hVIVO
part of Open Orphan plc

hLab – Virology Laboratory Services

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.

QUALITY STANDARDS

- GCLP
- HTA
- CAP Proficiency and external QA

Serological Assays *

FLU HAI/HA; RSV, HRV, FLU & CoV (endemic & SARS-CoV-2) MNA; FLU NAIs

Viral Titre analysis *

FLU & HRV $TCID_{50}$; RSV, FLU & CoV (endemic & SARS-CoV-2) Plaque/FFA; $TCID_{50}$ for SARS-CoV-2, HRV, RSV, FLU & SARS-CoV-2 qPCR; RSV & FLU qicPCR (triggered dosing); RSV Replicative qPCR

Compound efficacy & Viral Resistance Monitoring

EC_{50}/EC_{90}; Phenotypic and Genotypic – NGS; Allelic PCR

CMI and Immune-biomarker Analysis

ELISpot; sIgA & IgG ELISA;
MSD Cytokine / Chemokine biomarkers; FACS cell counting and differentials

Multi pathogen testing

BioFire; GenMark DX ePlex

* all assays are validated according to FDA/EMA/ICH guidelines

Molecular Services

- Purification of DNA, RNA from various types of samples
- Automated RNA extraction and qPCR assay setup
- Viral load end point data
- Fully Validated quantitative PCR Assays (LLOD, LLOQ, Linearity, Precision, Reproducibility, Range)
- Bespoke Assay Development / Validation
- Respiratory panel screening for active & passive surveillance programs

Cell Based Assays

- Serological Assays
- Infectivity Assays:
  - Quanitifcation of infections virus present in samples pre and post inoculation or exposure
  - Provides viral titre data
  - Plaque forming or tissue culture infectious dose (50%) ($TCID_{50}$) assay
  - Optimised for high throughput and validity of results

- ✓ **Biosafety Level 3 (Cat 3) – SARS-CoV-2** assays validated
- ✓ **highly experienced** in **Tech-transfer**
- ✓ **86,000 samples** each year, generating more than **300,000 aliquots** for analysis
- ✓ Bio-repository stores (excess of **500,000 samples**)
- ✓ **50 laboratory staff** (all specialists in clinical virology and immunology)
- ✓ **highly optimised** for **high throughput** for qPCR, serology & cellular infectivity assays

hLab 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

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Field Trial Biologistics

Sample Collection

- Bespoke sample collection kits
- Virus stabilisation / transport matrix
- Sample collection and storage instructions

hVIVO developed RSV stabilisation Matrix

- Stabilise RSV-A and –B over multiple freeze thaws, 4-8°C and <-20°C
- Long term stability data <-20°C and -80°C

Logistics

- Global field-trial kit distribution
- Central Lab facilities
- Subsequent laboratory sample processing and analysis

Proven track record supporting RSV field trials using our stabilisation matrix and downstream laboratory analysis

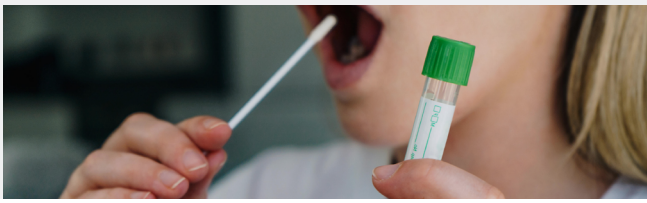
Case study 1

We supported a global study with virology assessment of nasal swabs from infants hospitalised with RSV disease. hVIVO's proprietary viral stabilisation matrix with 9months stability helped enable samples to be collect globally with kits delivered early and the trail completed within 1 respiratory virus season in both hemispheres.

Number of sites involved	Number of virological sample kits provided	Number of Analyses performed
> 135	> 4000	> 3000

Case study 2

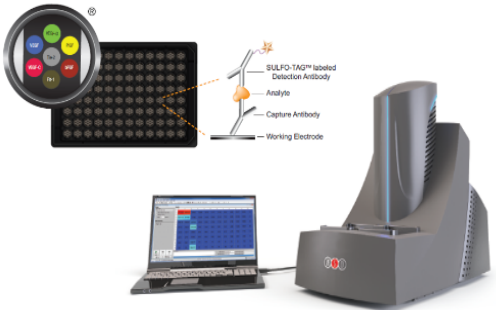
Rapid turnaround times of assay development supporting rapid deployment of assays to the field. As part of our setup for supporting COVID-19 trials we developed and validated multiple assays ready for clinical studies within three months. This timeline included setup our now fully live CL3 laboratory, which is available to support your trials.



Biomarker Analysis

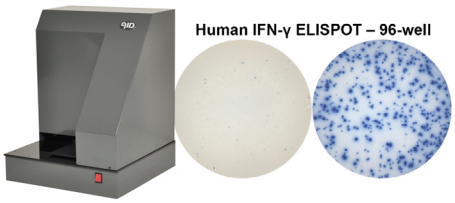
MSD biomarker (cytokine/chemokine) ELISA

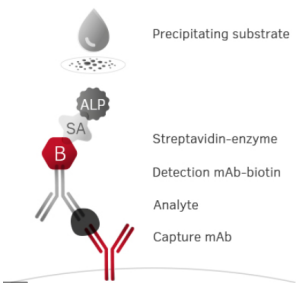
- Single and multiplex plate formats
- Highly sensitive imaging detection systems
- No complicated fluidics
- Large panel of validated assays for multiple matrix (e.g. saliva)



ELISpot

- PBMC analysis for RSV and FLU peptides
- Multiple analyte formats available
- Biobank of exploratory samples available for bespoke client studies





FACS

- High-performance T cell analysis and sorting