



Custom Biologics

**Exceptional Science.
Uncompromising Quality.**

We support every stage of biopharmaceutical drug development and commercialization:

Who We Are

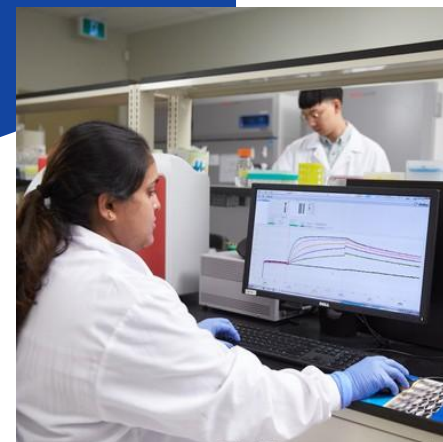
Global regulatory compliant large molecule bioanalytical CRO providing specialized, GLP-compliant assay development, validation, and testing services



Preclinical (CMC)



Clinical (PK & Immunogenicity)



Lot Release

Our History & Track Record

22

Years in Business

30

Full-Time Employees

150+

Customers Worldwide

200+

Pre-Clinical/CMC & Clinical Immunogenicity Studies



2004

Custom Biologics was founded. Provided contract R&D proteomic services and protein characterization using MALDI-MS and ESI-MS

2006

Expanded mass spec services to include small molecule quantification in biological matrices and implemented a GLP compliant quality system based on the FDA's 21 CFR Part 11 Guidelines

2010

Introduced large molecule cell-based assay testing services, further specialized in biologics, and introduced capabilities for genetic medicines

2015

Purchased 115 Skyway Ave. Major renovation of aging CDMO facility into a new state of the art GLP compliant bioanalytical testing laboratory

2024

Rebrand, new website launch, Custom Biologics celebrates 20th anniversary

Present

Expanding global presence & serving growing customer base

Core Capabilities



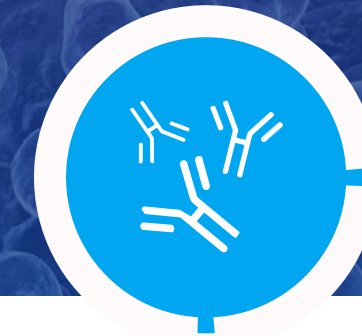
**Cell-Based
Potency Assays**



**GMP Lot & QC
Release Testing**



**Clinical Sample
Analysis (GLP)**



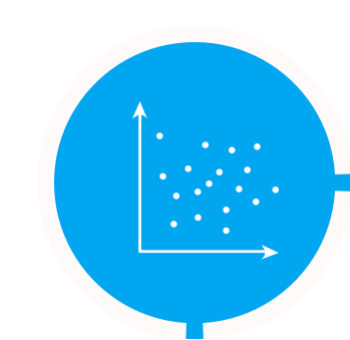
**Immunogenicity ADA
and NAB Assays**



**Biomarker
Quantification
(protein &
genetic transcripts)**



**LBA & Binding
Kinetics**



Flow Cytometry



ddPCR/qPCR

Next Generation Sequencing (coming soon)



Bioanalytical Testing for Different Drug Classes

Supporting biopharmaceutical clients at all stages of drug development for:

- Cell therapies
- Gene therapies/genetic medicines
- Vaccines
- Biologics
- Biosimilars
- Immunotherapies
- Antibody drug conjugates

Our Facility

- 12,000 sq. ft. total space, including 8,500 sq. ft. of purpose-built laboratory space
- Biosafety Level 2 (BSL-2) certified environment
- Health Canada-audited, cGMP-compliant
- Drug Establishment Licence: 3-002362-A
- Operates in compliance with FDA regulations, including 21 CFR Parts 11, 58, and 211



Infrastructure & Security

- Controlled access with 24/7 on-site monitoring.
- Continuous temperature monitoring of fridges, freezers and incubators.
- Fully validated computer systems and software.
- Automated data backup and redundant storage.
- Backup power supply with emergency generator to ensure uninterrupted operations.



Why Custom Biologics?

- **Built-in regulatory alignment** from preclinical through clinical stages of drug development.
- **Client-centered, science-led** approach.
- Specialized in **large molecule & genetic medicines**
- **Latest scientific instrumentation & equipment**
- **In-house Quality and Regulatory** teams
- **4-Point Pharmaceutical Quality Management System:**



1) Implementing quality-driven processes



2) Maintaining a clean & safe environment



3) Communication, transparency & integrity



4) Consistent quality across all our platforms



OUR SPECIALTY:

Excellence in functional characterization & clinical testing of biotherapeutics

What Our Customers Have to Say

“Custom Biologics is one of the few vendors I can honestly say I have full confidence in quality, deliverables, professionalism, and friendliness. They are pleasant, easy to work with, straightforward and upfront, and always ready to offer a solution that is realistic to implement.”

“The technical staff has consistently showed a high degree of scientific interest and engagement in a highly collaborative effort spanning several years. The team has been very responsive to our direction but have also been the source of key insights in the advancement of our methods.”

“Working with Dan and the Custom Biologics team, we were able to successfully develop and validate the required assay, allowing us to achieve our near-term drug development goals.”



The CB Team



Custom Biologics





Custom Biologics

Contact Our Team Today

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 Follow Us:





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