

Biosafety Capabilities and Expertise

Advanced mycoplasma and viral testing services to support development of biologics and cell & gene therapies.

PPD® Laboratory Services

Our **GMP lab** has expanded testing capabilities offering **compendial and novel validated biosafety methods**. With **extensive expertise in GLP and GMP regulations and PCR technologies**, our biosafety lab offers **fast, simple, and reliable options** for characterization of cell banks, unprocessed bulk and final products.



A culture of quality and service for 30+ years



Extensive regulatory experience in the U.S., U.K., Ireland and the EU



Flexible, customized solutions to meet customer needs

USP/EP/JP/PTC Compliant Mycoplasma Assays

- Culture method
- Indicator cell culture method
- MycoplasmaStasis assay
- MycoSEQ Plus real-time PCR assay
- Enrichment MycoSEQ Plus real-time PCR assay

Product Type Experience

- Analytical/master/working cell banks
- Cell and gene therapy
- Monoclonal antibodies
- Media

Viral Safety Testing

- In vitro adventitious viruses assays
- ViralSEQ real-time PCR assay for minute virus of mice
- Replication-competent assay for adeno-associated virus
- Replication-competent assay for lentiviruses

Study Type Experience

- Quality control and release testing
- Cell bank qualification and storage
- Comparability and validation studies
- Method transfer

PPD Laboratories Services GMP Lab met or exceeded expectations for quality of analytical testing for 98% of our customers.

1. Based on customer survey data

One lab, multiple locations



ATHLONE,
IRELAND

More than
84,000 sq. ft.
and **360+** staff



MIDDLETON,
WISCONSIN

More than
605,000 sq. ft.
and **2,200+** staff



FUNCTIONAL SERVICE
PARTNERSHIPS

Multiple client locations in the
U.S. and Europe
with more than **400+** staff

Well-designed environmental control systems

- Dedicated 2000 sq ft of HEPA filtered, restricted access lab space
- Dedicated lab areas for
 - Mycoplasma testing
 - Viral testing
 - Pre- / Post-amplification PCR
- REES Scientific automated temperature monitoring system

Key Instrumentation

- Nikon® microscope models Upright Eclipse Ci and Inverted Ts2-FL
- Eppendorf/BioRad PCR thermal cyclers
- Kingfisher Automated Nucleic Acid Extraction System
- Applied Biosystems™ 7500 Real-Time qPCR
- Implen NanoPhotometer® NP80 Spectrometer
- NucleoCounter® NC-202

PPD Laboratory Services

PPD® Laboratory Services 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.

For more information: www.ppd.com/our-solutions/ppd-laboratories/gmp-lab/

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