

TIER 3 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 3: SMALL MOLECULE BIOANALYSIS

Scenarios: NonGLP study with compound specific requirements such as proof of concept studies and nonGLP toxicology studies.

Typical number of molecules: 1 with or without metabolites

Method Development Cost Range (number of compounds dependent): \$2250/day typically 1-4 days

EXAMPLE ANALYSIS

LC/MS/MS Method Development: Compound infusion, MS autotune or manual tune. Ionization parameters optimization, HPLC column and mobile phase selection for acceptable peak shape, injection of compound at 1-5 ng/mL in water sample and acetonitrile standard.

Sample Extraction: Direct 5:1 acetonitrile precipitation of 25-50uL plasma/serum/tissue, centrifugation dry down under heated nitrogen and reconstitution in initial mobile phase. If target LLOQ is not met then other methods such as Solid Phase or Liquid-Liquid extraction evaluated.

Sample Extraction Sensitivity and Linearity: Assessment of duplicate standard curves for linearity and sensitivity and reproducibility on two different injection days.

Standard Curve in species matrix: Initial assessment of Tier 2 curve then optimization of 10 standards within linear range.

Extracted once and injected twice

Minimum Acceptance criteria: +/- 17.5% and +/- 25% LLOQ

Quality Controls: Dependent on Std Curve range; High, Medium and Low in duplicate from second working stock solution

Acceptance criteria: +/- 20%

Sample Batch Analysis: One standard curve at the beginning of run, interspersed QCs through samples, and second standard curve at the end of the batch of up to 70 samples.

Sample Analysis Cost Range: minimum batch cost of \$2000 for fluids and \$2600 for tissues, additional \$50/fluid sample or \$65/tissue sample above 40 samples for a single compound.

+ \$15/sample for 2 compounds/sample under analysis

+ \$25/sample for 3 compounds/sample under analysis

Results Reporting: Excel file (additional charge for standard report format)

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

QCs: Reporting of Used/Excluded, Nominal, Back Calculated, % Nominal

Samples: Calculated concentration in tabular format and PK input file



Christopher Crean
CEO, Principal Consultant
ccrean@xyzagen.com
919.812.8119

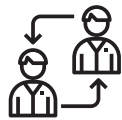
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www.xyzagen.com
480 Hillsboro St., Ste 140
Pittsboro, NC 27312