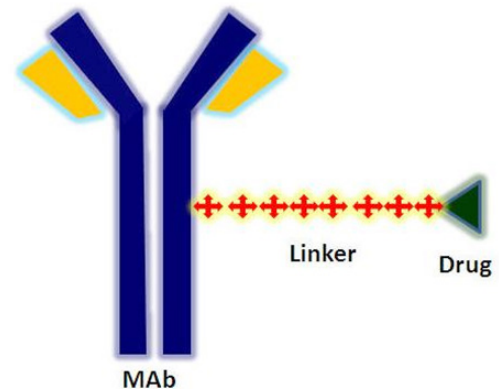




# Antibody Drug Conjugates (ADCs)

**ABOUT ADCs:** Potent and specific biopharmaceuticals that continue to show significant therapeutic promise, ADCs combine the specific targeting abilities of an antibody with cytotoxin that attacks cancer cells that contain a unique marker. This significantly improves delivery of the toxin to the target tissue or tumor while minimizing exposure to healthy tissue.

The complex nature of ADCs presents unique challenges in the bioanalytical laboratory that require thorough understanding of the chemistries and interactions between each component of the conjugate. Traditionally bioanalysis necessitates a combination of ligand binding and LC-MS/MS techniques to characterize the pharmacokinetics of the ADC. With advances in LC-MS/MS technology it is possible to perform each component on a single platform. Alturas has:



- ▶ Developed and validated >30 LC-MS/MS methods for different payloads
- ▶ Developed and validated all ADC methods in full compliance with FDA and EMA bioanalytical guidelines
- ▶ Collaborated on various unique ADC programs and analyzed >30,000 ADC samples
- ▶ Analyzed thousands of protein samples by LC-MS/MS of signature peptides

**About Alturas Analytics, Inc.:** Alturas Analytics is a GLP compliant bioanalytical CRO specializing in MS/MS solutions supporting early discovery through late phase clinical trials. In addition to providing PK support services to pharmaceutical companies worldwide, Alturas maintains an intensive research effort of applying new technologies leading to scientific advancement. The success of Alturas is built on building long term collaborations with clients by delivering personalized, bioanalytical results on time with the highest level of integrity.



## Focused on MS/MS Bioanalysis and PK Services

Known as the technology leader of MS/MS bioanalysis, Alturas Analytics delivers results on time with scientific integrity that exceeds industry standards. Privately owned and client focused, in our 20 years of operation Alturas Analytics has earned a reputation for personalized service and innovative MS/MS solutions.

### BIOANALYTICAL SERVICES

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- ▶ Methods Development, Transfer and Validation
- ▶ GLP and Non-GLP Sample Analysis
- ▶ Antibody Drug Conjugate (ADC) and Other Macromolecule Analysis
- ▶ Protein Binding Determination
- ▶ Dried Blood Spot (DBS) and Matrix Spot Analysis
- ▶ PK and TK Analysis and Reporting

### QUALITY SYSTEMS

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- ▶ Compliant to GLP and FDA, EMA and Crystal City Guidelines
- ▶ Onsite QA and IT Departments
- ▶ Thermo-Watson LIMS
- ▶ 21 CFR Part 11 Compliant
- ▶ GLP Validated Analyst Software
- ▶ Validated WinNonlin®
- ▶ Rush and Next Business Day Data Delivery Available

### RESEARCH

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- ▶ 15% of Capacity Reserved for Research
- ▶ New Bioanalytical Techniques Including:
  - ▶▶ Microflow LC-MS/MS
  - ▶▶ Immunocapture
  - ▶▶ Picofuze™
  - ▶▶ Creation of Novel Dye to Analyze Translucent Matrices Such As:
    - ◆ Tears, Cerebrospinal Fluid, Synovial Fluid

### FACILITIES AND EQUIPMENT

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- ▶ 15,000 Sq. Ft. Purpose-Built Facility
- ▶ Sciex 4000, 5500 and 6500 Mass Spectrometers
- ▶ Shimadzu UPLCs
- ▶ Waters M-Class Microflow UPLCs
- ▶ Watson LIMS system
- ▶ HTDialysis Micro-Equilibrium Devices

