



**AIT Bioscience**

*Transforming the Process. Partnering for Results.*

## BIOANALYTICAL SOLUTIONS FOR BIOTHERAPEUTICS AND SMALL MOLECULE THERAPEUTICS

### DISCOVERY PK SERVICE

#### Same day reporting of data with Discovery PK Service

##### Purpose

Our discovery PK service provides same day results to expedite your program. Our PK method development and qualification takes only 3 days for human IgG drugs dosed in rat, for non-compliant, discovery and research applications (non-GLP and non-regulated).

##### When to Use

- Discovery screening, non-GLP
- Lead optimization
- Early exploratory Tox

##### Advantages

- Ability to make informed decisions earlier in the process
- Provides same day results for 60 samples or less
- Produces rapid method development and qualification in only 3 days
- Requires low sample volume (as low as 2 uL)

##### What do I get?

- Qualification/validation performance data
- Concentration data (non-QA reviewed data)
- Graphic representation of regression with calculated fit

##### What do I pay?

- Discounted discovery rates
- Charged per 96 well plate

##### When do I get it?

- Same day results for 2 plates or less (60 samples in duplicate) if received before 10:30 am
- Within 3 days of sample receipt for 3 or more plates

##### Targeted Performance

- 15% total error (absolute value of %RE + %CV) for 3 QC levels

#### Our Differentiators: Speed Plus Science



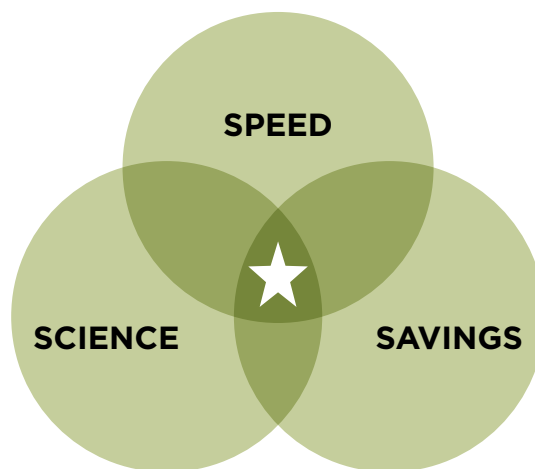
- Same day reporting of data



- 30-minute quantitative LBA results



- Team of scientists with extensive LBA expertise



### Method Development

- PK immunoassay development completed in 2 days
  - Establish range of standard curve, LLOQ, ULOQ, placement of 3 QC levels, MRD
  - Approximate range will be 2 ng/ml to 2,000 ng/mL (2.5 to 3 logs of dynamic range)

### Validation (Qualification)

- 3 accuracy and precision runs, 3 QC levels, dilutional linearity
- No stability testing

### What do I supply?

- Human IgG drug
- Matrix (serum or plasma)

Calibrator ng/mL	Mean Response	% CV	Back Calculated	% Bias	% TE
4000	3829598	1.3	4001	0	1.3
2000	3117366	1.0	2000	0	1.0
1000	1942815	1.4	1000	0	1.4
100	125493	1.3	99.6	-0.4	1.7
50	59700	1.2	50.9	1.8	3.0
25	34227	1.5	26	4.0	5.5
12.5	25089	3.0	14.3	14.4	17.4
0	512	4.8	N/A	N/A	N/A
Quality Control Samples ng/mL					
1000	1882120	0.7	965	-3.5	4.2
100	125835	0.5	99.6	1.4	2.1
50	56366	1.1	48.4	3.2	4.3
25	33498	0.3	25.2	1.0	1.3

Table 1. Representative discovery PK data. Humira was dosed in rats. Rat matrix (serum) was not diluted and applied directly to the immunoassay. Conjugated anti human IgG antibodies were diluted in assay buffer and pipetted into desired wells (master mix). Samples were added to the master mix at 25 uL per sample per well. The plate was placed on a shaker at 300 RPM for 30 minutes. The plate was evaluated by a plate reader.

### Frequently Asked Questions

**Q:** What if my species is not rat?

**A:** The service is still possible. Work with AIT Bioscience to determine next steps.

**Q:** What if my drug is not human IgG?

**A:** Other biologic drugs are possible for this discovery format. Work with AIT Bioscience to determine next steps.

Learn more at [www.aitbioscience.com](http://www.aitbioscience.com) or contact Mark Cameron, [mcameron@aitbioscience.com](mailto:mcameron@aitbioscience.com), Vice President of Scientific Services, Ligand Binding Assays, for additional information about this new service offering by AIT Bioscience.