



Technology Platform for Biotherapeutics

Innovative laboratory services for
pharma and biotech

Biotherapeutics

Biosimilars, Biobetters, Bioconjugates and nucleic acid-based therapeutics
(mRNA vaccines, ASO, siRNA, Aptamers)

Quality Attributes

Primary structure

- Sequence confirmation
- Intact mass (proteins, synthetic oligonucleotides, mRNA products)
- Post-translational modification (peptide mapping)
 - Phosphorylation
 - Lipidation
 - Glycosylation (N-, O- Linked)
 - Disulfide mapping
- Deamidation
- Oxidation
- Oligosaccharide profiling (HPLC-CAD)
- Sialic acid analysis
- Monosaccharide analysis

Quality Attributes

Target binding	<ul style="list-style-type: none">▪ Immunoassays
Strength (protein, RNA content)	<ul style="list-style-type: none">▪ Colorimetric and fluorescence assays/ detection▪ Activity assays
Process related impurities	<ul style="list-style-type: none">▪ Aggregates▪ Truncation/ Fragmentation/ partially reduced species▪ Residual deoxyribonucleic acid (DNA)▪ Expression inducers▪ Anti foam agents
Charge variants/ Distribution	<ul style="list-style-type: none">▪ cIEF▪ Capillary Zone Electrophoresis (CZE) Rapid Charge variant analysis
Chemical modifications/ Conjugates	<ul style="list-style-type: none">▪ PEGylation▪ AB Drug Conjugates (ADCs)▪ mRNA capping
Delivery methods	<ul style="list-style-type: none">▪ Lipid nanoparticles (RNA), Aptamers

UPLC-HRMS

ZenoTOF 7600

The system combines High selectivity (qualitative) with Quantitative power (MRM experiments)

- Intact mass analysis (spectral deconvolution processing)
 - Proteins (ABs, modifications)
 - Truncation, partial sequences, aptamers
 - Nucleic acids (DNA, modified RNA sequence , mRNA capping analysis)
- Peptide mapping
 - Sequence confirmation
 - Posttranslational modifications (glycosylation, phosphorylation,... etc.)
 - Oxidation, Deamidation, PEGylation
- Oligosaccharides profiling, Sialic acid analysis, Monosaccharide
- Lipid analysis



Capillary Electrophoresis

Sciex PA 800 plus, CE-HRMS analysis option

Compliant biotherapeutics QC analysis

- Proteins (ABs), Glycans
 - CE-SDS purity and heterogeneity
 - Charge variants and heterogeneity with cIEF and CZE
 - Rapid Charge variant analysis
 - Aggregates
 - Truncation/ Fragmentation (CE-SDS)
- Nucleic acids applications (DNA, ASOs, siRNAs, mRNAs and aptamers)
 - Purity and Integrity



Bioanalyzer

Agilent 2100 chip-based analyzer

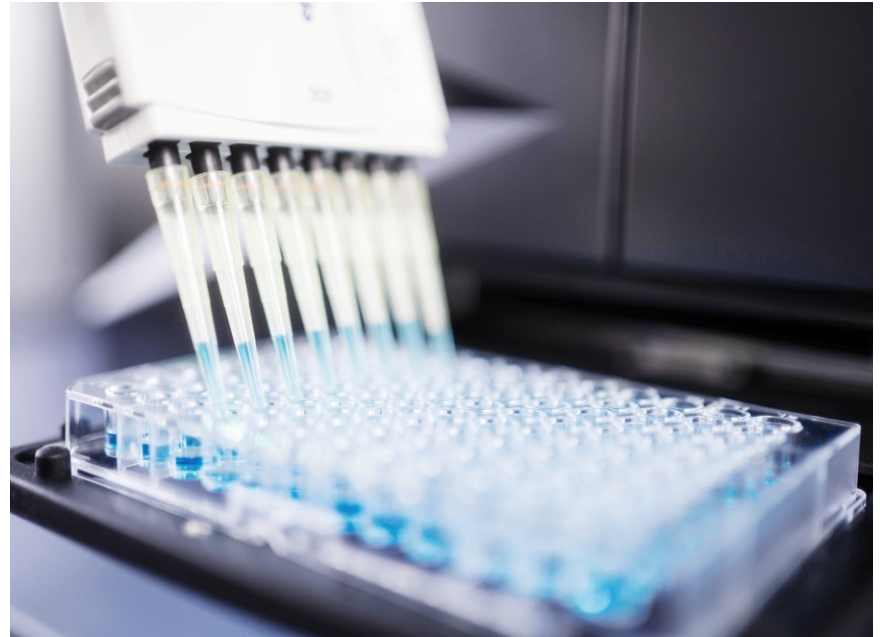
- Electrophoretic separations (QC)
 - DNA Assays
 - Sizing, quantitation, PCR product purity
 - RNA Assays
 - Purity & Integrity determination, total RNA, mRNA quantitation
 - Protein Assays
 - Sizing, quantitation, aggregates, truncation, fragmentation
- Flow Cytometry
 - Cell Assays (protein expression analysis, transfection efficiency monitoring, 2 color detection)



Microplate Reader (Fluorescence + UV-Detector)

Tecan Reader Infinite M nano+

- Protein and Nucleic acid content (Strength)
 - RNA, DNA quantitation assays
 - Protein quantitation (Bradford, NanoOrange assay)
- Endotoxin quantitation
- ELISA assays
 - Quantitative analysis for cytokines, phosphoproteins, oncogenes, biomarkers
- Interaction assays
 - Kinase, phosphatase, protease activity assays
 - Protein-protein, protein-peptide, and protein-DNA/RNA binding



UPLC–CAD

ThermoScientific Veo RS Charged Aerosol Detector

An alternative method to UPLC-UV for analytes with a weak UV response (lacking a chromophore). No need for derivatization.

- Quantitative chromatographic analysis
 - Impurity profiling
 - Native Glycans
 - Adjuvants
 - Amino acids
 - Lipids, phospholipids
 - Oligonucleotides
 - Biosurfactants



Thank you for your attention.

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