Laboratory Services



Our Expertise



drug discove pre-clinical and d models

Analysis of biomarkers from a broad spectrum of sample matrices









Laboratory Services Overview



- We process over 40,000 samples each year, generating around 80,000 aliquots for analysis
- Bio-Bank containing 200,000 plus samples

High throughput capacity

- Serology assays 1000 samples/wk
- qPCR 800 sample/wk
- Cellular Infectivity assays -1000 samples/wk
- Custom assay Development,
 Validation and Transfer to
 FDA and ICH guidelines
- Work with a small group of strategic partners
- 24/7 laboratory operation
- Multiple segregated laboratory spaces allow increased flexibility



Laboratory Services

Pre-Clinical

Compound Efficacy and Cell Cytotoxicity Analysis (e.g. Neutralisation and Plaque Reduction, IC50/IC90)

Virucidal / Virustatic Assays

Viral Resistance Screening/ Analysis

Immune-biomarker Analysis (ELISpot Analysis, Cytokines, ELISA) Phase II

Phase 0/I

Field Trial Kits and Sample Stabilisation

Serological Assays

Phase III

FLU HAI/HA, RSV, HRV, FLU & CoV MNA, FLU NAIS

Viral Titre analysis

FLU & HRV TCID50, RSV, FLU & CoV Plaque, HRV, RSV, FLU & CoV qPCR, RSV & FLU qicPCR (triggered dosing), RSV Replicative qPCR

Compound efficacy & Viral Resistance Monitoring

EC₅₀/EC₉₀, Phenotypic and Genotypic – NGS, Allelic PCR

CMI and Immune-biomarker Analysis

ELISpot Analysis, ELISA, MSD Cytokine / Chemokine analysis, FACS cell counting and differentials,

Multi pathogen testing
BioFire

Bespoke assays development and technology transfer

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



Field Trial Bio-logistics









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 turn stability data <-20°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 down
stream laboratory
analysis



Cell Based Assays



- Serological Assays
 - Determination of circulating antibody titres for identification of sero-susceptible volunteers and seroconversion following vaccination, prophylaxis or viral challenge.
- Infectivity Assays
 - Identification of infections virus present in samples pre and post inoculation or exposure
 - Provides viral titre data
 - Plaque forming or 50% tissue culture infectious dose (TCID₅₀) assay
- Optimised for high throughput and validity of results



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
- Qualitative PCR for triggered dosing & volunteer discharge
- Phylogenetic analysis and NGS

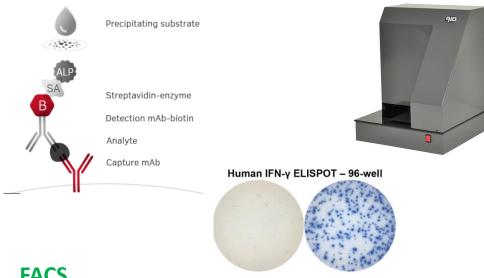




Biomarker Analysis

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)



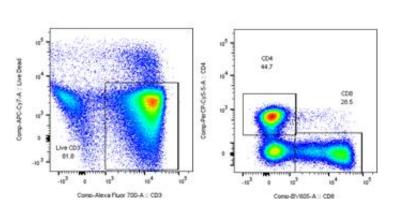
FACS

High-performance T cell analysis and sorting



ELISpot

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





Compound efficacy & Viral Resistance Monitoring

- Effective concentration 50% (EC_{50}) ($TCID_{50}$ and plaque reduction) determination for candidate antivirals against both RSV and FLU viruses
 - Comparison to antiviral compounds available commercially
- Compound efficacy against hVIVO GMP challenge viruses to inform study design
- Shifts in EC₅₀ and Next Generation sequencing (NGS) for phenotypic and genotypic (variant analyses) antiviral resistance monitoring

