

Oligonucleotide (Oligo) Development Expertise

Supporting customers through an efficient end-to-end journey of their oligonucleotide programs

PPD® LABORATORIES

PPD Laboratories' bioanalytical lab has been working with **oligonucleotide molecules** for more than **two decades** and has accumulated the experience needed to **understand and execute** oligo development programs for our customers.



20+ years working knowledge and 400+ oligo assays



Extensive regulatory experience



ELISA, immunogenicity, ADA, MS, PCR

Comprehensive oligonucleotide capabilities and bioanalytical service offerings

- Customized method development, transfer and validation U.S. Food and Drug Administration (FDA) good laboratory practices (GLP)
- Comprehensive immunochemistry services including candidate selection, discovery work, pre-clinical studies and clinical trials Phases I-III
- Broad chromatography services using ion-pair reversed-phase (IP-RP) ultra high performance liquid chromatography (UHPLC) coupled with mass spectrometry and hybridization AX-HPLC fluorescence as alternative techniques for quantitation or to evaluate potential oligo metabolites
- Wide-ranging molecular genomic services including PCR, real-time PCR, digital droplet PCR (ddPCR), Sanger sequencing, and next-generation sequencing (NGS) to support pre-clinical through post-licensure

Extensive expertise

- Electrochemiluminescent (ECL), colorimetric and fluorescent hybridization enzyme-linked immunosorbent assay (ELISA), and branched DNA (bDNA) methodology
- Immunogenicity/anti-drug antibody assay development and validation
- Target identification/confirmation and metabolite analysis/quantification using a variety of chromatography and mass spectrometry platforms
- Semi-quantitative and quantitative polymerase chain reaction (PCR), real-time PCR and digital droplet PCR
- High throughput liquid handling and sample analysis
- Tissue-based analysis
- Technology selection advice based upon sensitivity, selectivity, complexity, dynamic range, throughput and specific program needs
- Navigation of regulatory requirements for oligos and other cell and gene therapies

PPD Laboratories bioanalytical lab has been working with oligonucleotide molecules since 1997 and has a wealth of experience in pharmacokinetic/pharmacodynamic (PK/PD), immunogenicity and molecular genomics.

Analytes

- Aptamers
- CRISPR/Caspase9
- Gapmers
- Locked nucleic acid (LNA)
- Messenger RNA (mRNA)
- Small interfering RNA (SiRNA)
- Splice-Switching Oligonucleotides (SSO)
- Toll-like receptor targeted (TLR)
- Phosphorodiamidate Morpholino Oligomer (PMO)

Drug Delivery

- Naked nucleotides
- Targeted delivery (GalNAc, peptide-mediated)
- Lipid nanoparticles (PEG)
- Viral vectors (AAV/etc)

Key instrumentation

Including but not limited to:

- Perkin Elmer® VICTOR X4
- MSD MESO SECTOR S 600, Imager 6000, and PR 100
- Spectramax® Plus 384
- Applied Biosystems™ QuantStudio™ Dx, 6 and 12K Flex
- BioRad QX200™ Droplet Digital™ PCR System
- Applied Biosystems 3500 and 3730xI DNA Analyzer
- Illumina® MiSeq
- Various instruments for liquid chromatography, fluorescence detection and mass spectrometry including SCIEX, Waters and Thermo Fisher Scientific

PPD Laboratories

PPD Laboratories provides high-quality scientific expertise with industry-leading technologies supported by a commitment to exceptional quality. Our customers 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, vaccines, and cell and gene therapies allowing customers to make faster decisions about their compounds.

