


## The Role of Specialty Laboratories in Infectious Disease Research: A Multi-Faceted Approach

### Introduction

Specialty laboratories are at the forefront of infectious disease research and development, providing advanced capabilities that go far beyond routine diagnostics. Their strength lies in a multi-faceted approach, integrating molecular, virology, and immunology techniques to deliver comprehensive insights for vaccine development, antiviral drug discovery, and translational research. Cell culture serves as a critical foundation for viral propagation, drug screening, and physiology relevant modelling, complementing genomic and immunological analyses. This synergy ensures high sensitivity, specificity, and reproducibility, enabling accurate pathogen detection, immune profiling, and functional characterisation.

### Why a Multi-Faceted Approach Matters

Pathogens evolve rapidly, and single-modality testing often falls short in capturing the complexity of infectious diseases. Specialty labs combine genomic analysis, viral infectivity assays, and immune response profiling and cell culture systems to:




Improve diagnostic yield and accelerate turnaround times



Support regulatory-compliant workflows for clinical trials



Enable real-time surveillance and outbreak response



Drive innovation in therapeutic and vaccine development through physiologically relevant models



### 1. Molecular & Genomics

- qPCR & ddPCR for gene expression and viral load quantification
- Next-Generation Sequencing (NGS) for whole genome sequencing, variant calling, and microbiome analysis
- Multi-pathogen screening using advanced platforms (GenMark® ePlex®, BioFire®)
- Biomarker profiling for translational research and diagnostics

#### Applications

Biomarker discovery, diagnostics development, vaccine research, and Phase I—III clinical trials

### 2. Virology

- TCID50, Plaque Assays, and Focus Forming Assays (FFA) for viral quantification
- Drug potency assays (IC50/IC90) for antiviral screening
- Neutralisation and ligand binding assays for antibody functionality
- Resistance monitoring via NGS

#### Applications

Respiratory pathogen research, emerging infectious disease programs, antiviral drug development

### 3. Immunology

- ELISA for protein and antibody quantification
- ELISpot for antigen-specific T cell analysis
- Multiplex cytokine profiling for immune signaling
- Neutralisation assays for functional antibody activity
- PBMC isolation and immune repertoire sequencing

#### Applications

Vaccine development, immunogenicity studies, infectious disease research, cardiometabolic biomarker analysis

### 4. Cell Culture

- Establishing appropriate cell lines such as Vero, MDCK, HEK293, CHO which are cultured under strict conditions and used for critical steps such as respiratory virus propagation, and cell-based assays
- Primary human PBMCs for immunogenicity and host-pathogen interaction studies
- 2D and 3D culture models for physiologically relevant assays
- Lab scale bioreactors for appropriate scale-up and cell culture

#### Applications

- Viral infectivity and neutralisation assays
- Antiviral drug screening and cytotoxicity testing
- Vaccine candidate evaluation aligned with relevant regulatory guidelines
- Mechanistic studies of host-pathogen interactions
- Neutralising antibody assessments and biological potency measurements



Specialty laboratories like hVIVO will continue to lead innovation by integrating these technologies into validated workflows, ensuring resilience against evolving pathogens.

