hVIVO

Laboratory Services

Consolidating biomarker analysis to a single source lab will reduce time and costs throughout development programs

THE CHALLENGE

The annual challenge of the global health community is progressing innovative products (vaccines, antiviral drugs, immunomodulators) for the control of infections of significant disease burden in a timely manner at an optimum cost. hVIVO and its associated laboratory services provides a single, centralised testing ability to reduce time and costs and provide specialised scientific design services throughout all phases of your development program.

Innovative assays can speed up the testing process considerably, supporting swift market delivery of client products

hVIVO Labs is a highly specialised virology and immunology laboratory offering a suite of services to support pre-clinical and clinical respiratory drug and vaccine discovery and development

SERVICE OFFERING

Reliable laboratory analysis underpinned by scientific expertise is essential when processing and analysing clinical samples. Robust quality processes support our team of scientists in the delivery of submission ready data.

CLINICAL LABORATORY SERVICES

End to end lab support services, from clinical trial and field study sampling kit provision with sample stabilisation to data management and reporting

Quality management system supporting our project teams to deliver the highest standard of clinical data

Projects supported by a team of lab scientists working in a GCLP accredited lab, providing scientific oversight, project and data management, sample logistics and assays validated to FDA[1], EMA[2] and ICH[3] guidelines

BESPOKE ASSAY DEVELOPMENT

Ability to provide bespoke assays when needed to optimise study outcomes and provide exploratory endpoints

Extensive experience in assay development and validation to EMA[1], FDA[2] and the ICH[3] guidelines providing sensitive, clinically robust assays

BIOMARKER

Consolidating your biomarker analysis to a single source lab will reduce time and costs throughout client development programs

We offer a wide range of assays including:

- serological screening
- virus infectivity
- real-time quantitative RT-PCR
- rapid qPCR for triggered dosing challenges
- humoral & cell-mediated immune responses

Currently developing biomarker assays for Asthma and COPD models

ASSAY TABLE

List of Specific Services[$]						
	Serological Assays	MNA	HAI (Flu)	NAI (Flu)		Phase I-III
	CMI assays	FACS	MSD Cytokine/Chemokine	ELISpot		Pre-Clinical-Phase III
	Molecular assays	Quantitative Real-time RT-PCR	Respiratory panel PCR (multiplex qualitative diagnostic assay) for 21 respiratory viruses	Rapid, multiplex qualitative Real-time RT-PCR (qicPCR) (Flu, RSV)	replicative RNA qPCR (RSV)	Phase I-III
	Viral Titre analyses (Infectivity) assays	Plaque (RSV, Flu)	$TCID_{50}$ (Flu, HRV)			Phase I-III
	Compound efficacy	EC_{50}/EC_{90}	mutant analysis – genotyping & phenotyping			Pre-Clinical-Phase III

$ Where not specified the assay can be done for all 3 viruses – RSV, Flu, HRV
β broad virus range available incl Flu & RSV; HepA; Varicella Zoster; Mumps; Measles; Rubella; Norovirus; Adenovirus; CMV; EBV; HPV, Rabies; Rotavirus; Dengue

1 EMA: European Medicines Agency. 2 FDA: Food and Drug Administration. 3 ICH: International Conference on Harmonisation

INDUSTRY LEADING PROVIDER OF VIRAL CHALLENGE STUDIES

CHALLENGE STUDIES

Provide early human proof-of-concept efficacy data to support drug and vaccine candidate selection

Support accelerated development of pipeline compounds, through early identification of the appropriate endpoints, dose response and timing and biomarkers for incorporation in later clinical studies

Reduced costs as the model requires a relatively small number of subjects investigated over a shorter period of time to deliver an efficacy outcome

OUR CHALLENGE MODELS

INFECTIOUS DISEASES
- FLU
- HRV
- RSV

RESPIRATORY
- ASTHMA
- COUGH
- COPD

LAB SERVICES

LABORATORY OFFERING
- Virology
- Immunology
- Biomarkers

HVIVO HUMAN CHALLENGE FULL-SERVICE SOLUTION

Unparalleled experience in the design, conduct and analysis of human models of disease

- Study design & protocol development
- Recruitment
- Monitoring
- Ethics & regulatory submission
- Pharmacy
- Data management and biostatistics
- Laboratory support
- Biomarker development
- Clinical Study report
- Clinical Trial: Inpatient or outpatient

STANDARDISED STUDY PROCESS

'Commited to delivering study excellence'

Protocol design
- Study management process
- Services deliver quality results
- Meeting client needs and timelines
- Trials conducted using controlled settings and processes

Screening & recruitment
- Recruitment of volunteers in the UK using the 'FluCamp' brand

Quarantine
- Bespoke quarantine unit in Whitechapel, London for conducting challenge studies: 24 en-suite rooms

Viral challenge
- Well characterised challenge
- Exact exposure time to virus

Intensive sample collections
- Virology
- Immunology
- Biomarkers

Quarantine discharge and follow up
- Immunugenicity
- Seroconversion
- Standard 28 days can be up to 1 year

ABOUT HVIVO

Established in 1989 as a spin out from Queen Mary University, London, hVIVO is a trusted partner and industry leading clinical development services business pioneering human disease models based upon viral challenge. Using human challenge studies to establish early proof of concept, hVIVO's clinical trial platform can accelerate drug and vaccine development in respiratory and infectious diseases specifically leveraging hVIVO's established human disease challenge models in influenza 'flu', respiratory syncytial virus 'RSV' and human rhinovirus 'HRV' and more recently the expansion and development of these models in other respiratory indications for asthma, chronic obstructive pulmonary disease "COPD", cough and related new therapies and in special populations.

For more information contact: Labservices@hvivo.com

* human rhinovirus (HRV) and respiratory syncytial virus (RSV)