

## PPD cGMP Laboratory Test Menu

Biomolecule Test Category	Testing Capabilities
Characterization-Molecular Mass/Size	MS SEC-MALLS SDS-PAGE (Reduced, non-reduced and native) CE-SDS CGE Agarose Gel Electrophoresis Dynamic Light Scattering
Characterization-Sequence and Composition	Sequencing by MS/MS N- & C- Terminal Sequence Confirmation Biomolecular Modifications Peptide Mapping Amino Acid Analysis Disulfide Bond Analysis Glycosylation Analysis FTIR 2D Gels Immunoblots ELISA
Characterization-Charge	IEF cIEF IEX MS
Assay/Purity/Degradants	UV Colorimetric Protein Assay RP-HPLC SEC SDS-PAGE CGE CE-SDS IEX cIEF IEF ELISA
Biological Activity	Cell-Based Bioassay Receptor Binding Assay Antibody Binding Assay Kinetic assays (Enzyme activity & $K_M/k_{cat}$ )
Residuals	Host-Cell Protein Host-Cell DNA Head-Space GC, GC/MS IC MS HPLC ICP-MS AA
Microbiology	Endotoxin Sterility Microbial Limits Antimicrobial Effectiveness Microbial Identification
Container Closure	Extractables/Leachables Package Integrity
Formulation Verification including Vaccines	Analytics applied as indicated