IQVIA LABORATORIES

Vaccine Laboratory Services

IQVIA Laboratories' scientific experts integrate therapeutic insights, state-of-the-art technologies, best-in-class methods and quality systems to optimize your vaccine study design

Meeting our customers' unique vaccine development needs

With emerging and re-emerging infectious diseases, the development of new antiviral and vaccines presents many challenges. We understand these challenges, and our scientific experts can provide you with the strategic guidance to develop and validate custom assays and provide you with the high-quality laboratory services you need to ensure regulatory success.

Vaccine development requires a partner that understands your specific and complex needs. Our scientific experts provide unique insights, enable end-to-end solutions, and liaise with our clinical CRO to optimize your study designs, ensuring better outcomes and accelerating vaccine regulatory approval.

With more than 35 years of experience in infectious disease and immunology assay development and clinical trial testing, we provide comprehensive end-to-end vaccine and antiviral services. Our global network of laboratories serves as an extension of your libraries to scale quickly and efficiently to meet demands for specialty testing for all phases of development.

Our solutions include assay development, immunogenicity testing, genomic solutions, efficacy monitoring, project management and data management to meet your vaccine testing needs, whether product development or large-scale clinical trials.

Early engagement with our scientific experts provide you with:

- Unparalleled experience in applying the right laboratory-based tools to achieve high-quality data
- Scientific and therapeutic knowledge to utilize innovative technologies for clinical trials involving emerging and re-emerging infectious diseases
- Insights for optimal sample integrity

We offer an extensive test menu for vaccine and antiviral efficacy and immunogenicity. We can collaborate with you on developing and validating customized assays to meet your vaccine drug development goals.

Vaccines credentials

Respiratory	• Seasonal and Pandemic Influenza • Hemophilus influenzae B • Respiratory Syncytial virus • Neisseria meningitidis • Streptococcus pneumoniae • Bordetella pertussis	• Corynebacterium diphtheriae • Rhinovirus • SARS-CoV-1 • SARS-CoV-2 • MERS
Enteric	• Escherichia coli • Shigella spp. • Clostridium difficile • Rotavirus • Salmonella typhimurium	
Sexually Transmitted	• Cytomegalovirus • Herpes simplex virus -1/-2 • Hepatitis A, B, C • Epstein Barr Virus	
Vector/ Zoonotic	• Chikungunya • Zika • Dengue • Ebola • Malaria	• West Nile • Tick-borne encephalitis virus • Yellow Fever • Nipah
Other Infectious Diseases	• Human papilloma virus • Adenovirus • Adeno-associatedvirus (AAV) • Coxsackie virus • Measles • Mumps • Rubella • Varicella Zoster	• Tetanus • Staphylococcus aureus • Streptococcus agalactiae (GBS) • Lymphocytic choriomeningitis mammarenavirus (LCMV) • Poliovirus • Vaccinia

SARS-CoV variants (VOCs/VOIs)

VARIANT	LINEAGE	ORIGIN	PSEUDOVIRUS NEUTRALIZATION ASSAY (PNA)	ELISA
D614	NA	China	Validated	Validated
RBD	NA	China	NA	Validated
Nucleocapsid	NA	China	NA	Validated
D614G	B.1	Multiple Countries	Validated	Ag available
Alpha	B.1.1.7	UK	Optimized	Ag available)
Beta	B.1.351	South Africa	Validated	Ag available
Delta	B.1.617.2	India	Validated	Ag available
Delta+	B.1.617.2 + K714N	India	On going	Ag available
Epsilon	B.1.429	USA / California	On going	Ag available
Eta	B.1.525	Multiple Countries	On going	NA
Gamma	P.1	Brazil	Optimized	Ag available
Iota-1 and 2	B.1.526	USA / NY (1 and 2)	On going	Ag available
Kappa	B.1.617.1	India	On going	NA
Lambda	C.37	Peru	Optimized	NA
Mu	B.1.621	Colombia	Optimized	NA
Omicron	BA.1/B.1.1.529.1	South Africa	Validated	Qualified
Omicron	BA.2/B.1.1.529.2	Multiple Countries	Validated	NA
Omicron	BA.4/5; B.1.1.529.4/5	Multiple Countries	Validated	NA
Omicron	BA.2.75	Multiple Countries	On going	NA
Theta	P.3	Philippines	On going	NA
XBB.1	BA.2.10.1	NA	On going	NA
XBB 1.5	BA.2.10.5	NA	On going	NA
XBB 1.16	Close related to XBB 1.5	India / Nepal	Validated	NA
XBB 1.9.1	Close related to XBB 1.5	Indonesia	On going	NA
XBB 1.9.2	Close related to XBB 1.5	Indonesia	On going	NA
BQ.1	BA.5 derivative	NA	On going	NA
CH.1.1	Derivative Delta	India	On going	NA
Pirola	BA.2.86	On going	On going	On going
SARS-CoV-1	NA	NA	On going	On going
MERS	NA	NA	On going	On going

Various pathogens

PATHOGENS	LINEAGE	ASSAY TYPE	VALIDATION LEVEL
SARS-CoV-2 Spike (peptides)	Wuhan	14-colors ICS	Qualified
SARS-CoV-2 Spike (peptides)	Wuhan	IFNg ELISPOT	Qualified
SARS-CoV-2 Spike (peptides)	Wuhan	IFNg/IL-5 ELISPOT	Qualified
RSV	A2	µneutralization	Qualified
RSV	A-Long	µneutralization	Qualified
RSV	B	µneutralization	Qualified
RSV	A/B	Double-Color ELISPOT IFNg/IL-5	Optimized
Chikungunya virus	NA	µneutralization	Qualified
Chikungunya virus	NA	ELISA (kit)	Optimization ongoing
Anti-Pertactin	NA	ELISA (kit)	Validated
Anti-Tetanus Toxoid	NA	ELISA (kit)	Qualified
Anti-Filamentous Haemagglutinin (FHA)	NA	ELISA (kit)	Qualified
Pertussis		SBA	Qualified
Anti-Pertussis	NA	ELISA (kit)	Qualified
Anti-Diphteria Toxoid	NA	ELISA (kit)	Qualified
Anti-VZV	NA	ELISA (kit)	Validation ongoing
Anti-Rubella	NA	ELISA (kit)	Validated
Anti-Measles	NA	ELISA (kit)	Validated
Anti-Mumps	NA	ELISA (kit)	Validated
Anti-Haemophilus Influenza B (HiB)	NA	ELISA (kit)	Validation ongoing
Anti-Hepatitis B (HepB) HBsAg	NA	ELISA (kit)	Validation ongoing
Anti-Hepatitis A (HepA)	NA	ELISA (kit)	Validation ongoing
24-plex Pneumococcal Polysaccharide Serotypes	NA	Multiplex	In development
24-plex Pneumococcal Polysaccharide Serotypes	NA	24 WHO ELISAs	In development
24-Plex Pneumococcal	NA	Multiplex Opsonophagocytosis Assay (MOPA)	Qualification ongoing

Our clinical trial vaccine laboratory services include:

- Lab services to support vaccine immunogenicity and efficacy studies
- Viral neutralization assays across multiple platforms: PRNT, RVP, microneutralization
- Custom PCR development to support vector-specific detection
- Immunoassay development in ELISA, MSD and Luminex platforms
- Full range of lab services to support influenza vaccine trials

Capacity and high-quality infrastructure

- Quality Management Systems
- Bio-containment Capacity
  - » Access to three BSL-3 suites
  - » Extensive BSL2 lab space
- Throughput Capacity
  - » Phase I through Phase IV studies supported in a QA-controlled environment
  - » Sample size of supported trials: ~100 to >30,000

Quality systems

IQVIA Laboratories' client-focused project managers implement best-in-class quality systems across our global network. Combined with our supply chain and quality management systems, we ensure sample integrity for high-quality data delivery and better outcomes.

All testing is performed to the level of GCLP. Dedicated BSL-3 containment suites are also available to accommodate infectious agents requiring that level of containment. We provide infectious disease vaccine response studies for efficacy, immunogenicity, dose-response and potency. We also utilize WHO and CDC reference methods for studies when applicable

IQVIA Laboratories vaccine global delivery network

Our multi-faceted global vaccine network helps to meet your critical study milestones. With insight into regulations, customs and sample requirements, we help our customers achieve global, local or regional vaccine study milestones.

Project management

Our experienced and trained global project managers have knowledge of vaccine and infectious disease studies to provide our customers with a proactive, seamless approach to deliver responsive support across your trial. Our project managers are a single source of contact to simplify your study process while maximizing quality and efficiency. They will proactively manage your trial for delivery of consistent quality data on time and within budget.

Our responsive project management team also provides the following support:

- Multilingual investigator support for rapid response to inquiries
- Risk mitigation and solution-driven oversight
- Management of study set-up database design, kit creation, sample handling, reporting and database lock
- Validated process: systemized audit trail for SOPs and compliance

Our sample management team provides distinct quality control measures to ensure the integrity of specimens from sample acquisition to transit to testing for optimized study results.

IQVIA Laboratories is an active participant in setting global immunogenicity assay standards. Partnering with the WHO and other global organizations, we provide insights and expertise to ensure best-in-class methods. We incorporate those standards to increase your probability of study success.

IQVIA Laboratories is your partner of choice for vaccine and antiviral development needs. With our breadth of experience in infectious diseases, depth of expertise in immunology assay development and clinical laboratory testing, and global reach within our worldwide network of labs, we are prepared to support your study across the entire vaccine development life cycle.

IQVIA Laboratories has

Provided immunogenicity data to support licensure of Ebola and Dengue vaccines

Been selected as a CEPI core laboratory in support of SARS-CoV-2 and other emerging infectious disease vaccine

Collaborated with the WHO for their recent work in the establishment of SARS-CoV-2 reference standard for quantitation of vaccine-induced Immune antibody responses

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