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# High-resolution mass spectrometry for quantitative analysis of drugs, biologicals and biomarkers in clinical and preclinical research

The quantification of therapeutics and associated biomarkers is crucial for understanding drug efficacy and patient response in personalized medicine, and in clinical studies. Liquid chromatography-tandem mass spectrometry (LC-MS/MS) offers unique advantages for high resolution quantitative analysis of small-molecules, peptides and even proteins that are used as therapeutics (including monoclonal antibodies, bispecific antibodies and antibody-drug conjugates). Mass spectrometry offers quantitative analyses with higher specificity and sensitivity compared to traditional immunoassays.

We have developed and validated a broad spectrum of LC-MS/MS methods for quantitative analyses of drugs and metabolites as well as biomarkers, with high standards needed for pharmacokinetic (PK) and pharmacodynamic (PD) studies. We also offer therapeutic drug monitoring for patients in vitro diagnostic quality. We enable analyses in various matrices such as in plasma, urine, tissue, cultured cells, organoids, and dried blood spots (DBS). Our workflow incorporates advanced sample preparation techniques and targeted proteomics approaches, ensuring full compliance with key validation parameters such as accuracy, precision, selectivity, linearity, recovery, matrix effect, carry-over, and stability.

In various clinical and in vitro research projects, we have successfully analyzed a wide range of antineoplastic small molecule drugs, including tyrosine kinase inhibitors (TKIs), phosphodiesterase inhibitors, ion channel inhibitors, immunomodulators, neuropsychiatric agents, and MDM2 inhibitors. We have successfully expanded our methods for analysis of peptides and proteins for quantification of biotherapeutics such as monoclonal antibodies and antibody-drug conjugates.

Our current focus extends to the simultaneous quantification of biotherapeutics while monitoring relevant biomarkers, providing comprehensive molecular-level insights into individual bioavailability and treatment response. This integrated approach enables the study of efficacy and safety of biological therapeutics, as well as the identification of novel protein biomarkers associated with treatment response and disease progression. Our LC-MS/MS platform represents a powerful tool for advancing biotherapeutic development and personalized medicine, supporting preclinical and clinical drug development.

## Research type

Clinical research

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