AbZelectPRO™

Achieving high-titer productivity & accelerated timelines with enhanced cell line platforms

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Abstract

Our **fully integrated AbZelectPRO™ platform** enables the rapid delivery of stable, high-producing cell lines to support the production of complex biologics. The platform combines our AbZelectPRO™ CHO-K1 and AbZelectPRO™-KO GS knockout cell lines together with ProteoNic's 2G UNic® premium vector technology and an optimised process to generate fast doubling, higher-producing, stable cell lines expressing up to 10 g/L of product, and **DNA to RCB in as little as 10 weeks**.

The AbZelectPRO™ platform supports a diverse range of modalities from antibodies and more difficult-to-express proteins such as fusion proteins, bispecifics, vaccines and other novel modalities. Furthermore, the platform also allows for program derisking by using early material generation from stable pools to remove activities such as downstream method development and formulation development from the critical path. Backed by our **comprehensive analytics portfolio**, the AbZelectPRO™ platform simplifies the development process and helps to deliver therapeutic proteins successfully to the clinic.

Flexible options

AbZelectPRO™

Cell Line:	**CHO-K1**
• GMO:	None
• IND:	10+
Vector*:	**2G UNic®**
• Selection:	Low MSX
• IND:	20+

** License fee at IND*

AbZelectPRO™ KO

Cell Line*:	**CHOSOURCE™**
• GMO:	GS -/-
• IND:	90+
• MA†	4
Vector*:	**2G UNic®**
• Selection:	No MSX
• IND:	20+

** License fees at IND* *† Market authorisation*

Timelines for standard mAb

- **DNA to Stable Pools:** 3 wks
- **DNA to RCB:** 10 wks
- **DNA to Lead Clone Selection:** 26 wks

Figure 1. Multiple Cell Lines – One Platform.
Abzena integrates leading partnered technologies such as 2G UNic® (ProteoNic) and CHOSOURCE™ GS KO cell line (Revvity) to streamline and accelerate CLD workflows. This unified approach enhances productivity, flexibility, and performance across platforms.

Optimised CLD process

AbZelectPRO™ CLD Platform

1. Vector Construction

ProteoNic's 2G UNic® GS vector:
- Optimised dual promoters
- Epigenetic stabilisation
- Improved transcription and translation efficiency

2. Transfection

Optimised CHO-K1 Host Cell Lines:
- Fast PDT (18-20 hrs)
- High VCDs (≤ 40 E+06 cells/mL)
  →**Stable Pools: 3-5 g/L** with small scale productivity and **PQA**
- *Optional: **Early Material Generation***

3. Single Cell Cloning

- **Cyto-Mine®** single cell cloning with HT FRET selection
- **Cell Metric®** imaging for clonality assurance

4. RCB Generation

- RCB generation on 24 lead Clones
  →**GMP-ready RCB**

5. ambr®15

- Top 24 clones in **ambr®15 bioreactors** with **PQA** on top 12 clones
- **2L STR** characterisation of lead clones
  →**Top clones: 6-8 g/L**
- *Optional: **Early Optimisation** of lead Clones*

6. Stability Study

- Top clones progress to **60+ Generation** stability study (representative of a 2000 L bioreactor)
- Small-scale productivity and **PQA**
  →**Lead Clone selected for MCB generation**

- **High productivity** from stable pools and clones
- **Optimized platform** that can accommodate **diverse formats**
- **Fast doubling times** - DNA to RCB in 10 weeks
- **High clonal stability** over 60+ generations
- **Reproducible PQA** at all stages

The **CLD process has been optimised** to maximise efficiency, ensuring high productivity from stable pools and clones while providing a **robust process from DNA to RCB and beyond**.

Early-stage material generation (≥ 10 g)

Accelerate development using **Stable Pools** to generate **early** material for non-GMP studies:
- Formulation, analytical and early DSP method development
- *In vivo* studies

Figure 2.
Stable pool material generation (≥ 10 g for standard mAbs). Purified using state-of-the-art ÄKTA™ systems yielding ≥ 95% purity and low endotoxin.

Single cell cloning: population enrichment and clonality assurance

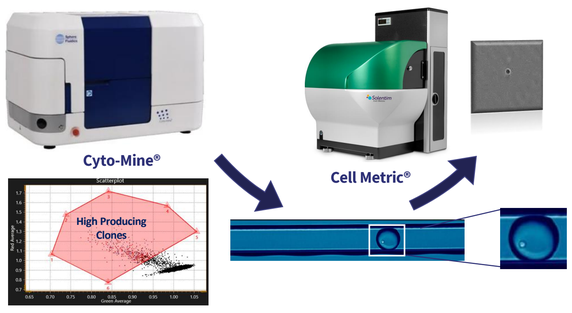
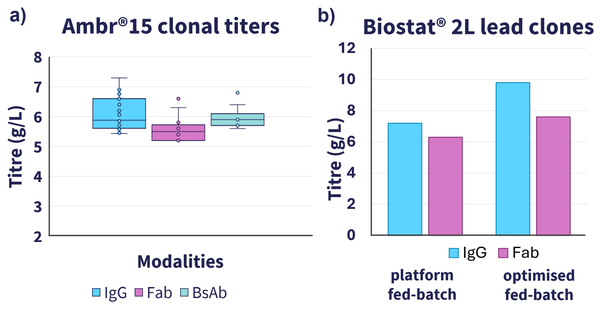


Figure 3.
Cyto-Mine® provides early population enrichment and single cell encapsulation for initial evidence of monoclonality with secondary evidence provided using Cell Metric® images throughout the single cell outgrowth time-course

RCB characterisation in ambr®15 and 2 L STR



Titre quantitation was performed by Octet® BLI with quantitative HPLC final titre confirmation.

Figure 4.
a) AbZelectPRO™ RCB titres under platform fed-batch conditions in **ambr®15** for top-performing clones across **three molecule types: IgG, Fab, and Bi-specific.**

b) 2L Biostat® B-DCU production runs using platform conditions demonstrate robust scalability from ambr®15. **Early process optimisation** significantly **enhances titres**.

Clonal stability study (60 Generations)

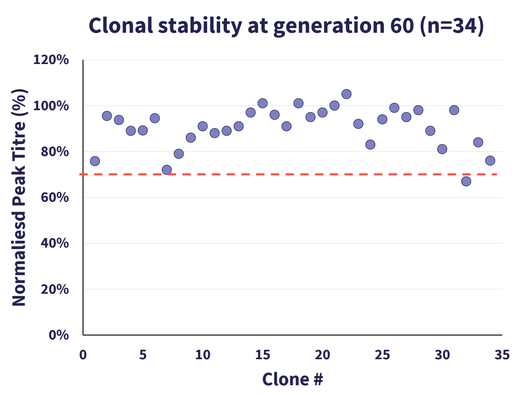


Figure 5.
AbZelectPRO™ clones exhibit **>97% stability** over a 60+ generation time-course, based on normalised titre relative to Generation 0. Data is representative of 34 clones of **different molecule types**.

Clone stability is further supported by consistent cell-specific productivity (Qp) and PQA (data not shown).

State-of-the-art analytical support

Platform PQA methods:
(used throughout the CLD Process)
- SE-HPLC / CE-SDS
- LC-MS / cIEF
- Binding ELISA

Extended PQA methods:
- N-Glycan
- Sialic acid
- Peptide mapping

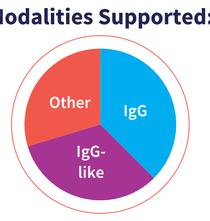
Structure

- Immunogenicity assays
- Cell-based assays
- Biacore™ SPR

Function

- Biologics Characterization
- Mass-Spec Capabilities
- Developability Assessments
- Formulation Development

Modalities Supported:



150+
Individual CLD programs with CHO-K1 cell line

IgG:	IgG1, IgG2, IgG4, variants thereof and other species
IgG-like:	Bi- and multi-specifics, Fabs, VHH, scFv, Fc-fusions
Other:	Nanoparticles, Protein fusions, enzymes, IgA, IgE, Viral subunits, Vaccines

Overview

Trusted technology: AbZelectPRO™ is built on an established CHO-K1 platform – well recognised in industry and by regulators.

Experienced team with proven track record: CLD team has delivered 150+ CLD programs with CHO-K1 cell line.

Compliance assured full traceability: Established robust processes compliant with ICH-Q5 guidance.

Integrated platform with end-to-end support under one organisation across all stages of the drug development process.