



PPD® LABORATORIES

PPD®

## Vaccine Sciences Capabilities

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

With state-of-the-art 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 industry-leading 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
- + Support for both adult and pediatric indications
- + Extensive regulatory experience consisting of 15 FDA approved vaccines

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

### COMPREHENSIVE CAPABILITIES

PPD Laboratories' vaccine sciences lab offers diverse capabilities and services that support vaccine development.

- + Development, qualification and validation
- + Extensive statistical and regulatory expertise
- + High-throughput, automated and/or multiplex assays

### 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 best technology and expertise available 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

### 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

# Vaccine Sciences Capabilities



## BROAD THERAPEUTIC AND RESEARCH EXPERIENCE

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

- + *Clostridium difficile* (C. diff)
- + Cytomegalovirus (CMV)
- + Diphtheria, tetanus and pertussis (DTP)
- + Haemophilus influenzae type b (Hib)
- + Hepatitis A and B
- + Human immunodeficiency virus (HIV)
- + Human papillomavirus (HPV)
- + Human rhinovirus (HRV)
- + Influenza virus
- + Measles, mumps, rubella (MMR)
- + *Neisseria meningitidis* (meningococcal)
- + Norovirus
- + Respiratory syncytial virus (RSV)
- + Rotavirus
- + *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 unique 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/HAI
  - MSD® electrochemiluminescence
  - Luminex® multiplexed
- + Cell-based and functional assays
  - 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 fully develop a client-initiated assay process, and transfer (with concordance) a fully validated client assay.

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PPD Laboratories has worked on 15 FDA-approved vaccine programs... More than any other CRO lab.

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## ABOUT PPD LABORATORIES

PPD Laboratories provides world-class scientific expertise with state-of-the-art 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.