

## 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.

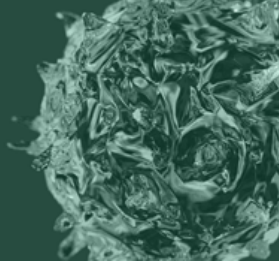
### VACCINE TRIAL EXPERIENCE

**EBV | CMV | HPV | ZIKA**

**CHIK | RSV | Influenza | SARS-CoV-2**

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

**HTLV | JCV | HDV | HEV**



### 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.

For more information, please contact [clinicaltrials@bcl.eurofins.com](mailto:clinicaltrials@bcl.eurofins.com)

