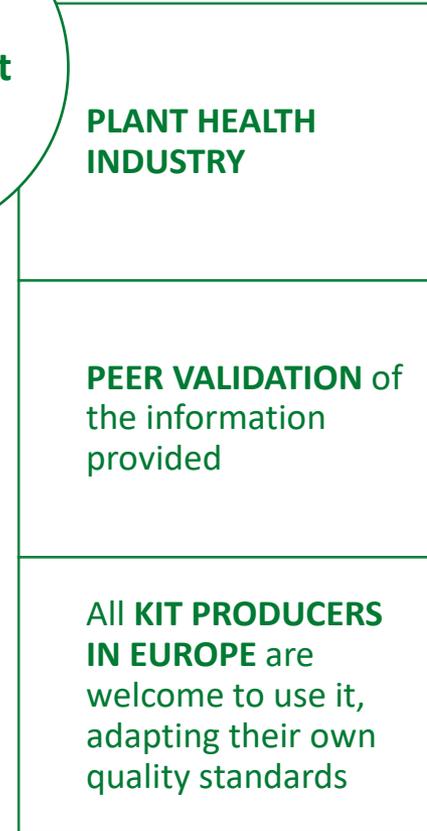
How is this charter going to be implemented?



Visibility



Management





Poll 4

What will be the use(s) of the charter in your context?

select maximum 2 answers

- Accreditation
- Selection of a new method
- Comparison/update to current method
- Recognition of its use as a quality Standard
- I do not intend to use it

We invite you to participate on the construction of the quality charter

qualitycharter@epdia.eu



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VALITEST

EU Plant Health Diagnostics Industry Association

Camilo Gianinazzi

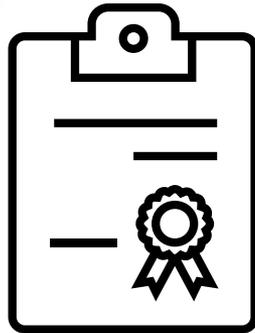


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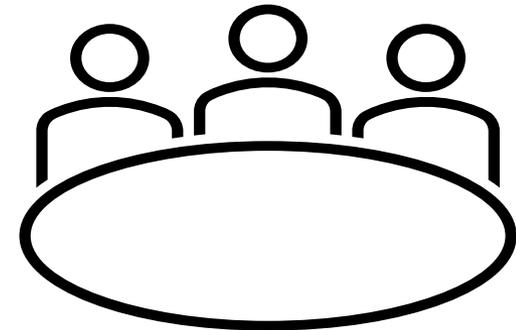


Quality Charter management



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WHO will be in charge of the management, the improvement and the promotion of EPDIA Charter?



EU Plant Health Diagnostic Industry association



EPDIA
Quality Charter

MANAGE

IMPROVE

PROMOTE





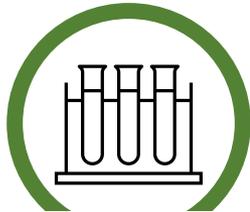
EPDIA a key player in the sector



Global end-users



Plant health diagnostics products
Quality
Validation



Laboratories



epdia

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Manufacturers

Stakeholders and
Policy makers

Validation data

Reference material

TPS and PT
information and
participation

Products availability

Validation data

Reference material

TPS and PT
information and
participation

Accreditation bodies
requirements

Representative organisation

Unique interlocutor

Information sharing

EPDIA Quality Charter





EPDIA Vision and Mission

THE PURPOSE

The association purpose is to make reliable and validated products available to more end-users and help laboratories to move towards a more efficient and sustainable path

THE MISSION

- Be the **European voice** of the Plant Health Diagnostics manufacturers in Europe
- Highlight the **value and contribution** of plant health diagnostics products and solutions for the plant production chain
- **Promote and manage the EPDIA Quality Charter**
- Promote the phytodiagnostic technologies and their validation
- Be a **trusted partner** to EU policy-makers and other key stakeholders



EPDIA main tasks

SHARING with European institutions and stakeholders on the needs and / or difficulties of end-users in the use of reliable, validated and qualitative phytodiagnosics tools

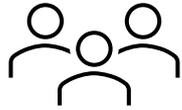
ESTABLISHING and **REINFORCING** the link with European Institutions and NPPO in order to improve the quality and performance of the tools offered to the market by the plant diagnostics Industry (transfer of validation data, standardization of validation methods, reference material, TPS, etc.)

INTERACTING with the European institutions and other stakeholders in order to contribute to effective policy, legislation and regulation in the plant health at the European level

ENGAGING partnerships with EURLs (European Union Reference Laboratories)

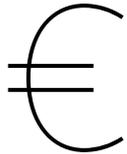


Organisation of EPDIA



EPDIA MEMBERS

Manufacturer SMEs, Private laboratories, Research institutions, Agro industries, NPPOS



EPDIA FINANCING

Members' fee, Public funding

**Launch in
June 2021**



EPDIA CHANNELS

Working groups, Webinars, Conferences, Publications, Website, Social media



Poll 5

How would you interact with EPDIA?

select maximum two answers

- Newsletter
- Participation to working groups
- Conferences / webinars
- Become a member
- Website



EPDIA website

EPDIA

Home About us Membership European Quality Charter Diagnostics kits Research projects Resources & News

WELCOME TO THE EPDIA WEBSITE
The voice of the European Plant Diagnostic Industry

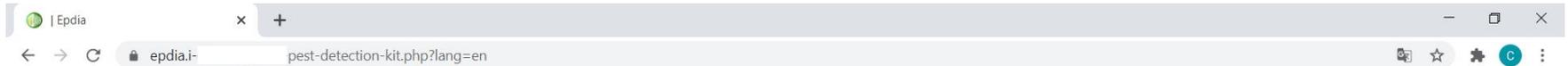
Under construction

EPDIA is the voice of the **European Plant Diagnostic Industry** and represents the interests of those active in **research, development, validation, production** and **marketing of kits and methods for plant health diagnostic testing.**





EPDIA Database



Under construction

Guide your choice among the EU plant pests detection kits available on the market.

References and/or validation data

TAXONOMIC GROUP	ORGANISM	MANUFACTURER	TYPE OF TEST	DESCRIPTION OF TEST	R/V DATA
Virus	Plum Pox Virus	BIOREBA	ELISA test		
Virus	Plum Pox Virus	PRIMEDIAGNOSTICS	ELISA test	DAS ELISA	✓
Virus	Plum Pox Virus	LOEWE	Molecular test		
Virus	Plum Pox Virus	SEDIAG	ELISA test		
Virus	Plum Pox Virus	IPADLAB	Molecular test		
Nematode	<i>Bursaphelenchus xylophilus</i>	CLEARDETECTIONS	Molecular test		
Bacteria	<i>Xylella fastidiosa</i>	IPADLAB	Molecular test	Real Time PCR	✓





EPDIA database

Under construction

Taxonomic group	Bacteria
Organism	Xylella fastidiosa
Manufacturer	IPADLAB www.ipadlab.eu
Country of production	Italy

Validation data

EPDIA Charter	Manufacturer	Others
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References

Type of test	Type of detection	Description of the test	Type of sample
Molecular test	Molecular	Real Time PCR	Woods Roots

Target(s)	Number of target(s)	Available extraction method	Scope
Xylella fastidiosa	1	-	-

Product code	Web shop	Format(s)	Components
qPCR-X.fas-100Liq	info@ipadlab.eu	100 tests	Master mix Positive control Negative sample

Other information	FAM detection
--------------------------	---------------

User guidelines / protocol / manual	IPADLAB – qPCR-X.fas-100Liq
MSDS sheet	IPADLAB – qPCR-X.fas-100Liq
Others	-



Poll 6

Why do you think EPDIA website will be useful for?

select maximum two answers

- Database
- Newsletter
- Research project information
- Quality charter information
- Interaction with members

We invite you to participate on the
construction of EPDIA

contact@epdia.eu



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Thank you for your attention!

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Register now if you want to test a kit!