Introducing SUPR

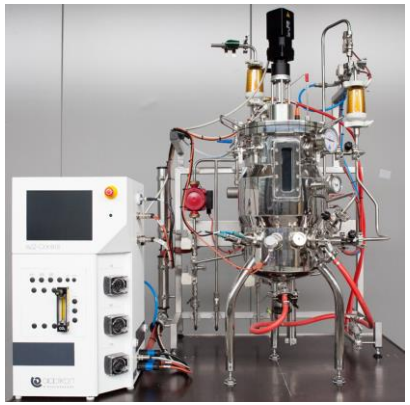
Filling the gap in our singe-use portfolio

15 February, 2024

Getinge Applikon Bioreactor system landscape

Proprietary | Lucullus, OPC, DeltaV | Siemens, Rockwell (Allen Bradley), iFix, DeltaV

SOFTWARE



250 mL | 3 L | 10 L | 140 L | 5000 L

Lab | Pilot | Production

SUPR

The true single-use bioreactor system

Ease of use

*Easy-to-use and highly configurable pilot and production scale single-use bioreactor system will enable users to bring pharmaceutical and biotech products **faster to market***

True bioreactor specialist

*Leveraging **five decades** of experience, to create a true single-use bioreactor scale-up, on a platform designed for bioreactors*

Entry level solution

*Offer an optimized system configuration and **cost-effective** investment that match your customers dedicated needs*

Quality you can trust

*Ensuring the customer's ease of mind, by creating single-use products to prevent cross contamination with the **Getinge quality culture***

Case study Aragen

Bioprocessing Global Sales Meeting

Dai Quach

Tuesday January 23rd, 2024

GETINGE

GETINGE SINGLE-USE BIOREACTOR (SUPR)

FED-BATCH PRODUCTION RUNS

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Prospect of Scale Up in 50L, 250L Getinge SUPR

- The purpose of this study is to validate the application of Getinge 50L and 250L Single-use bioreactor in production.
- A 2L Applikon stirring glass bioreactor was also run in parallel to compare the cultivation data.
- A 50L, and 250L SUPR for cultivation CHO cell line were used.
- Seed Train using 2L, 7L, and 15L Applikon stirred glass bioreactor
- Vessel geometry
    - Proportionate geometries : impeller diameter, vessel diameter, liquid height.
    - Similar conditions such as stirrer type, sparge type, gassing device, and pressure


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Cell Line Development Lab

SUPR at Aragen

Scale up

2L

50 L

15 L

250 L

SINGLE-USE BIOREACTORS ADVANTAGES

- Single-Use bioreactors are used to culture cells in large volume in contrast to traditional stirred glass/steel bioreactor.

Time

- Omitting cleaning and sterilization step
- Turn around time between production batches

Flexibility

- Mobile
- Process set up
- Scalable
- Production volume

Cost

- Labor, operating cost
- CIP
- Capital investment
- Utility and space

50L-SUPR vs 2L-Stirring Glass Bioreactor

Growth Profile

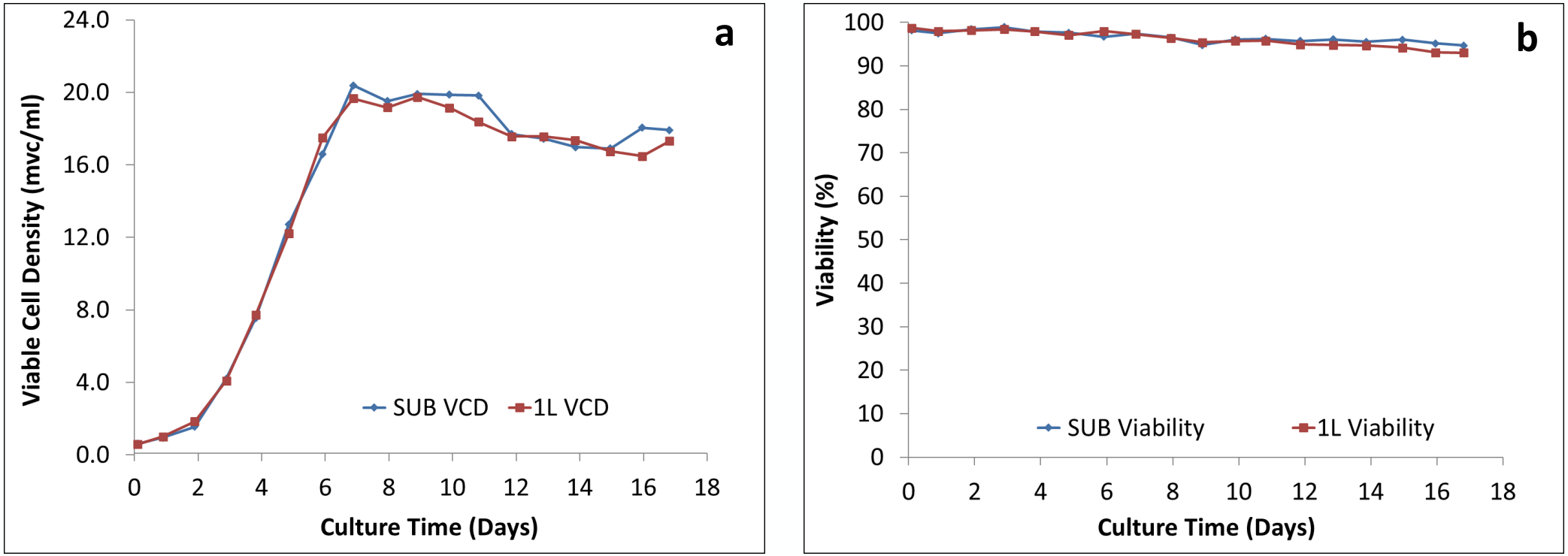


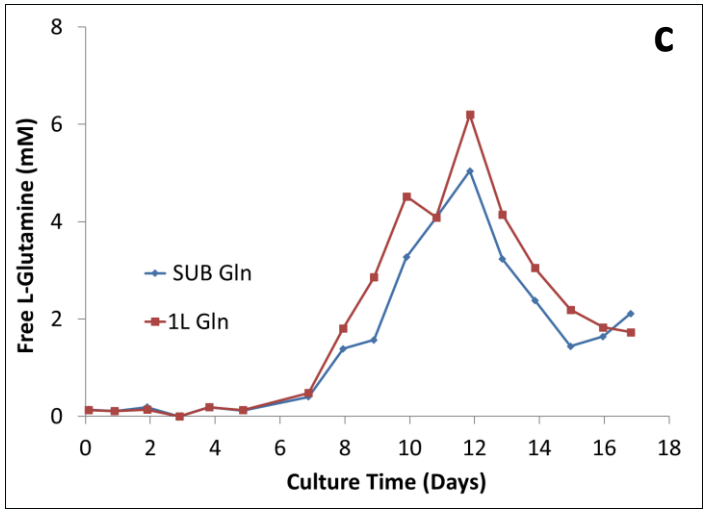
Fig. 1 Comparison of the growth behavior

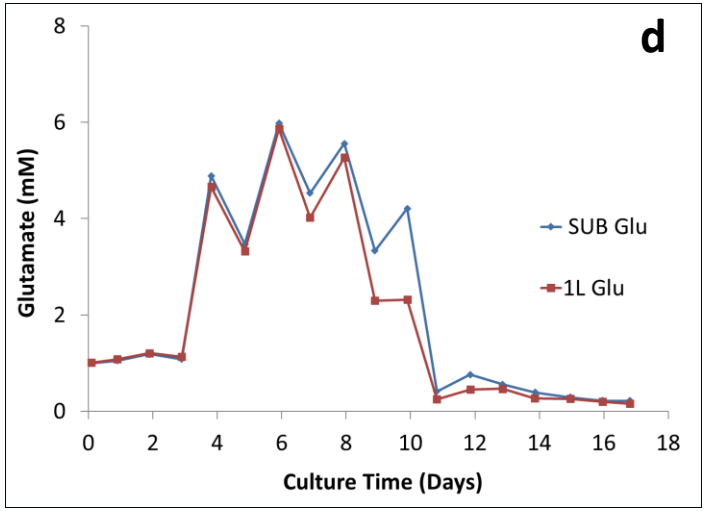
a. Viable cell density

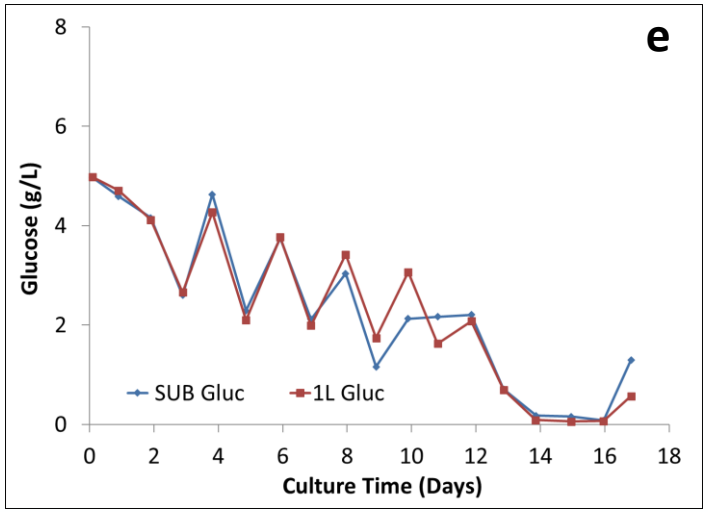
b. Viability

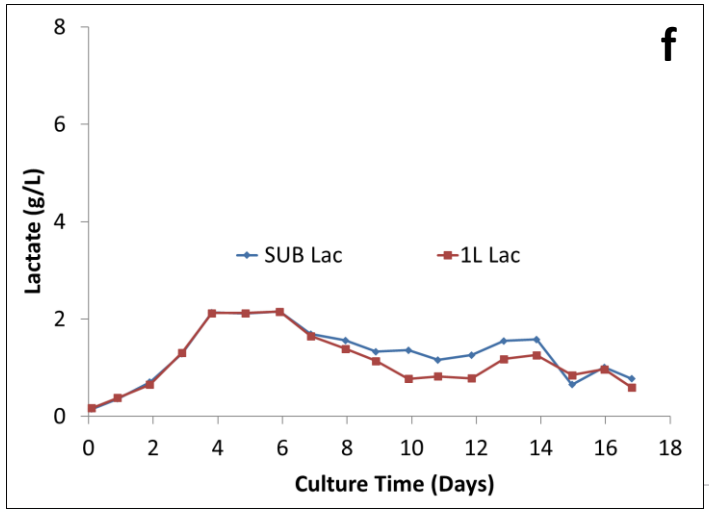
50L-SUPR vs 2L-Stirring Glass Bioreactor

Metabolic Profile









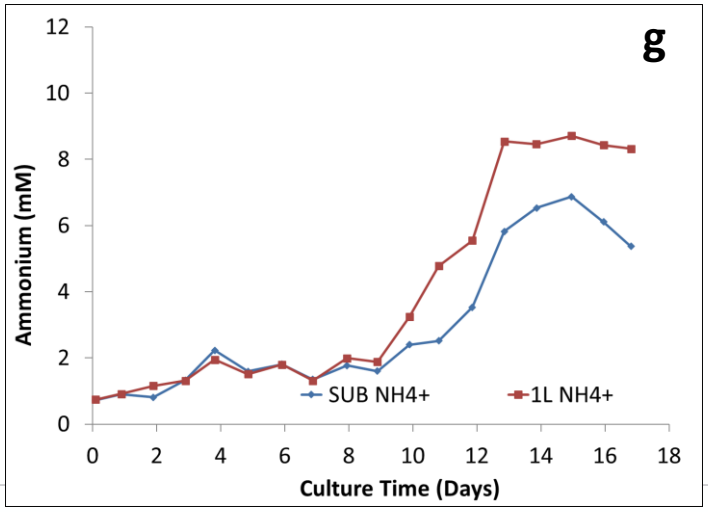
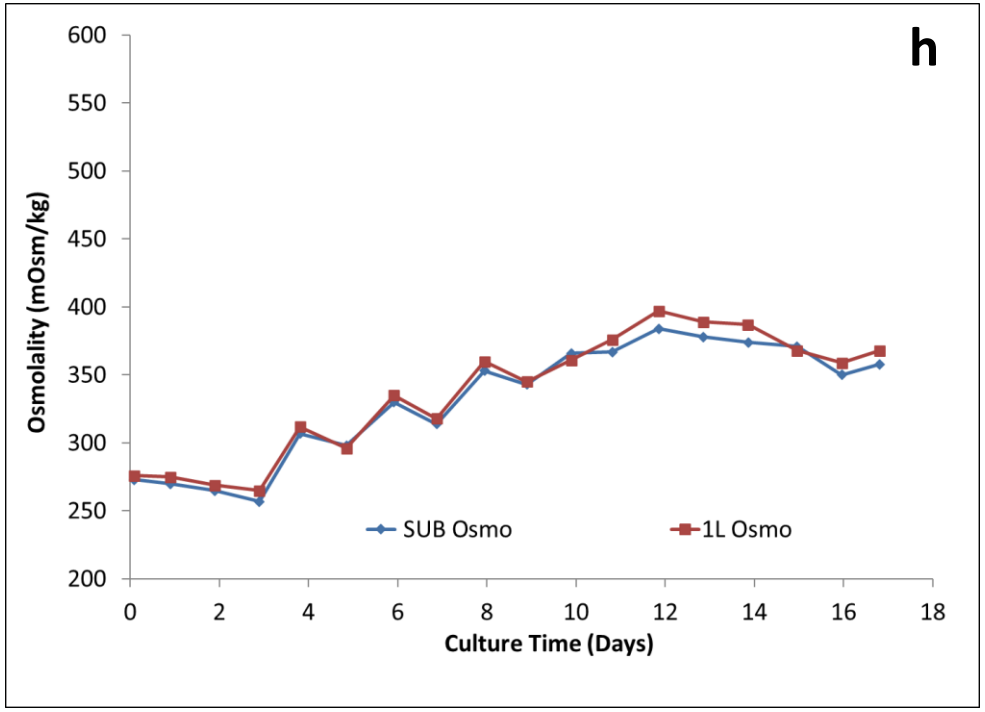


Fig. 3 Comparison of the metabolism profiles
c. L-Glutamine
d. Glutamate
e. Glucose
f. Lactate
g. Ammonium

50L-SUPR vs 2L-Stirring Glass Bioreactor



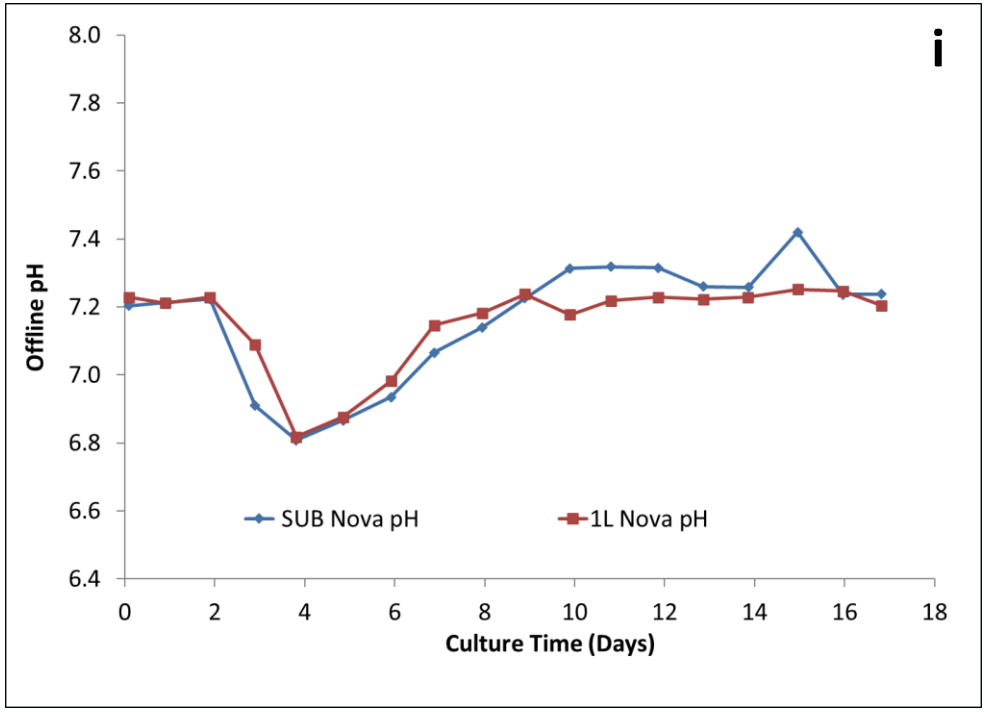


Fig. 1 Comparison of the (h) osmolality and (i) pH offline

50L-SUPR vs 2L-Stirring Glass Bioreactor

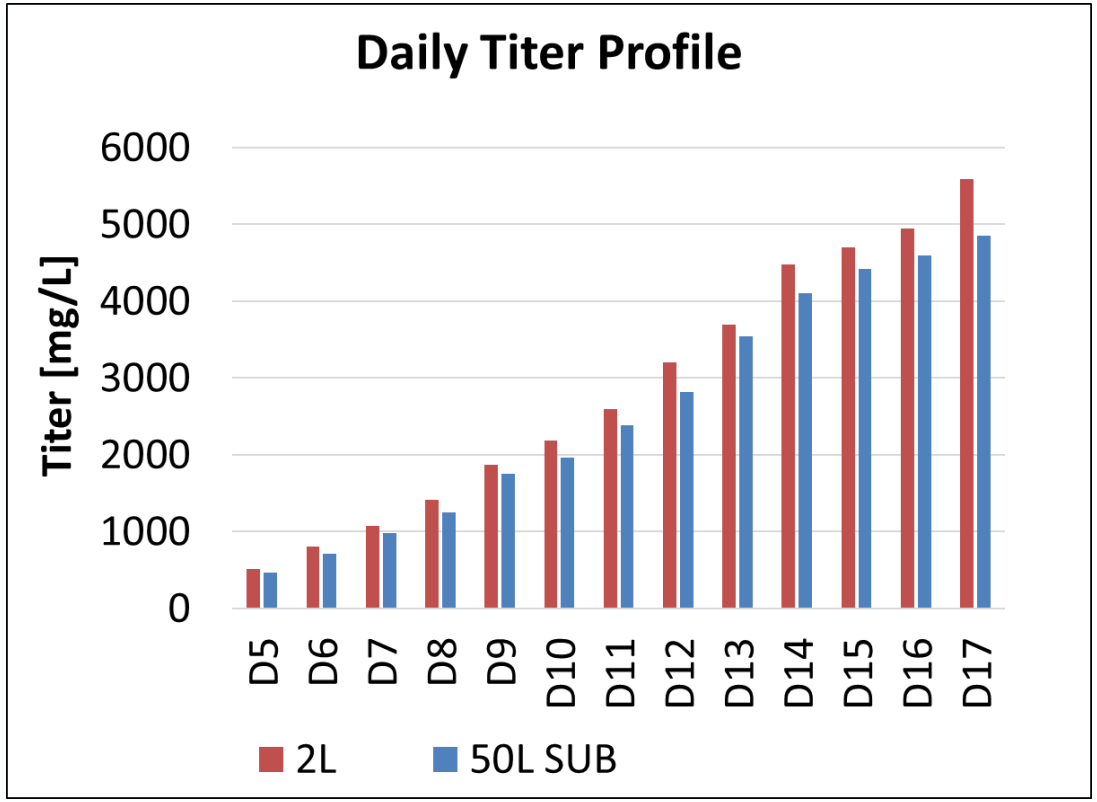


Fig. 2 Comparison titer profile between the 5-L-SUPR and 1L-glass BR.

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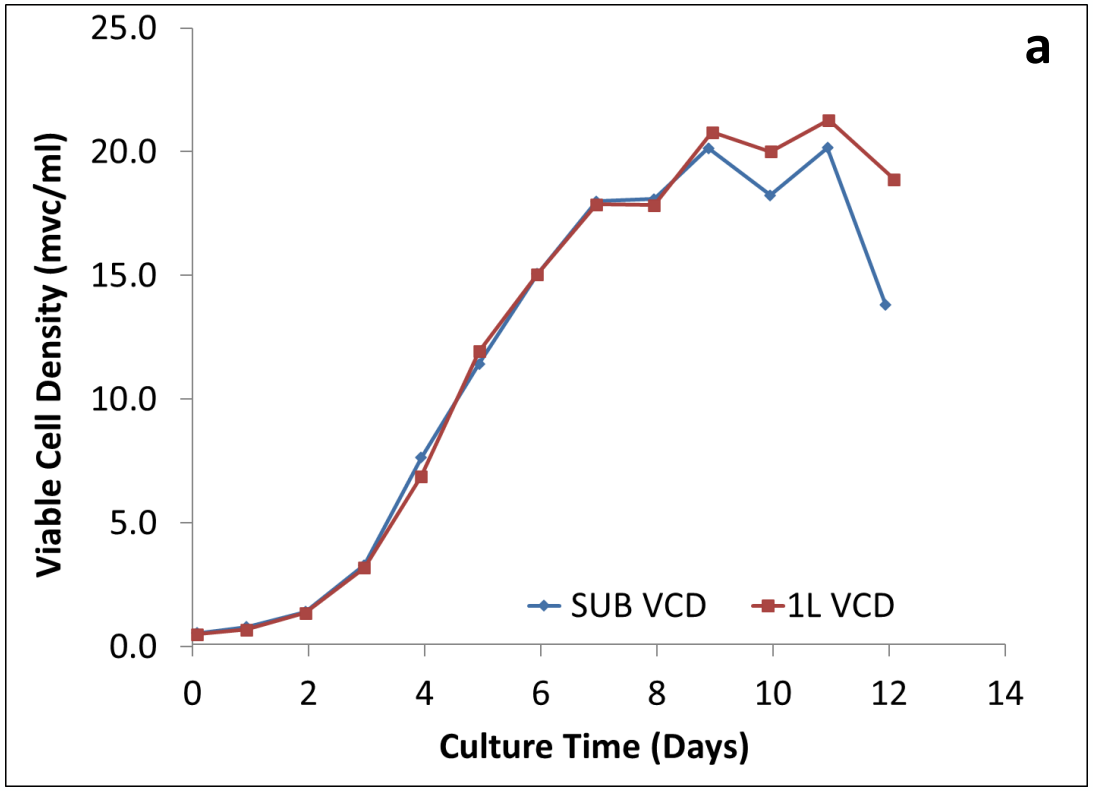
250L-SUPR vs 2L-Stirring Glass Bioreactor

Growth Profile



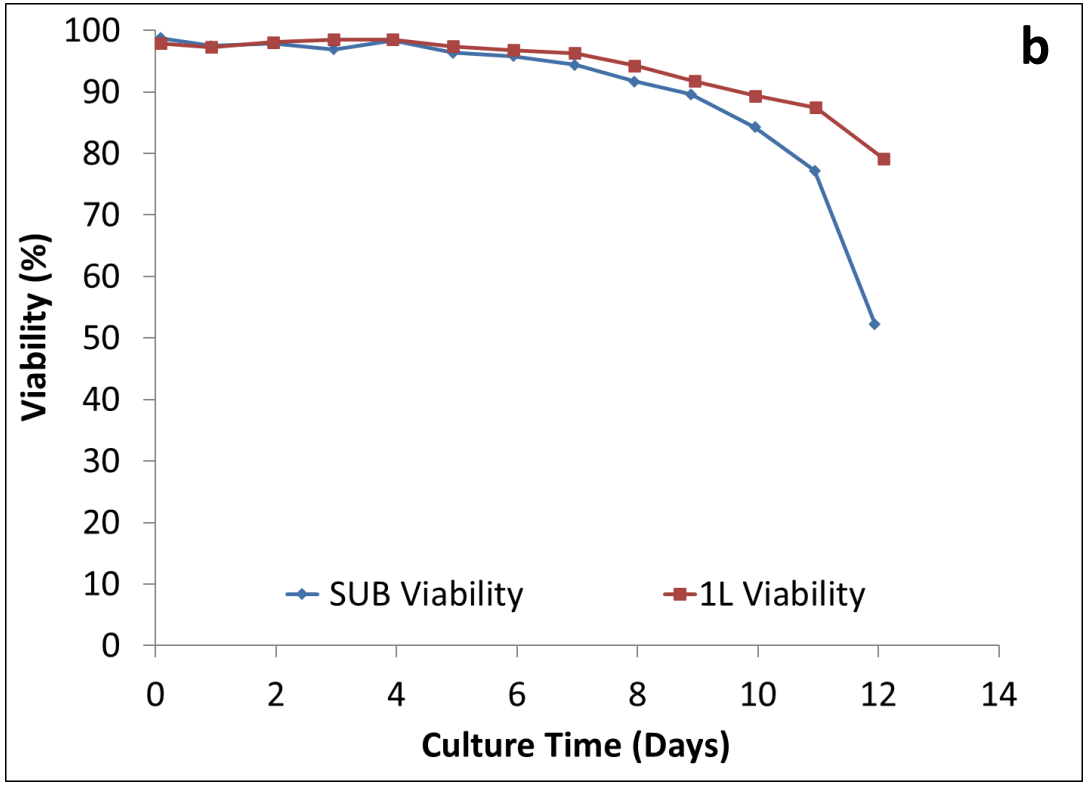


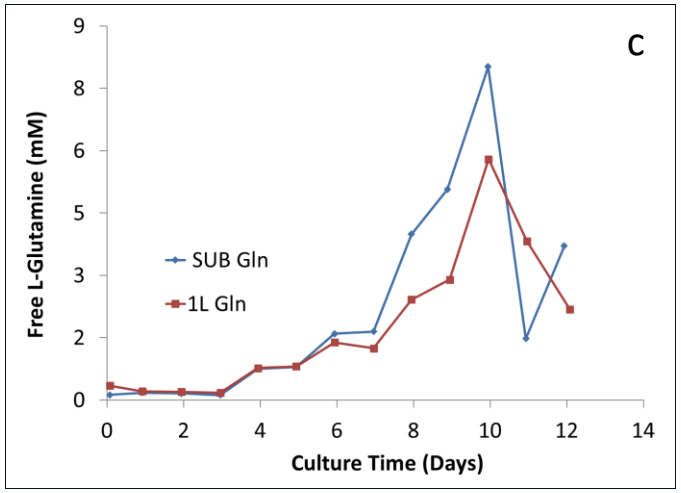
Fig. 3 Comparison of the growth behavior

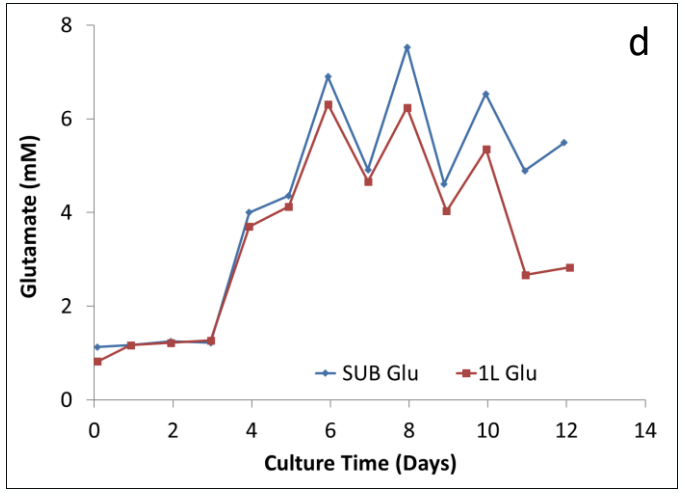
a. Viable cell density

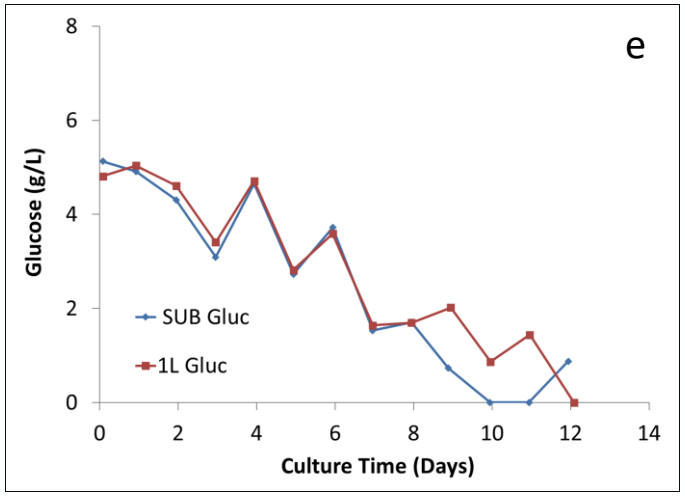
b. Viability

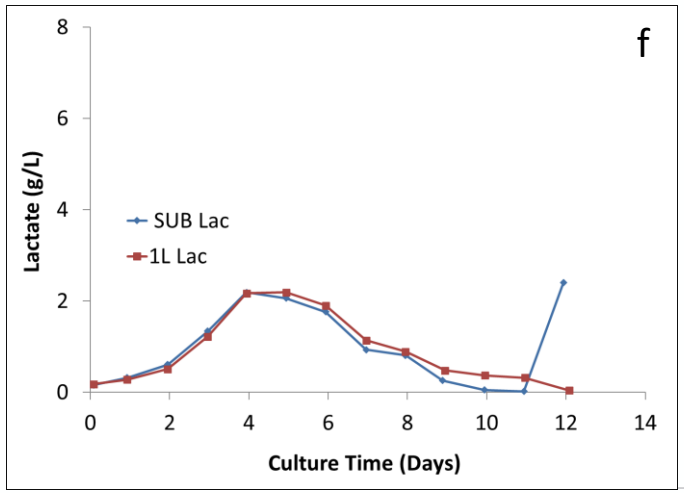
250L-SUPR vs 2L-Stirring Glass Bioreactor

Metabolic Profile









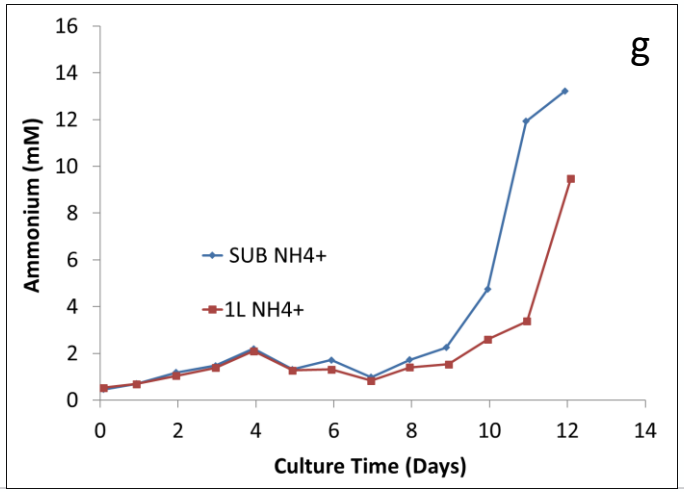
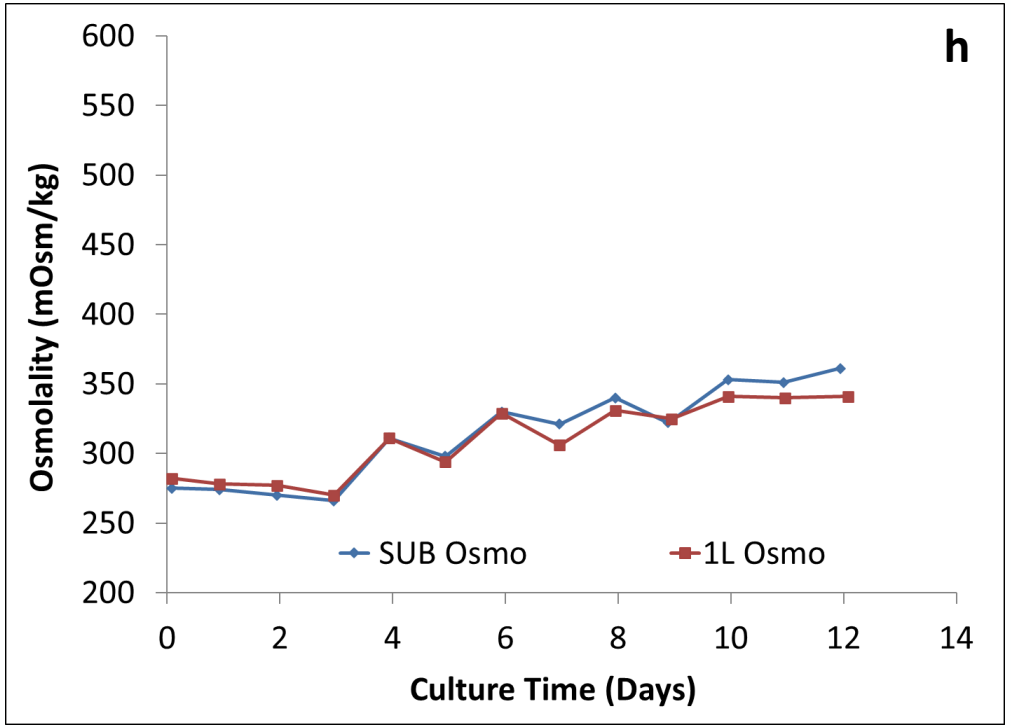


Fig. 3 Comparison of the metabolism profiles
c. L-Glutamine
d. Glutamate
e. Glucose
f. Lactate
g. Ammonium

250L-SUPR vs 2L-Stirring Glass Bioreactor



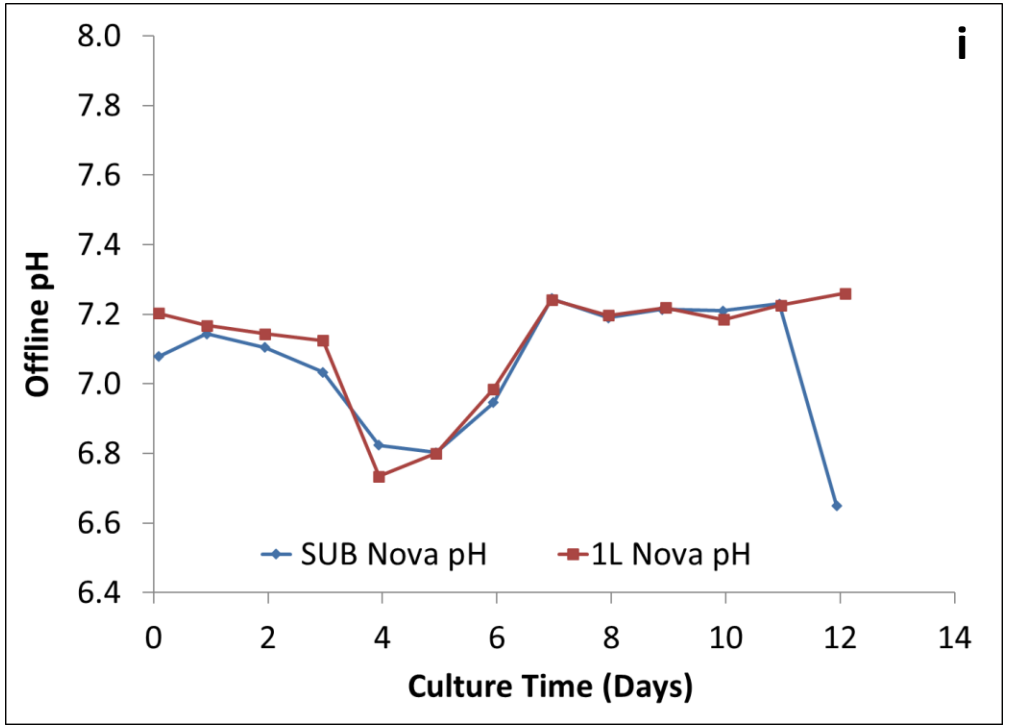


Fig. 3 Comparison of the (h) osmolality and (i) pH offline

250L-SUPR vs 2L-Stirring Glass Bioreactor

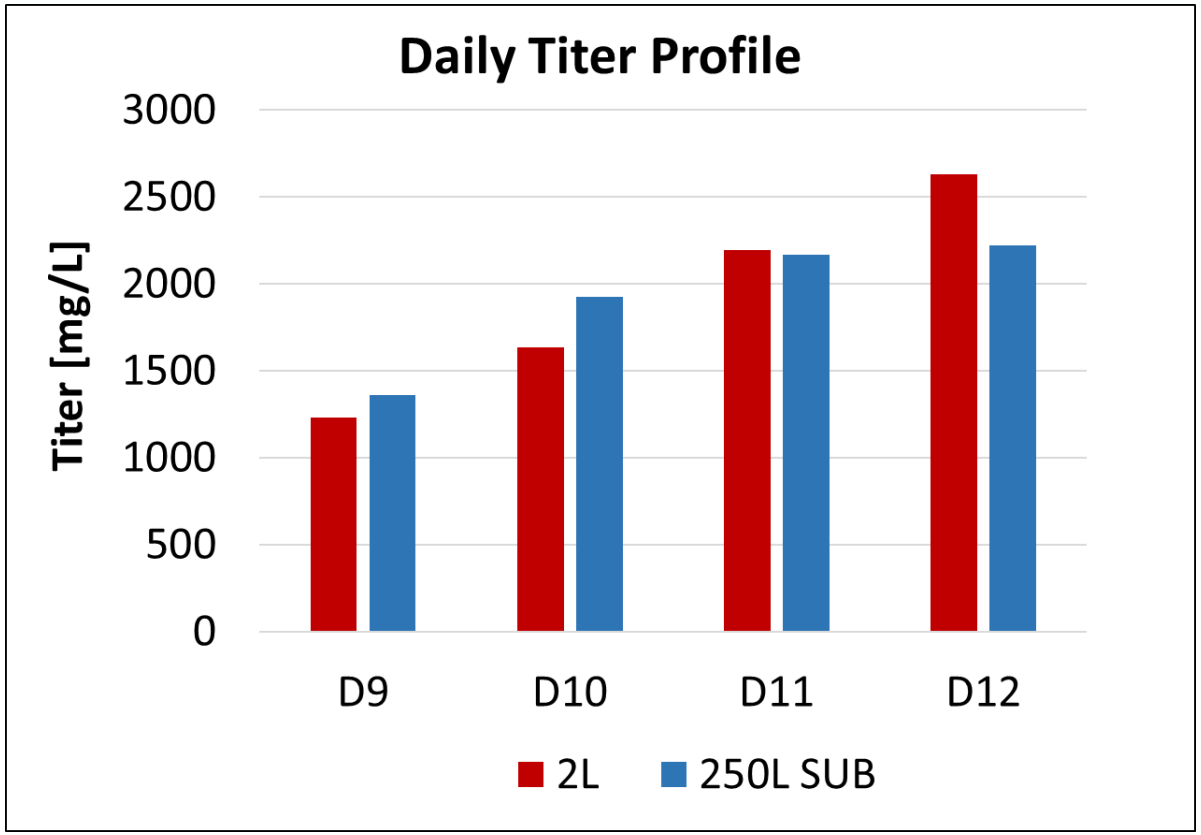


Fig. 4 Comparison titer profile between the 250L-SUPR and 2L-glass BR.

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Production Results

- Cell growth pattern are very similar at all scales: 1L glass, 50L SUB, and 250L SUB
- Metabolites profiles (glutamine, glutamate, glucose, lactate, ammonium) behaved the same ways of all scales.
- All scales showed similar osmolality as well as pH profiles.
- Production yield profiles (Mab concentration in mg/L over time) at all scales are comparable
- Using standard scale up criteria both 50L & 250L SUB from Getinge, showed very comparable data with 1L BR.

Experience with SUB

- Qualities
  - User friendly set up of the SUPR
  - Controller interface: touch screen, easily navigate, control, and monitor process data
  - KleenPak connector convenient (50L)
  - Built in probe (pH and optical DO) accuracy

- Improvement:
  - Use KleenPak connectors instead of quick connectors in 250L Bag
  - Longer sample-line with clamps
  - Keep the 50L pH cable the same as 250L (sturdier)
  - Clamps for 250L SUPR need to be changed

Acknowledgements

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  - Lakshman E Rajagopalan
  - Sufia Karim
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- Getinge
  - Venkatesh Gopal, Jorge Bolder, Timo Walvoort, Meigan Morikawa, Marlous Van Dijk, Austen Smith
- Special thanks to Kirby Cafuir, Pete Gonzalez (Aragen Facility) for wonderful help during working and non-working hours

THANK YOU

In every molecule is the possibility for better health.

True scale-up specialists – From lab to production

Scale-up from lab to production

Max Working Volume

500 mL | 3 L | 15 L | 50 L | 250 L

Total Volume

AppliFlex ST (GMP)

SUPR