

Analytical Support for Cell Line Development

BioReliance’s Analytical Services offers clients an array of analytical methods to test the purity, identity, potency, and stability of their monoclonal antibody (mAb) and recombinant protein products. These methods are crucial for the analysis and characterization of biologics as well as for ensuring the safety, stability, and efficacy of the product at every stage of development.

Analytical Assays for Clone Selection

With state-of-the-art analytical instrumentation and over 60+ years experience in the industry, Analytical Services at BioReliance can assist clients at all stages of process development including cell line development (CLD) and Master Cell bank (MCB) development services. We provide analytical tests (**Table 1**) that are directly applicable to the characterization and selection of clones to be used in product development as well as methods that can accelerate downstream protein purification and quality testing programs.

Table 1: Assays for Clone Selection

Clone Selection Assays			
Assay Name	Recombinant Protein	Monoclonal Antibody	Instrument
Molecular Weight	✓	✓	LC-MS, SDS-PAGE
Antibody Subunit Analysis		✓	LC-MS
Charge Profile	✓	✓	cIEF, IEX

Note: In addition to the analytical assays listed, BioReliance is able to offer a complete suite of testing for the characterization of MCB and CLD, including identity, purity and suitability tests. For a full list, please contact BioReliance at the address shown below

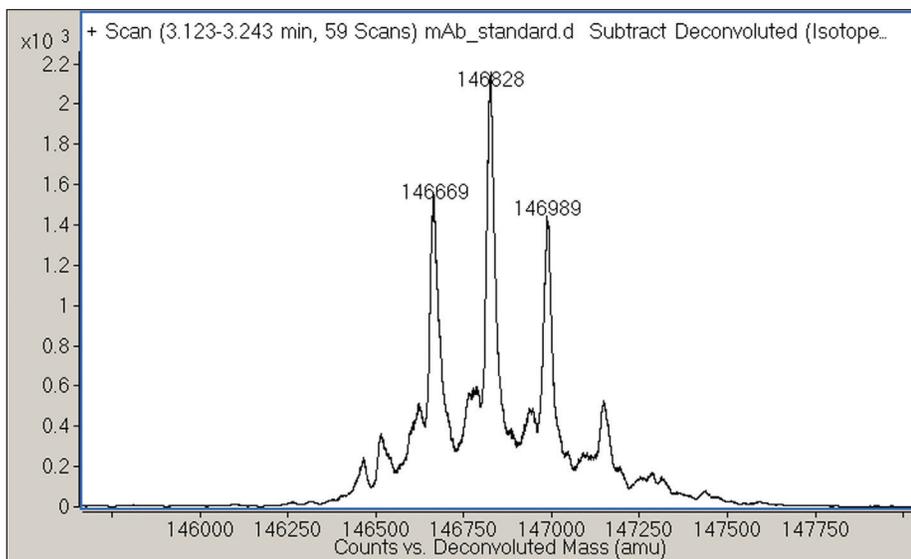


Figure 1: Determination of Molecular Weight

State-of-the-art instrumentation and cGMP capabilities provide results you can trust

Reliable service with fast turnaround delivers data on time

Analytical testing programs are designed by industry experienced scientists to suit your needs

BioReliance

Analytical Services

Over Sixty Years of Experience

BioReliance has a long history of experience in the field of biological testing and analysis. BioReliance offers a comprehensive range of customizable analytical testing services to ensure the purity, safety, and potency of a product. With industry leading turnaround times and state of the art instrumentation (**Table 2**), we are well positioned to support our clients throughout the biologic manufacturing process.

Table 2: Equipment with analytical capabilities

Instrument List
Agilent 6540 QTOF Mass Spectrometer with ChipCube
Agilent 1260 Bio-Inert HPLC
Agilent 1290 Infinity Binary UHPLC
ProteinSimple iCE3 Capillary electrophoresis protein analyzer
Beckman PA 800+ Pharmaceutical Analysis System
Agilent 2100 Capillary SDS



Cutting Edge Technology

As a leader in innovation and technology, BioReliance uses state of the art instrumentation such as UHPLC and Mass Spectrometry to conduct analytical testing. Our significant in house capabilities give our clients the choice of customized testing from a broad range of high complexity and low complexity techniques. Our industry trained analytical scientists can assist in the design of a successful analytical testing strategy for your monoclonal antibody or recombinant protein.

www.bioreliance.com

North America Toll Free: 800 553 5372 Tel: 301 738 1000
Europe & International Tel: +44 (0)141 946 9999 • Japan Tel: +81 (0)3 5796 7430
Email: info@bioreliance.com

©2014 Sigma-Aldrich Co. LLC. All rights reserved. BioReliance and SAFC are trademarks of Sigma-Aldrich Co. LLC or its Affiliates, registered in the US and other countries. F-1320714
RDL

 **BioReliance**[®]
by **SAFC**