

CRITICAL REAGENTS SERVICES

Reagent support from antibody & assay experts



- Critical reagent generation support
- Critical reagent labeling (biotin, sulfo-TAG, DIG, etc.), characterization, qualification
- Fab fragment digestion, purification, characterization

- Critical reagent lot bridging
- Biomarker calibrator material characterization and stability
- Reagent characterization and stability

- Reagent purification
- Multiple labeling service options to meet needs at all stages of drug development
- Additional a la carte service options also available

Reagent Generation Support from Antibody and Assay Experts

- Fully customizable antibody campaign support model:
 - Monoclonal and polyclonal anti-drug antibody campaigns
 - Biomarker assay reagent campaigns
- Comprehensive project management
- Data review and clone selection
- Seamless in-house/in-assay testing of early clones
- Recombinant production of selected clones at preferred vendor

Protein Analytics Expertise

- Protein concentration
- Octet® binding kinetics and epitope binning
- FPLC analysis including:
 - Purity of preparation
 - Degradation analysis
 - Aggregation status
- Determination of label incorporation ratios



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SERVICE	PILOT LABELING	LABELING OPTIMIZATION	PRODUCTION LABELING
Scale (per label)	(1-2.5)mg	6x1mg	up to 10mg
Number of Labeling Conditions	up to 2	up to 6	1
Buffer Exchange (if necessary)	x	x	x
Concentration / %Recovery	x	x	x
CONJUGATION			
Biotin	x	x	x
Ruthenium	x	x	x
DIG	x	x	x
Post-Conjugation Cleanup	x	x	x
Concentration / %Recovery	x	x	x
LABEL INCORPORATION			
HABA Assay	x	x	x
MSD Cuvette Test	x	x	x
Octet Streptavidin Testing	If necessary	If necessary	If necessary
SAMPLE QC			
Pre-Conjugation FPLC-Analysis			x
Post-Conjugation FPLC-Analysis			x
Dilution/Aliquot of Reagent(s)			x

Pilot Labeling: Designed to demonstrate that molecule can be successfully labeled. Includes basic characterization (non-GLP/exploratory). Limited to 2 labeling conditions and 2.5mg.

Labeling Optimization: Recommended for molecules with no labeling experience or that have complex structures and where multiple variables need to be tested to find optimal labeling conditions. Up to 6 buffer and/or labeling ratios at 1mg can be tested. Additional troubleshooting can be done at a daily rate, as needed.

Production Labeling: Generates the final labeled reagents, and accompanying characterization, to support the assays from method development through validation and sample testing.