eurofins | Clinical Trial Solutions

Vaccine Development Services

With over 40 years of experience, Eurofins Viracor BioPharma provides comprehensive support throughout all stages of vaccine development - from pre-clinical to human pharmacology studies [phase I], therapeutics exploratory studies [phase II], clinical efficacy and safety studies [phase III] and post authorization surveillance [phase IV]. With large sample volumes across multiple locations, our expert global logistics team ensures specimen integrity, fast turnaround times, and seamlessly integrated global data. Eurofins Viracor BioPharma is your trusted partner for all your vaccine development needs.

Global Laboratory CRO to Support Multi-center, Multi-country Studies in over 85 Countries

- 6 dedicated testing facilities in USA, Europe and Asia
- 3 wholly owned Kit Packing and Distribution facilities
- Access to the broader Eurofins global network of 125+ laboratories
- Access to the Eurofins PBMC processing network

Regulatory Compliance

- Non-clinical and GLP regulatory frameworks
- Applicable Good Clinical Laboratory Practice (GCLP) standards
- 21 CFR Part 11 where applicable
- CAP/CLIA

Assay development, validation and testing for the Moderna mRNA-1273 COVID-19 vaccine clinical trial

- Development of SARS-CoV-2 RT-PCR test, performed on all Phase II & III clinical trial samples
- Spike-gene sequencing assay (SARS-CoV-2 S gene NGS assay) and Whole Genome Sequencing (WGS) assay performed on nasal swabs to assess SARS-CoV-2 variants in the study population
- RT-qPCR assay designed by Eurofins Viracor, has also now been utilized world-wide to provide >20 million COVID-19 infection results

World Renowned Assay Development and Testing Capabilities

- Assay development, transfer, and fit-for-purpose validation
- Safety and Efficacy Testing
- Immunoassays including
  - ELISA
  - Luminex® Microbead arrays
  - MSD® electrochemiluminescence
  - ELISpot
  - Flow Cytometry including 25 Color NovoCyte® Quanteon™ and BD FACSymphony™ A5 (27 color)
- Immunogenicity, ADA and NAb Testing
- Biomarkers
- Molecular Testing including
  - qPCR, RT-qPCR, ddPCR
  - NGS and Sanger sequencing
  - Respiratory Pathogen Panels

Matrices

Tissue, Blood, Serum, Plasma, Saliva, Oral Mucosa, Nasal Swab, Nasal Lavage, Pulmonary Lavage, Urine, Stool, Occlusive Dressings, Surface Lesions, Anogenital Area

VACCINE TRIAL EXPERIENCE

EBV | CMV | HPV | ZIKA

CHIK | RSV | Influenza | SARS-CoV-2

BKV | HCV | HHV (6/7/8) | VZV | Denque

HTLV | JCV | HDV | HEV

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Eurofins Kits Packing and Distribution

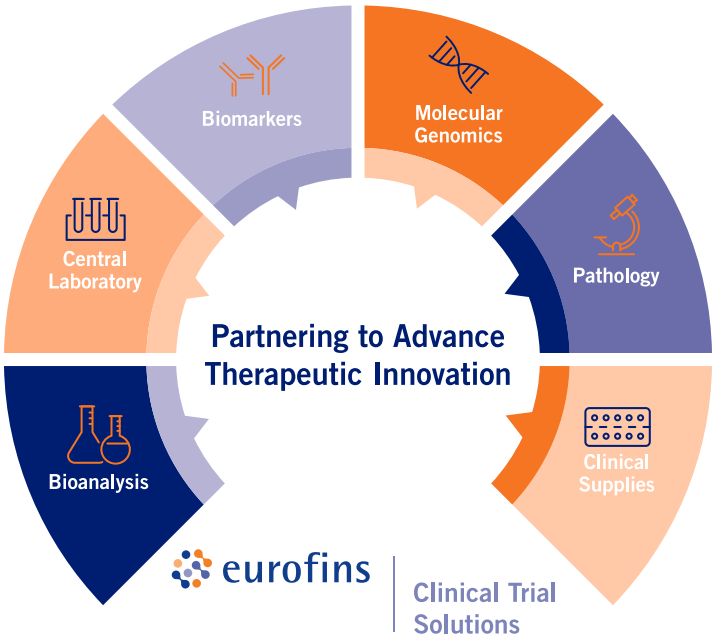
- 3 wholly-owned Kit Packing and Distribution facilities in USA, Europe and China
- Over 25 years of experience providing sample collection kits for clinical trials, commercial DNA testing, clinical monitoring programs and post marketing surveillance, both inside and outside Eurofins
- High quality GMP and FDA compliant specimen and transportation kits to be distributed worldwide, including home collection kits

Eurofins PBMC Processing

- 35+ qualified and harmonized laboratory locations worldwide
- New locations being added steadily based on new study requirements
- Global service offering effective harvesting, processing, cryopreservation, and analysis of peripheral blood mononuclear cell (PBMCs)
- We have supported 25+ different sponsor-defined processing protocols, including less than 24 hours TAT and less than 8 hours TAT requirements
- Specialized downstream testing services include cell-based assays, (flow cytometry, ELISpot), RNA/DNA isolation and sequencing analysis, protein extraction and quantification, and virology specimen stabilization

Eurofins provided support to multiple SARS-CoV-2 mRNA vaccine protocols

- One of the programs enrolled more than 40,000 healthy participants in multinational trials in Europe and Latin America
- Program included rapid study set-up and pre-planned wave-based distribution of specimen collections kits
- 100% paperless requisitioning for sample tracking from site through final analysis



For more information, please contact clinicaltrials@vbp.eurofinsus.com

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