

# TIER 1 LC/MS/MS BIOANALYSIS

## ANALYTICAL SYSTEMS

- SCIEX 4000 TRIPLE QUAD MASS SPECTROMETER
- AGILENT 1100 HPLC
- AGILENT DIODE ARRAY
- CTC PAL AUTOSAMPLER
- MP BIO HOMOGENIZER
- SOLID PHASE EXTRACTION
- REFRIGERATED CENTRIFUGES



## TIER 1: SMALL MOLECULE BIOANALYSIS

**Scenarios:** Medicinal chemistry in vivo screens such as cassette dosing, cassette analysis, sparse time point studies, or rapid in vitro stability or protein binding studies.

**Typical number of molecules:** 1-10

**Method Development Cost Range** (number of compounds dependent): \$1000-6500

## EXAMPLE ANALYSIS

**LC/MS/MS Method Development:** Compound infusion, MS autotune or manual tune. Minimal ionization optimization, HPLC column selection for acceptable peak shape, injection of compound at 25 ng/mL in water sample and acetonitrile standard to assess peak shape.

**Sample Extraction:** Dependent upon the water and acetonitrile standards assessment; either direct 4:1 acetonitrile precipitation of 25-50uL plasma/serum, centrifugation and injection, or acetonitrile precipitation, centrifugation and 3:1 dilution with mobile phase.

**Sample Extraction Sensitivity and Linearity:** Not Conducted

**Minimum Acceptance criteria:** +/- 30% center of range, +/- 40% ULOQ and LLOQ

**Quality Controls:** Not implemented

**Sample Batch Analysis:** One standard curve (5000, 2000, 500, 200, 50, 20, 5, 2 ng/mL, Blank, Double Blank) interspersed through samples, curve can contain 1-5 compounds (excluding internal standard), batch is 30-40 samples.

**Sample Analysis Cost Range** (number of compounds dependent): \$1500-3800

### Example Analyses:

**30 samples/1 API-** \$1500 (1 API in plasma/serum/in vitro matrix)

**40 samples/5 APIs -** \$3800 (5 APIs in plasma/serum/in vitro matrix):  
\$50/sample w/1 API, \$65/sample w/2 APIs, an additional \$10/API up to 5 APIs/  
sample

**Results Reporting:** Excel file

**Standards:** Reporting of Used/Excluded, Nominal, Back Calculated, % Nominal

**Samples:** Calculated concentration in tabular format.



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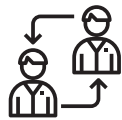
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