



## 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

# Biotherapeutics

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

# 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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