



PPD® LABORATORIES
VACCINE SCIENCES LAB



Specialized Vaccine Development Capabilities

PPD® Laboratories vaccine sciences lab builds upon **three decades** of pharmaceutical development **expertise to support vaccine programs** from pre-clinical through post-approval.

Comprehensive capabilities

PPD Laboratories' vaccine sciences lab offers diverse capabilities and services that support vaccine development. With industry-leading facilities and instrumentation, we help you achieve the highest scientific standards for your programs while focusing on efficiencies to speed the introduction of life-changing vaccines.

Our comprehensive capabilities ensure development of innovative analytical methods and accurate, high-quality test results.

- More than 25 years of experience in providing a full range of vaccine services
- Development, qualification and validation
- Extensive statistical and regulatory expertise
- High-throughput, automated and/or multiplex assays
- Support for both adult and pediatric indications
- Extensive regulatory experience consisting of 15 FDA approved vaccines

Vaccine testing services

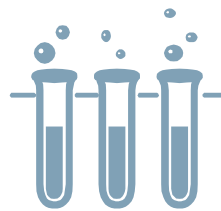
Our vaccine sciences lab supports submissions for new, modified and combination vaccines by providing efficacy and concomitant use testing services. From assay development and validation to clinical testing and regulatory approval, we offer the technology and expertise required for fast and complete vaccine development, including:

- Antigen detection/quantitative RT-PCR/sequencing
- Traditional and multiplex immunoassays
- Neutralization assays
- Cell-mediated immunity methods
- Viral and bacterial functional assays

PPD® Laboratories **partners closely with clients** to drive development with **well-defined assays**



325+
scientists



65,000+
sq. ft. vaccine lab



25+
years
of experience

Statistical support services

- 15+ years' experience
- Routinely provide reports for assay qualification, validations, transfers, optimization, reagent qualification, stability studies, relative-potency rate
- Recommend assay acceptance criteria
- Design of experiments (DOE)
- Support for regulatory responses
- Reference standard calibration

Broad therapeutic and research experience

The vaccine sciences lab provides a specialized resource to aid in the development of vaccines. Our vaccine development experience includes:

- Clostridium difficile (C. diff)
- Diphtheria, tetanus and pertussis (DTP)
- Haemophilus influenzae type b (Hib)
- Hepatitis A and B
- Human immunodeficiency virus (HIV)
- Human papillomavirus (HPV)
- Influenza virus
- Measles, mumps, rubella (MMR)
- Neisseria meningitides (meningococcal)
- Norovirus
- Respiratory syncytial virus (RSV)
- Staphylococcus aureus (Staph. aureus)
- Streptococcus pneumoniae (pneumococcal vaccine)
- Varicella-zoster virus (VZV/chickenpox and shingles)

Diverse experience with multiple assay formats

The vaccine sciences lab has a useful and diverse collection of techniques and instrumentation to support your development and testing needs.

Our diverse capabilities include:

- Molecular assays
 - PCR
 - Sequencing
- Immunology assays
 - ELISA/EIA
 - MSD® electrochemiluminescence
 - Luminex® multiplexed
 - Flow cytometry
 - Opsonophagocytic assays (OPA/OPK/MOPA)
 - Enzyme-linked immunospot (ELISPOT)
 - Serum bactericidal assay (SBA)

With our knowledge and experience come the ability to work collaboratively with clients to develop an assay de novo, transfer and develop a client-initiated assay process, and transfer (with concordance) a validated client assay.

About PPD Laboratories

PPD Laboratories provides high-quality scientific expertise with industry-leading technologies supported by a commitment to exceptional quality. Our clients benefit from comprehensive lab services spanning bioanalytical, GMP, central lab testing, vaccine sciences and biomarkers. Our laboratory services accelerate pharmaceutical development for small molecules, biologics and vaccines, allowing clients to make faster decisions about their compounds.