

## Specialist Infectious Disease and Immunology Laboratory Solutions

### Purpose built to accelerate the development of new medicines

As part of **hVIVO**, a global leader in human challenge studies, our laboratory is rooted in a legacy of **scientific innovation** and clinical impact. We combine **world-leading expertise** with a **participant-oriented approach**, delivering diverse lab services that are not only technically robust but also deeply aligned with drug development needs. Our strength lies in a multi-faceted approach, integrating molecular, virology, immunology, and bacteriology. This synergy ensures high sensitivity, specificity, and reproducibility, enabling accurate pathogen detection, immune profiling, and functional characterisation.

-  **100,000 +**  
samples annual processing capacity
-  **Robotics and automation** for high throughput and scale
-  **50,000 +**  
samples in our biobank
-  **Regulatory support**  
for Fast Track Designation and EMA PRIME
-  **BSL2 and BSL3**  
facilities
-  **14** World leading human challenge models available
-  **24/7**  
sample receipt and processing capabilities



### Why sponsors choose to work with us

Specialised testing powered by **advanced technology** and a **GCLP/GxP-compliant framework**. Our processes deliver **high reproducibility**, ensuring consistent and reliable results. With a team of experienced professionals and broad **specialty assays**, we offer flexibility through **customised assay development** tailored to your unique needs. Outsourcing to us saves time, reduces risk, and guarantees quality—so you can focus on innovation while we handle the complexity.

#### Scientific Leadership

1

Our team brings decades of experience in virology, immunology, and translational science — helping you choose and develop the right assays for your clinical study generating the data that you require.

#### Clinical Co-location

3

State of the art laboratory embedded within a clinical and participant recruitment facility; we enable seamless integration between lab and participants— accelerating timelines and reducing friction.

#### Ready to scale with you

5

Our flat structure, peer to peer communication and experienced project management team, takes you from developing the right assays for discovery to GxP validated assays for clinical trials.

#### Continuous Investment

7

We will upgrade and invest in new technologies as they emerge to suit sponsor requirements.

#### Diverse Technology Platforms

2

From molecular and biomarker analysis to drug efficacy we offer flexible, scalable solutions tailored to your pipeline, helping you achieve research, clinical and commercial milestones.

#### Ethical Oversight and Compliance

4

Operating under strict regulatory requirements our team will ensure all compliance checks are in place, ensuring sample integrity.

#### End-to-End Solutions

6

From regulatory consultation, to assay development, translational research to high volume bioanalysis for clinical trials and sample storage, hVIVO laboratories supports you at every step.

✓ **Rooted in Labs.**  
**Driven by Science.**  
**Trusted by Industry.**

## Our Laboratory Solutions

### Pre clinical services

- Consultation on drug development plans
- Translational modelling
- Translational research
- Regulatory support and due diligence

### Clinical Trial Solutions

- Bespoke kit production
- Laboratory Manuals
- Site training
- Clinical bioanalysis from Phase I-III

### Sample Processing network

- PBMC & cell isolation network, processing and downstream analysis
- Sample processing and stabilization for long term storage and shipping
- Cell culture Laboratory

### Assay development and validation

- Bespoke assays and customization
- R&D assay development and optimization
- Off the shelf assays

### Bioanalysis and characterisation

- Pathogen propagation & titration
- Validated virology and immunology assays
- Multi-pathogen testing and quantification
- Drug and virus potency testing

### Techniques and automation

- Sample handling robotics and automation

### PK/PD Assays

- Cell-based assays
- ELISA
- Multiplex cytokine analysis
- qPCR and ddPCR

### Genomic Assays

- Next-Generation Sequencing (NGS)
- Microbiome sequencing

### Immunoassays

- Detection of binding antibodies
- Detection of neutralizing antibodies
- Ligand binding assays
- ELISpot



## Master Pathogen List

VIRUS	
Adenovirus (Including Type 1, Type 2 and Type 3)	Influenza - A/New Caledonia/20/99 (H1N1 )
Adenovirus F40/41	Influenza - A/West Virginia/30/2022(H1N1)
Astrovirus	Influenza - A/Wisconsin/67/2022 (H1N1)
Chikungunya	Influenza - B/Austria/1359417/2021
Cytomegalovirus (CMV)	Influenza - B/Connecticut/01/2021
Dengue (serotypes 1,2,3 and 4)	Influenza - B/Phuket/3073/2013
Ebola	Lassa
Enterovirus (EV)	Marburg
Equine Encephalitis (WEEV & VEEV)	MERS-CoV
HCoV- Coronavirus HKU1	Nipah
HCoV- Coronavirus NL63	Norovirus GI/GII
HCoV- Coronavirus OC43	Parainfluenza virus 1
HCoV-Coronavirus 229E	Parainfluenza virus 2
Herpes simplex virus 1 (HSV-1)	Parainfluenza virus 3
Herpes simplex virus 2 (HSV-2)	Parainfluenza virus 4
Human herpesvirus 6 (HHV-6)	Rabies
Human Metapneumovirus (hMPV)	Respiratory Syncytial Virus (RSV A)
Human parechovirus (HPeV)	Respiratory Syncytial Virus (RSV B)
Human Rhinovirus (HRV-16)	Rotavirus A
Human Rhinovirus/Enterovirus	Sapovirus (I, II, IV, and V)
Influenza - A/Brisbane/10/2007(H3N2)	SARS-CoV-1
Influenza - A/California/123/2022 (H3N2)	SARS-CoV-2
Influenza - A/California/45/2023 (H3N2)	Semliki Forest
Influenza - A/Croatia/10136RV/2023 (H3N2)	Varicella zoster virus (VZV)
Influenza - A/District of Columbia/27/2023 (H3N2)	West Nile
Influenza - A/Georgia/12/2022 (H1N1)	Yellow Fever
Influenza - A/Massachusetts/18/2022 (H3N2)	Zika



## Master Pathogen List (contd.)

### BACTERIA

Acinetobacter calcoaceticus-baumannii complex	Enterobacterales
Bacteroides fragilis	Enterococcus faecalis
Bordetella parapertussis (IS1001)	Enterococcus faecium
Bordetella pertussis (ptxP)	Escherichia coli (E. coli)
Campylobacter (C. jejuni / C. coli / C. upsaliensis)	Haemophilus influenzae
Chlamydophila pneumoniae	Klebsiella aerogenes
Clostridioides (Clostridium) difficile (toxin A/B)	Klebsiella oxytoca
E. coli -Enteropathogenic (EAEC)	Klebsiella pneumonia group
E. coli - Enteropathogenic (EPEC)	Leptospira spp.
E. coli -Enterotoxigenic (ETEC) lt/st	Listeria monocytogenes
E. coli - O157	Mycoplasma pneumoniae
E. coli - K1	Neisseria meningitidis
E.coli - Shiga-like toxin-producing (STEC) stx1/stx2	Plesiomonas shigelloides
E.coli - Shigella/Enteroinvasive E. coli (EIEC)	Proteus spp.
Enterobacter cloaca complex	Pseudomonas aeruginosa

### YEAST

Candida albicans	Candida parapsilosis
Candida auris	Candida tropicalis
Candida glabrata	Cryptococcus (C. neoformans/C. gattii)
Candida krusei	

### PARASITES

Cryptosporidium	Plasmodium falciparum
Cyclospora cayetanensis	Plasmodium vivax/ovale
Entamoeba histolytica	Plasmodium spp.
Giardia lamblia	



### Quality & Trust

ISO 17025:2017, GCLP, Collage of American Pathologists (CAP), Human Tissue Authority (HTA), and UKAS ISO 17025 (in progress). IATA training for most laboratory staff.



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