Accelerating Candidate Screening Through A Reliable Transient Expression Platform

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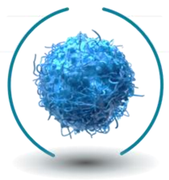
Abstract

Chinese Hamster Ovary (CHO) cell lines are widely used to produce therapeutic biomolecules. In the competitive, risky and expensive biopharmaceutic industry, it is crucial to rapidly produce high quality biotherapeutics at early stage. Early screening and selection of top-drug candidates is one of the best strategy for cost-controlling and risk-mitigation in this industry. While functional studies and therapeutic evaluation are essential, screening for variants with the best in-cell productivity and required quality attributes is also fundamental to securing projects.

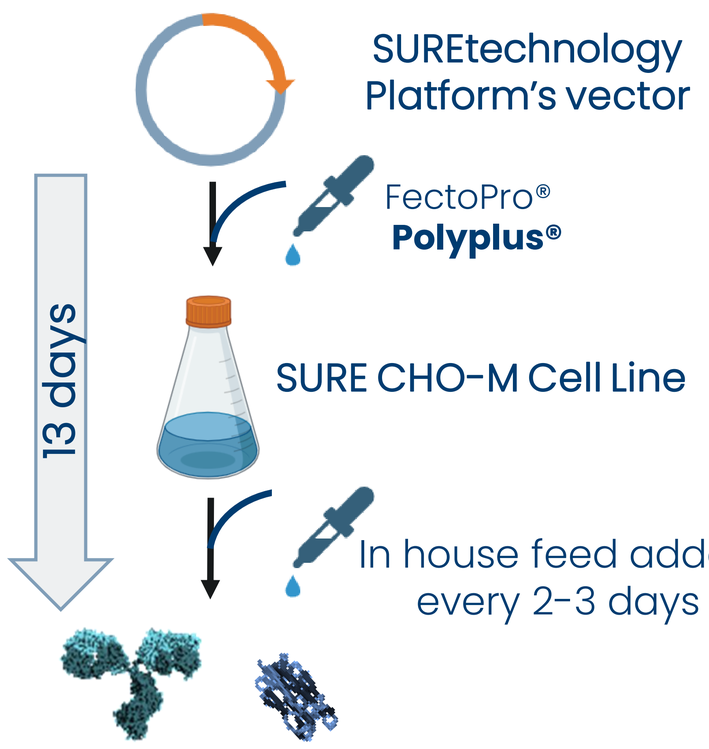
At KBI Biopharma, we have leveraged our decades of experience in leading the global CHO cell line development (CLD), powered by Selexis®. In this study we demonstrated the high titers of our transient platform as well as its reliable predictivity of productivity and quality attributes for future stable expression. In summary, our new transient CHO platform is an excellent complement to our mammalian CLD services based on our SUREtechnology Platform™ and SURE CHO-M Cell Line ™.

SURE CHO-M Cell Line™



- Derived from CHO-K1 cell
- Fast doubling time
- Consistent high-level expression
- Comprehensive documentation and ease of transfer for cGMP-scale production
- Fully- sequenced and annotated genome and transcriptome

Method



Our Transient Platform Produces Biotherapeutics With High Yield And Purity

8 therapeutic biomolecules (2 IgG1, 1 IgG4, 3 Fc fusion proteins and 2 bispecifics) were produced in 20 mL shake flasks. After 13 days, supernatant was collected, purified using Protein A affinity chromatography and analyzed.

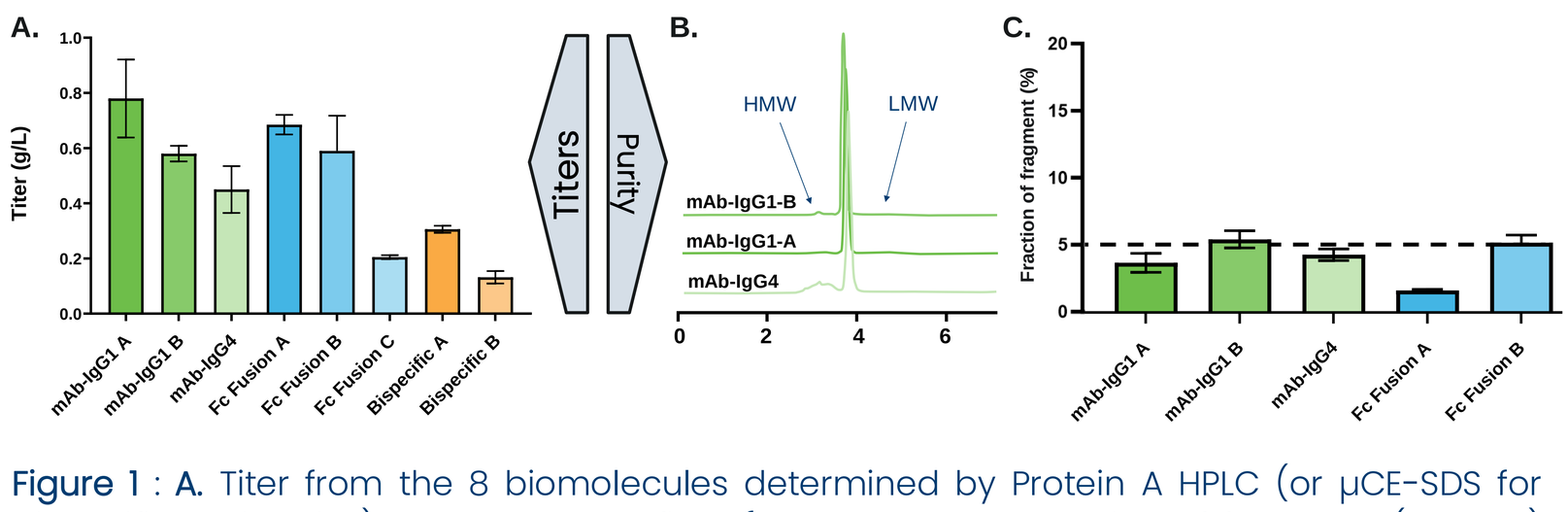


Figure 1 : **A.** Titer from the 8 biomolecules determined by Protein A HPLC (or µCE-SDS for bispecific antibodies) **B.** SEC UPLC profile of the 3 mAbs **C.** Fraction of fragment (or LMW) determined by µCE-SDS.

Transient Production Gives Reliable Trends In Titers And PQ Profile Over Stable Expression

Several biomolecules with different attributes (high/low titers or aggregates, high Man5…) were produced using our transient platform. Titer, aggregation, charge variant and N-glycans were analyzed and compared to stable pool performance.

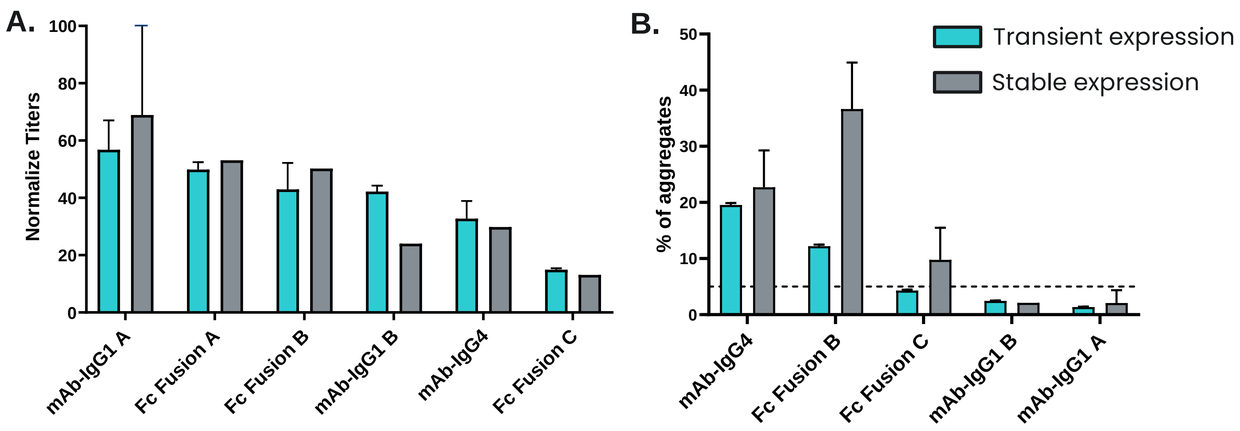
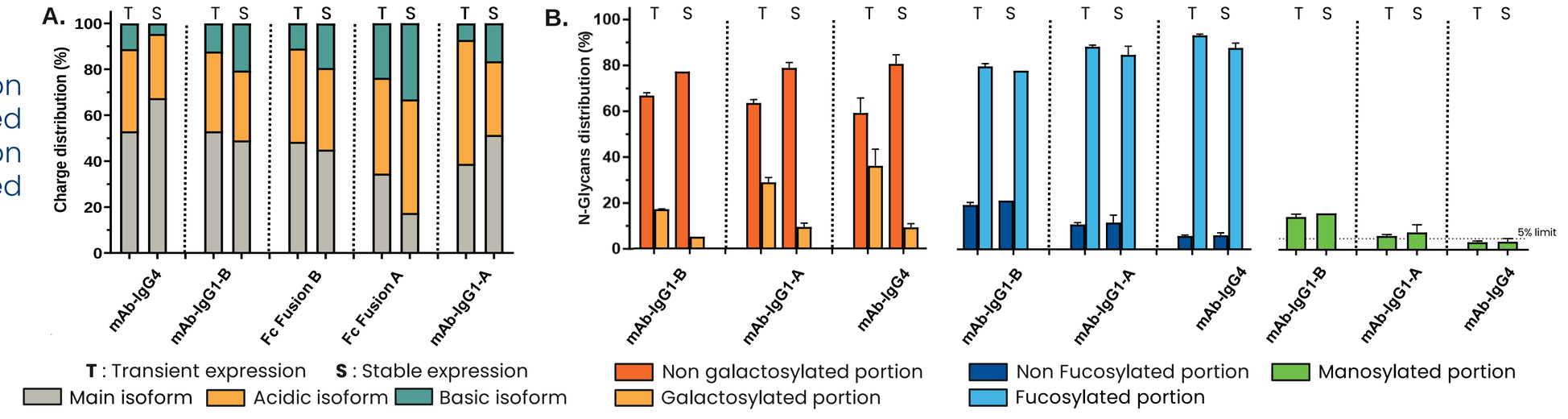


Figure 2 : **A.** Relative titer from biomolecules produced in our transient or stable pool platform. **B.** Percentage of aggregates determined by SEC-UPLC from biomolecules produced in our transient or stable pool platform.

Figure 3 : **A.** Charge distribution from iCIEF analyzes on purified samples **B.** N-Gylcans distribution from LC-MS analyzes on purified samples.



In Short

KBI Biopharma offers a **high performing transient expression platform** using the **SURETechnology Platform's vector** and **SURE CHO-M Cell Line.** The combination of **high titers** and **reliable performance trends** over stable expression enables accelerated and derisked selection of lead candidates.