

## At the crossroads of Biological Expertise

With over 50 years of experience, Cerba Research continues cultivating one of its innovative visions to support the development of in-vitro-diagnostics (IVD) and medical devices (MD).

Through **Cerba Xpert**, our specialized IVD and MD division, we provide high-quality and reliable services to support and anticipate the future needs of IVD and MD manufacturers.

Our approach is agile and proactive for fast-track commercialization. Whether it is **to support your product's IVDR or FDA compliance, design and manage a clinical trial, perform a large-scale testing project, or even a biospecimen collection**; we will use our in-depth knowledge and worldwide resources to make your project a success!

### Figures

 **45M** patients

 Over **15,000** employees

 **Over 2,500** types of tests

 Over **320,000** tests performed every day

 **1000+** Clinical pathologists

 **2.1** billion revenues in 2021

### Therapeutic areas

Allergology	Infectiology – Parasitology
Cardiology and hematology	Metabolism
Dermatology	Neurology
Endocrinology	Onco-Hematology
Gastro-Entero-Hepatology	Oncology
Gynecology	Rheumatology
Immunology	Toxicology

## Where to find us?

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## Get in touch

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Cerba Research 



# Cerba Xpert: Your partner for In Vitro Diagnostic and Medical Device Studies

Advancing Research, Advancing Health

## Biospecimen Procurement

### Retrospective collection

- Large variety of matrices
- Analysis results associated
- Relevant demographics: age, gender, date and country of collection
- Broad range of 250,000 samples processed per day

### Prospective collection

- In-house IRB protocol writing and submission
- Ready-to-use IRB protocols covering 5 Therapeutic Areas and 30+ diseases
- Specific Inclusion and Exclusion Criteria
- Specific matrix, quantity and Clinical Data requirements
- Partnerships with private and public health institutions in France and Africa

## Testing and IVD Evaluation Services

- Analytical and/or Clinical Performance Evaluation for CE mark under IVDR/MDR (Performance Evaluation plan and report, post-marketing surveillance plan and reports) and FDA approval (510(k), PMA)
- Ability to manage from single test to large series
- Comparison studies of IVDs kits and instruments for proof of concept and marketing studies
- Usability studies
- Technical platforms in Europe, Africa, and soon in the USA
- Ability to build external laboratories for your verification and validation studies



**Broad range of 2,500+ analysis**



**1100** instruments available



**400** instrument models



**ISO 9001** and **ISO 15189** certified laboratories

### Cutting Edge Technology

- Biochemistry and immunochemistry (Roche Cobas, Abbott Alinity, Siemens Attelica, Beckman DXi/AU, Diasorin Liasion XL etc...)
- Mass spectrometry (Bruker, Agilent, etc...)
- Hematology-Hemostasis (Siemens Advia, Beckman DxH, Sysmex, Werfen and Stago)
- Molecular biology (BIO-RAD's Droplet Digital PCR, Roche Cobas, Abbott Alinity M, Hologic Panther. Elitech InGenius, Thermofisher, Seegene, etc...)
- Cytogenic, non-invasive pre-natal test and onco-hematology are covered by Next Generation Sequencing (Illumina solution).

## Patient Identification and Enrollment Services

- Patient enrollment for MD/IVD: Non Interventional to Interventional Studies
- Patient enrollment for Rx and OTC Meds: Observational studies
- Decentralized Clinical Trials
- RWE and Secondary Data Collection
- Patient Identification Solution in Cerba network to speed up the enrollment of eligible patients

