



EUROPEAN REFERENCE LABORATORIES (EURLs) IN SPAIN: QUALITY & SAFETY FOR CLASS D IVD DEVICES



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Healthy services through science, technology and innovation

Analytical chemistry, (nano)-biotechnology, immunoassays, NAT assays, biosensing, clinical trials, software design, development and integration in health ecosystems...

Innovative SME

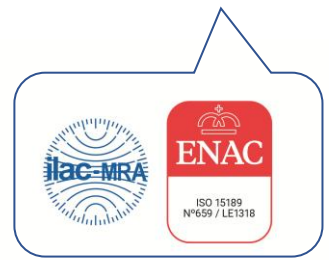
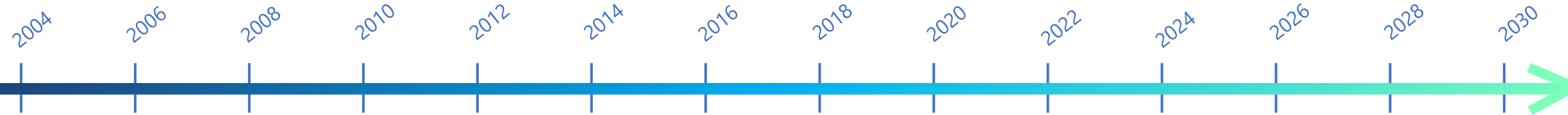
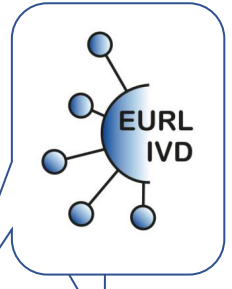


National and International projects



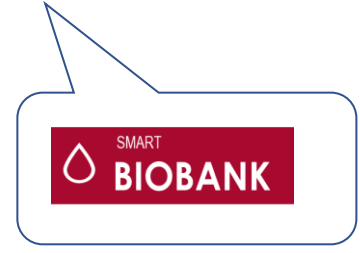
EURL-IVD:

Herpesvirus, bacterial agents, parasites, blood grouping



First accredited private clinical laboratory in Spain (ENAC).

UNE-EN ISO 15189. Medical laboratories - Requirements for quality and competence



Biobank Smart biobank software

Registered at Instituto Salud Carlos III Comunidad de Madrid

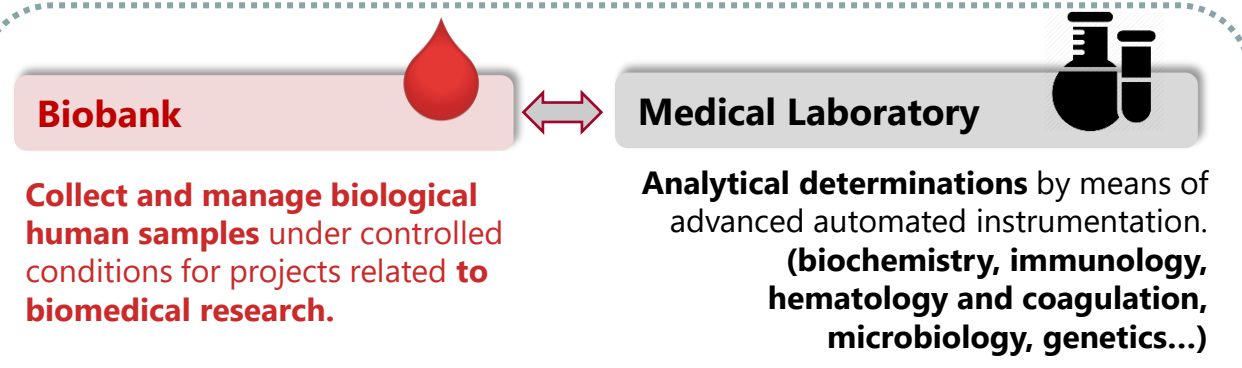


Smart QMS software
Quality Management System



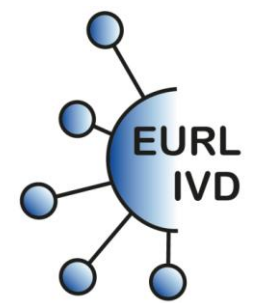
UNE-EN ISO 17025
In process

General requirements for the competence of testing and calibration laboratories



R+D

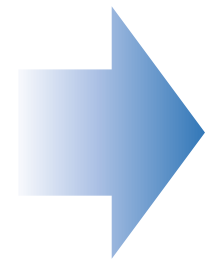
Research and consulting works in the fields of **technology and biotechnology.**



EURL-IVD Ref. Laboratory

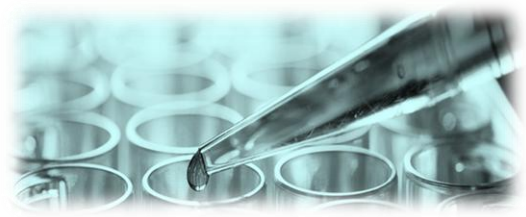
Categories II, III, VII, VIII

eurl-ivd@cqslab.com



- Herpesvirus
- Bacterial agents
- Parasites
- Blood grouping

R
+
D



BIOTECHNOLOGY: research/consultancy in **IVD tests for biomarker detection** that can be applied to the diagnosis of the health status of the patients

TECHNOLOGY: research, design, develop and implementation of **software tools** (for data communication) in order to ensure the **highest standards in security, traceability and quality.**



Revamp of EU regulatory framework for IVDs

Regulation (EU) 2017/746 (IVDR)



IVD device
Manufacturer



Conformity assesment



Device on market (CE-marked)

Directive 98/79/EC
on *in vitro*
diagnostic medical
devices



Regulation (EU)
2017/746 on *in vitro*
diagnostic medical
devices

adopted in 2017
application 2022



- New **risk-based classification system for IVDs** (class A-D in order of increasing risk)
- More **detailed and stringent rules** on the evaluation of device performance
- Greater involvement of **independent conformity assessment bodies (notified bodies)**



For **Class D IVDs**: Adittional layers of control:

INDEPENDENT SCIENTIFIC BODIES

- Expert panel
- **European reference laboratories (EURLs)**

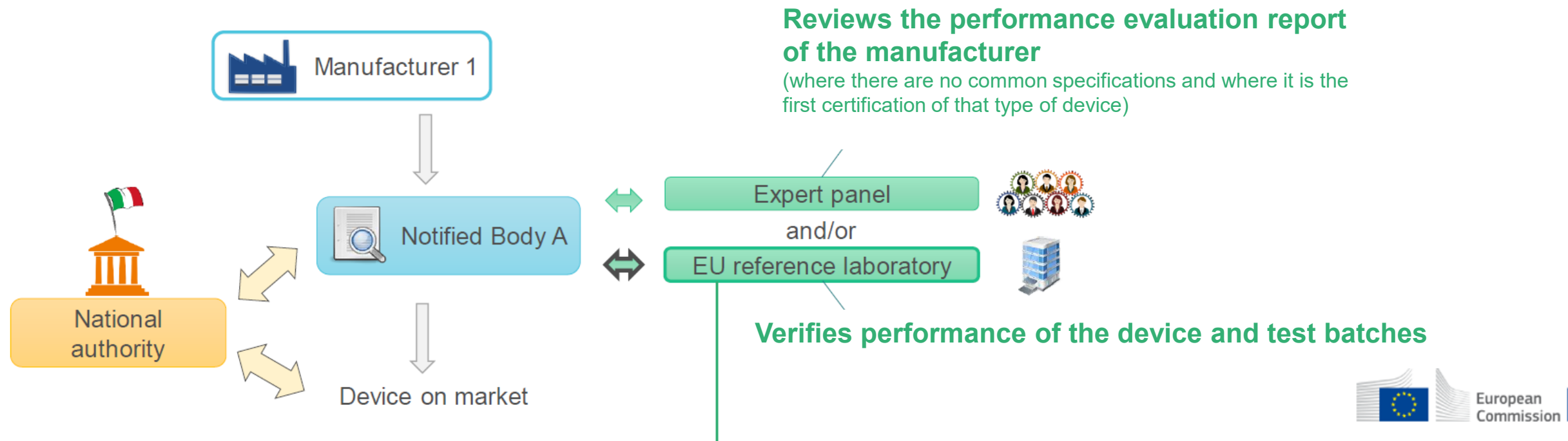


Low risk
device (A):
Self-
declaration by
manufacturer

Medium risk
device
(B,C):
Proportionate
involvement of
notified body

High risk
device (D):
Full
assessment
by notified
body





AEMPS
 Spanish Agency of Medicines and Medical Devices

- EURL-IVD **CQS** - Consulting Químico Sanitario (Spain)
- EURL-IVD **ISCI** - Instituto de Salud Carlos III (Spain)
- EURL-IVD **SERMAS** - Consortium of Hospitals of the Madrid Health Service (Spain)
- EURL-IVD **RISE** - Research Institutes of Sweden (Sweden)
- EURL-IVD **PEI** – Paul-Ehrlich-Institut (Germany)

EURL-IVD network

Class D categories

Scopes of designation (EURLs network and subnetworks)



Category 1

Detection or quantification of markers of **Hepatitis or Retrovirus infection**

HBV, HCV, HDV, HEV, HIV1/2, HTLV I/II...

Category 2

Detection or quantification of markers of **Herpesvirus infection**

Cytomegalovirus, Epstein Barr virus...

Category 3

Detection or quantification of markers of **Bacterial Agents**

Treponema Pallidum...

Category 4

Detection or quantification of markers of **Arbovirus infection**

Wast Nile virus, Dengue virus, Zika virus, Chikungunya virus...

Category 5

Detection or quantification of markers of **Respiratory virus infection**

Highly virulent influenza virus, highly virulent coronavirus...

Category 6

Detection or quantification of markers of **Hemorrhagic fever viruses or other BSL4 virus**

Ebola virus, Marburg virus, Lassa virus, Smallpox virus, Crimean Congo virus...

Category 7

Detection or quantification of markers of **Parasite infection**

Plasmodium spp., Trypanosoma cruzi, Toxoplasma gondii...

Category 8

Detection of **blood grouping markers**

ABO, Rhesus, Kell, Kidd, Duffy

Subnetwork 1

Subnetwork 2

Subnetwork 3

Subnetwork 5

Subnetwork 7

Subnetwork 8

1st Oct 2024

1st Oct 2024

1st Oct 2024

1st Oct 2024

1st May 2026

1st May 2026

Instituto de Salud Carlos III

National Center of Microbiology

EURL-ISCI

Director: José Miguel Rubio

Coordinator scope 1, 2, 3 : Ana Avellón aavellon@isciii.es

Coordinator scope 7: María Delmans Flores

Laboratory specialists of:

- Hepatitis
- Retrovirus
- Herpesvirus (serology and NAT)
- Treponema
- Parasites

Location: Majadahonda. Madrid. Spain

CNM-EURL-IVD@isciii.es

MISSION

To contribute to the improvement of citizens' health and the fight against diseases, through the promotion of research and innovation in Health Sciences and Biomedicine, the provision of reference scientific-technical services and the development of teaching programs aimed at the Spanish National Health System.



*We protect your health
through Science*

SCIENTIFIC-TECHNICAL SERVICES AND CONSULTANCY

The ISCIII manages, develops and offers the State scientific-technical reference services on prevention and control of communicable and non-communicable diseases, Environmental Health and Public Health, biological products and those potentially dangerous to Public Health.

Likewise, it offers scientific-technical advice to support decision-making in health technologies and health services in the Spanish National Health System, among others.

ISCIII'S CENTERS*

- Health Technology Assessment Agency (AETS)
- National Center for Epidemiology (CNE)
- National Center for Tropical Medicine (CNMT)
- National Center of Microbiology (CNM)
- National Center for Environmental Health (CNSA)
- Rare Diseases Research Institute (IIER)
- Doping Control Laboratory (LCD)
- Biological Alert Laboratory Network (RE-LAB)
- Technical Scientific Central Units (UCCTs)
- Functional Research Unit in Chronic Diseases (UFIEC)
- Research Unit in Health Care and Services (INVESTÉN-ISCIII)
- Research Unit in Telemedicine and Digital Health (UITeS)

National Center of Microbiology



- ✓ Reference Laboratory: Portfolio of tests including Virology, Bacteriology, Micology and Parasitology with Quality accreditation ENAC 15189, 17025)
- ✓ Microbiology Alerts covered 24/7 (HantaV, EbolaV, Crimea Congo...)
- ✓ BSL3 working, BSL4 in construction
- ✓ Outbreak microbiology investigation (genomic epidemiology)
- ✓ Research in Microbiology



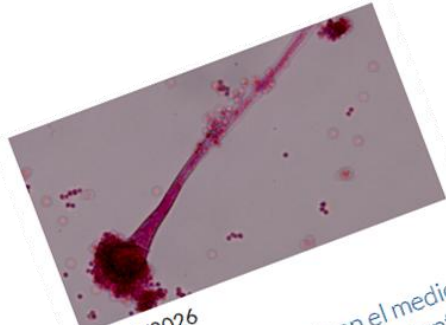
EURL-IVD

La Comisión Europea ha designado 5 laboratorios diferentes en Europa de conformidad con el artículo 100 del Reglamento (UE) 2017/746 . La...

[Learn more](#)

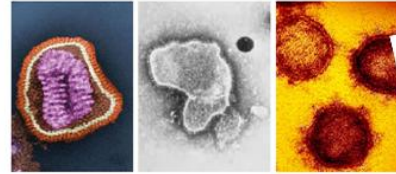


National Center of Microbiology



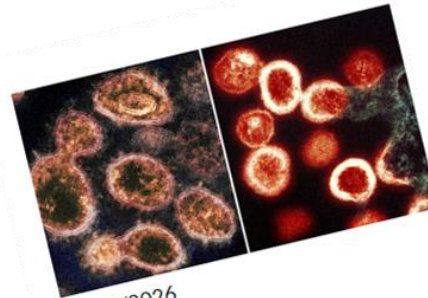
12/03/2026

Analizan la presencia en el medio ambiente de un hongo resistente a los antifúngicos



09/02/2026

5 años del sistema de vigilancia de infecciones respiratorias agudas graves en España



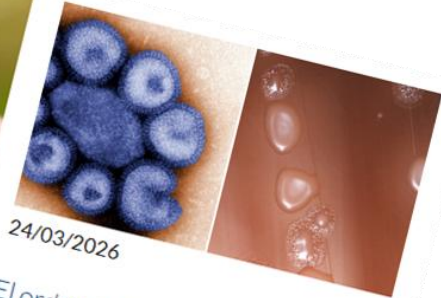
31/03/2026

La 'huella' del SARS-CoV-2 persiste en personas con VIH



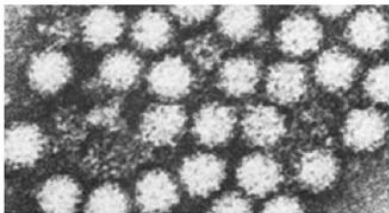
26/03/2026

¿Cómo mejorar la utilidad real de pruebas diagnósticas en enfermedades desatendidas?



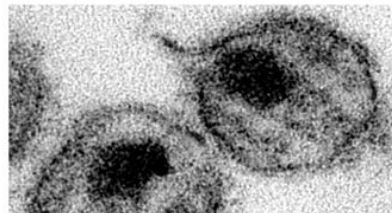
24/03/2026

El orden de infección determina la respuesta inmunitaria frente a virus y bacterias



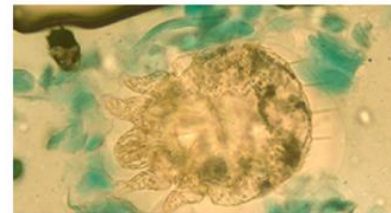
03/12/2025

Cambios genéticos en un norovirus explican el aumento de brotes de gastroenteritis



01/12/2025

Día Mundial del Sida: así impulsa el ISCIII el estudio del VIH



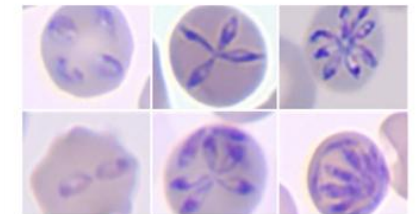
27/11/2025

Un estudio confirma un aumento muy significativo de la sarna en España



27/01/2026

Vacuna frente al neumococo: menor enfermedad invasiva pediátrica por cepas resistentes



20/04/2026

Hallazgo en babesiosis humana: nueva especie de parásito

Main EURL NETWORK expected activity:

- Performance verification of class D devices (every 5 years)
- Batch verification (periodic, every batch)



Advisory activity:

Advisory tasks and networking activities

- c) Scientific & tech. assistance
- d) Advice in state of the art
- e) Set-up and manage a NRL network
- f) Contribution in testing and analysis methods
- g) Collaboration with NBs in best practices
- h) Recommendations in suitable ref materials
- i) Contribute to develop. of CS and IS
- j) Scientific opinions to NBs consultations

CONTINUOUS HARMONIZATION PROCESS OF THE NETWORK

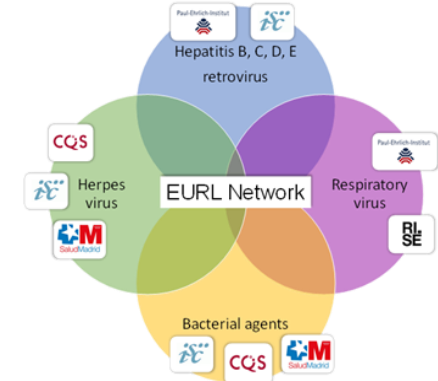
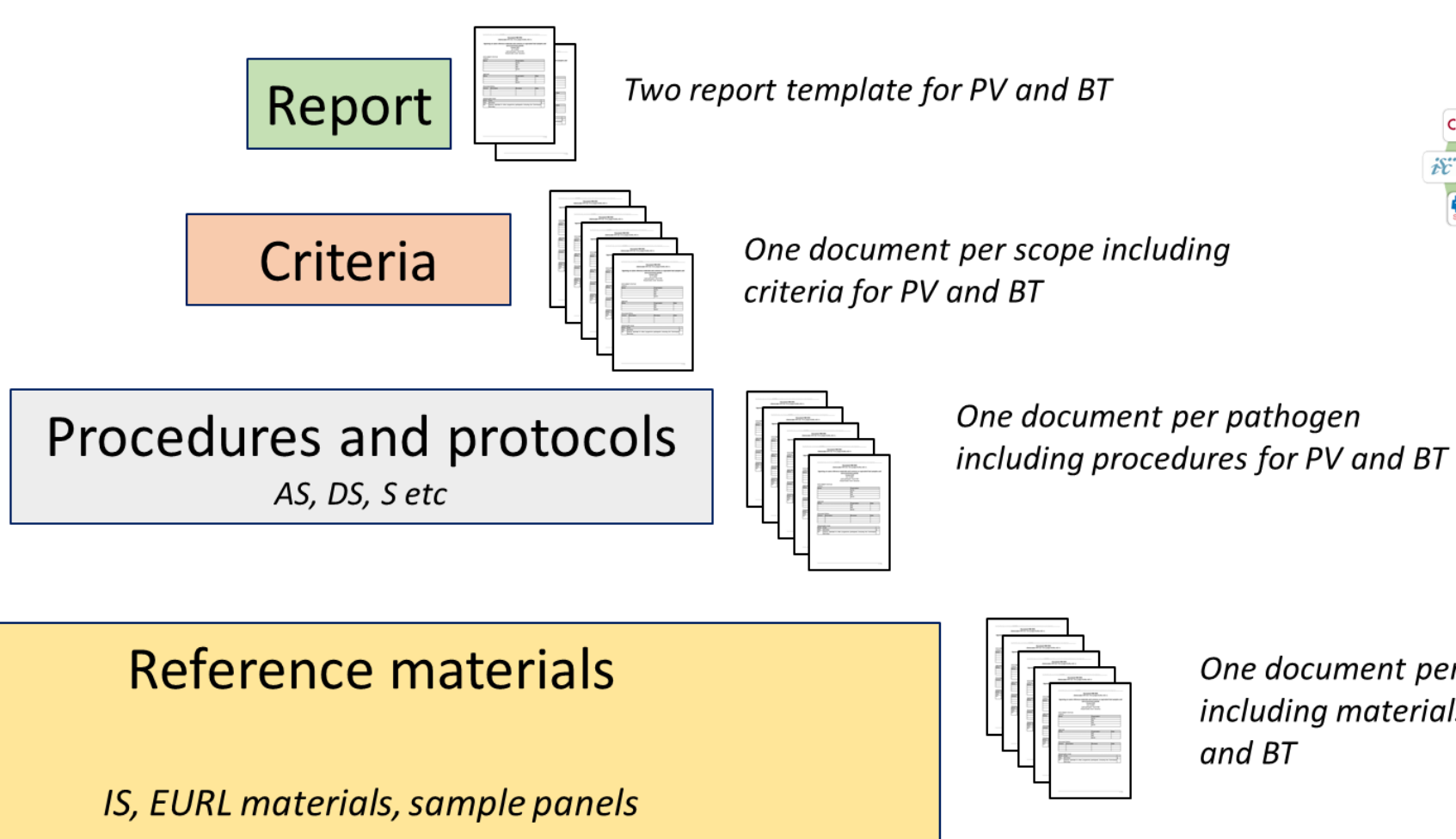
Supported by the EU



Direct Grants 2024, 2025, 2026

EURL NETWORK HARMONIZATION PROCESS

- Harmonization between EURLs
- Harmonization between scopes (Subnetworks)



EURL NETWORK HARMONIZATION PROCESS

- Harmonization between EURLs
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Report

Two report template for PV and BT

Criteria

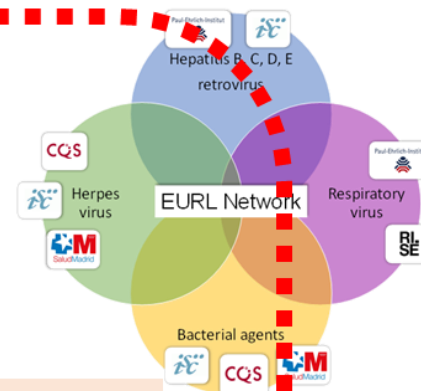
One document per scope including criteria for PV and BT

***Control of the system: EQA,
Proficiency testing, Peer review system***

Reference materials

IS, EURL materials, sample panels

One document per pathogen including materials for PV and BT





Three leading tertiary hospitals. One European reference laboratory

Real clinical environment

- Continuous exposure to routine diagnostics
- Complex patient cohorts
- Access to clinically relevant samples
- Transplantation & infectious diseases expertise

Independent public consortium

- Multi-center structure
- Complementary scientific expertise
- Shared infrastructures and distributed workload

Scopes II & III

EURL-IVD NETWORK MILESTONES





MedTech Europe

from diagnosis to cure

- **The legal framework is in place, but the EURL system for Class D IVD devices is still being implemented**
- **The EURL-IVD network is working in developing SOPs and harmonization processes**
- **Batch testing is steadily increasing**
- **In 2028 most class D IVD devices are expected to be tested**



- **CQS EURL-IVD:** eurl-ivd@cqslab.com
- **National Center of Microbiology:** cnm-eurl-ivd@isciii.es
- **SERMAS EURL-IVD:** eurl-ivd.sermas@salud.madrid.org

