

Vaccine Development Services

With over 35 years of experience, Eurofins Vaccine Development Services comprehensive capabilities supports vaccine development programs from pre-clinical to human pharmacology studies [phase I trials], therapeutics exploratory studies [phase II], clinical efficacy and safety studies [phase III] and post authorization surveillance [phase IV]. With large sample numbers distributed over many locations, a need for expert global logistics support to maintain specimen integrity, quick turnaround time of results and the necessity for globally combinable data, Eurofins is your go-to partner to support your Vaccine Development programs.

Global Laboratory CRO to support multi center, multi country studies in over 85 countries worldwide

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

Regulatory compliance

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

World renowned Assay Development and Testing Capabilities

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

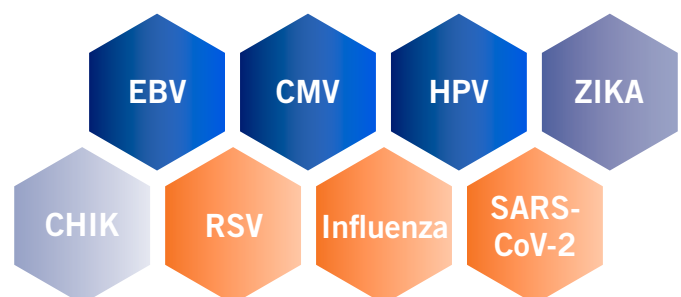
Assay Development, validation and testing for the Moderna mRNA-1273 COVID-19 vaccine clinical trial

- 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

Matrices

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

VACCINE TRIAL EXPERIENCE



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 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

Eurofins PBMC Network

- 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.



BioPharma Services

For more information, please contact vaccines@eurofins.com

