

Advancing Cell Culture Media Preparation in CDMOs

Kaitlynn Bayne¹, Chris Cline², Mark Patton², Scotty Bailey², and Sharyn Farnsworth²

¹Single-use Technology, FUJIFILM Irvine Scientific, 1830 E. Warner Ave., Santa Ana, CA 92705, USA

²Upstream Development, FUJIFILM Diosynth Biotechnologies, Research Triangle Park, 101 J Morris Commons Lane, Morrisville, NC 27560, USA

INTRODUCTION

As a supporting process in biopharmaceutical workflows, the hydration of media, feeds, and buffers has often been overlooked as an area for process optimization, risk mitigation, and cost reduction. There are many challenges faced during media and buffer preparation including that it is labor intensive, time-consuming, and can be prone to inconsistency. FUJIFILM Irvine Scientific developed a solution to address these issues, the Oceo Rover, an automated hydration system for media feeds and buffers. In a single-unit operation, the Oceo Rover both hydrates and filter sterilizes the media feed or buffer being manufactured. Using a single-use flow path, this closed system process results in rapid media production, on-demand delivery, and a consistent product.

This poster presents data generated by FUJIFILM Diosynth Biotechnologies (FDB), which compares the performance of their platform CHO cell media hydrated in the Oceo Rover versus media hydrated using their traditional method and media purchased in liquid form.

FUJIFILM Diosynth Biotechnologies is a leading Contract Development and Manufacturing Organization (CDMO). They specialize in the development and manufacturing of biopharmaceuticals, offering comprehensive services to support the entire product life cycle. With advanced technologies and facilities, they produce biologics such as monoclonal antibodies, proteins, gene therapies, and viral vaccines. As a CDMO, FDB develops and optimizes manufacturing processes for their clients.



PROJECT PARAMETERS

STUDY DESIGN

The purpose of this project is to evaluate media made in Oceo Rover vs. 1) premade liquid formulations, 2) premade Oceo Rover media (aged three months) and 3) powdered media hydrated using a conventional mixing technology.

- **Cell Line:** mAb expressing Apollo X test cell line made by FUJIFILM Diosynth Biotechnologies
- Seed Train Medium: FDB proprietary media
- Production Medium: FBM514, Proprietary media
 - Liquid media, (FUJIFILM Irvine Scientific prepared liquid)
 - Standard hydrated powder media, (Powder)
 - Oceo Rover hydrated powder media, (OR) both on-demand media and 3-month-aged media
- **Feed Media:** Cell Boost 7A/7B Feed, Hyclone
- 10 L Bioreactor Run
- Monitor growth and metabolites on NOVA Flex 2
 - VCD, viability, cell size
 - Glucose, lactate, glutamine, glutamate, osmo, ammonium, and salts that are standard tests on the NOVA
- Monitor mAb titer on Cedex

CONDITIONS

- Powder- Traditional media preparation hydrated by FDB (001,002)
- Liquid Media- FUJIFILM Irvine Scientific manufactured media (003,004)
- Oceo Rover Stability- Media hydrated in the Oceo Rover in March 2023 (005,008)
- Oceo Rover Fresh- Media hydrated in the Oceo Rover a few days prior to seeding the bioreactors (006,007)

MEDIA PREPARATION TIME

	Oceo Rover	Traditional Preparation
Time (Minutes)	34	231
Volume Prepared (L)	200	20

SUMMARY

Media prepared in the Oceo Rover is equivalent to media prepared in FUJIFILM Irvine Scientific manufacturing and media prepared traditionally by FUJIFILM Diosynth Biotechnologies.

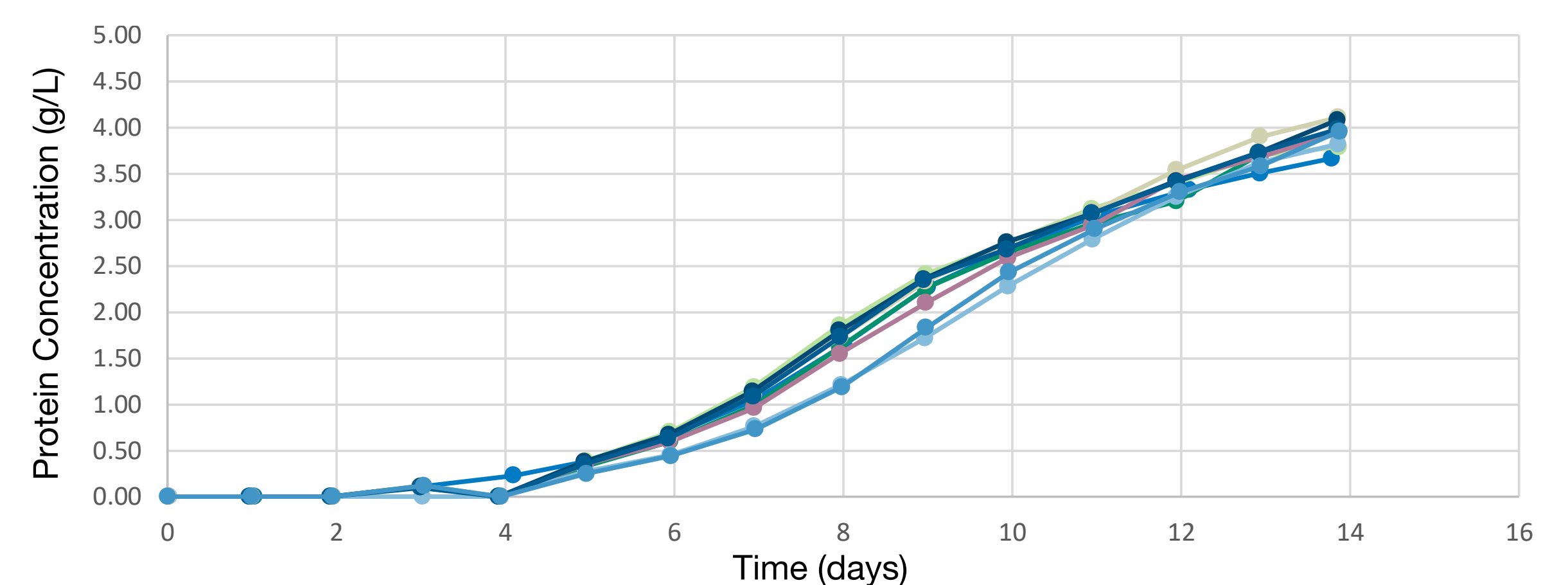
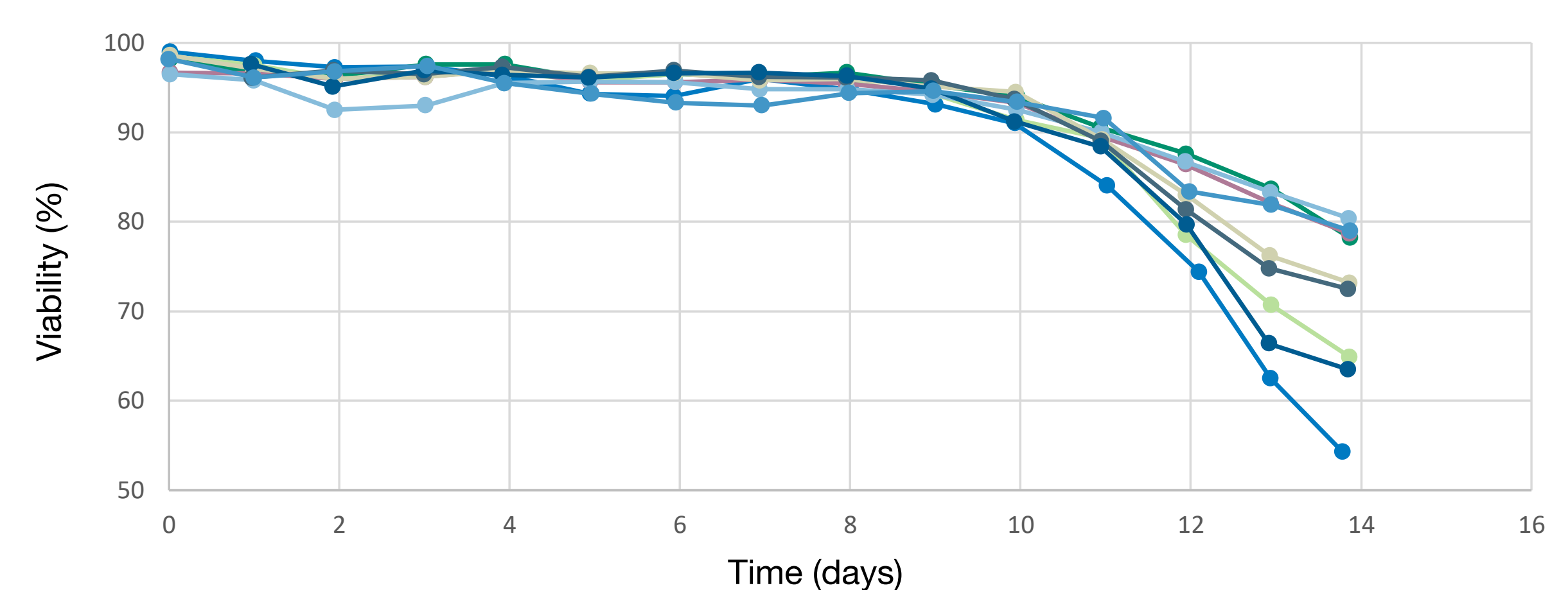
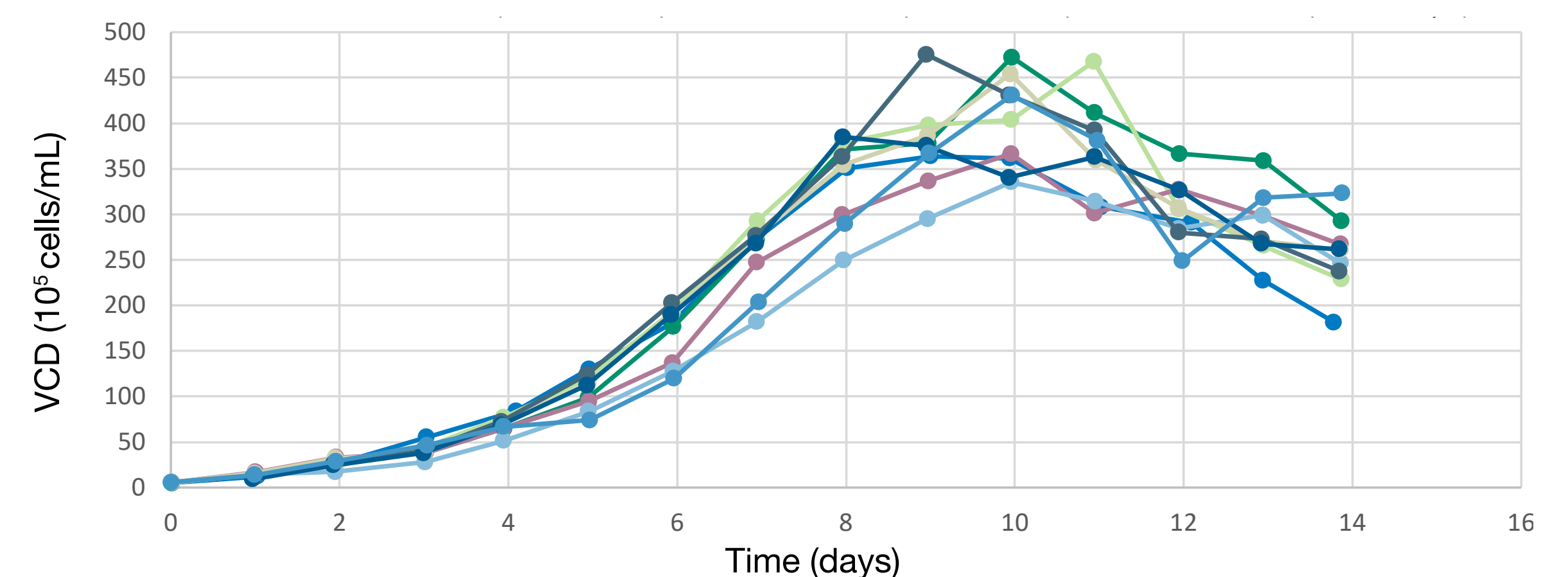
- The Oceo Rover is able to make FBM 514 media in a much shorter amount of time than the current FDB powder process (34 minutes vs. 3.5+ hours)
- Cell growth is equivalent in media made by the Oceo Rover both on demand or in advance vs. made using other methods
- Titer is equivalent in media made by the Oceo Rover vs. using other methods
- Nutrient, metabolite, and osmolality data is comparable in media made by the Oceo Rover vs. made using other methods

RESULTS

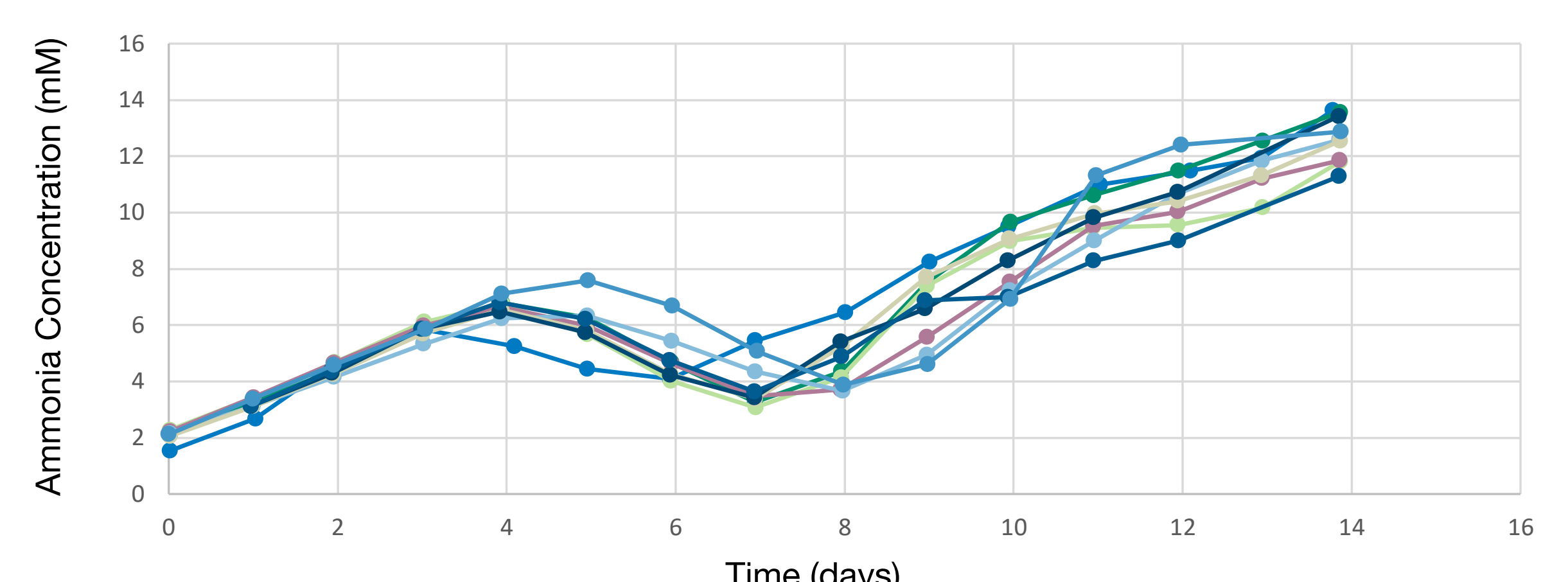
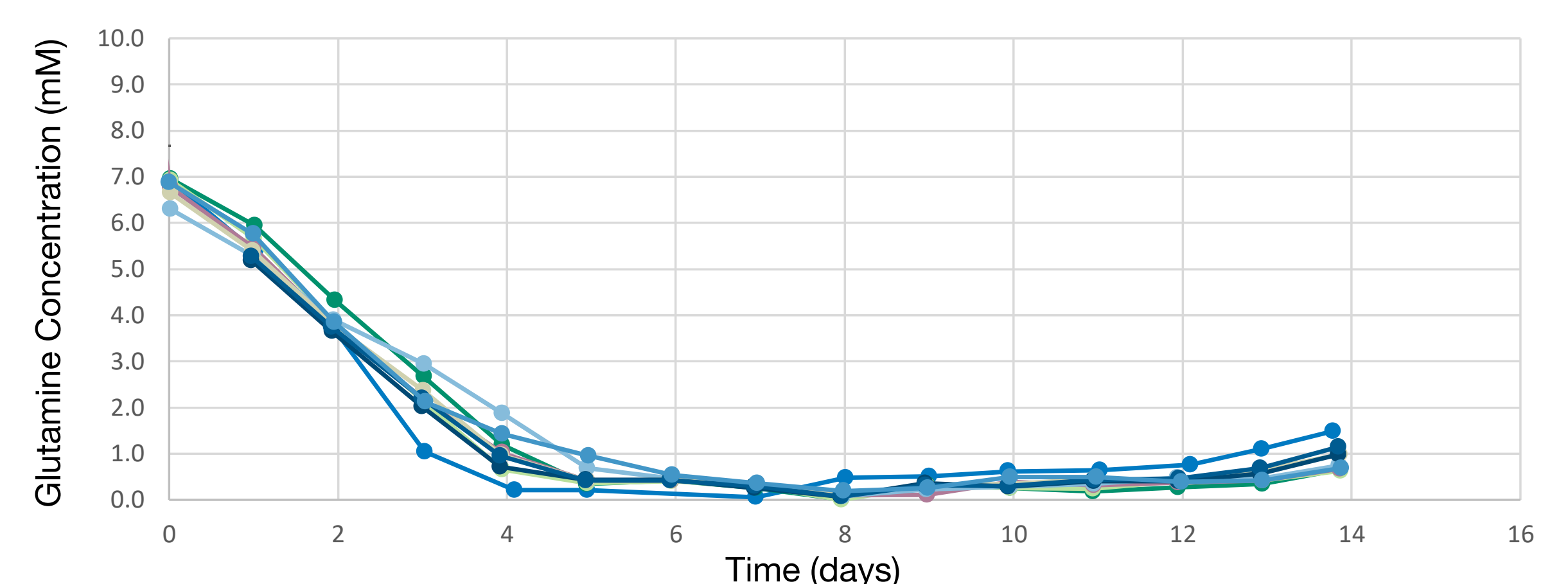
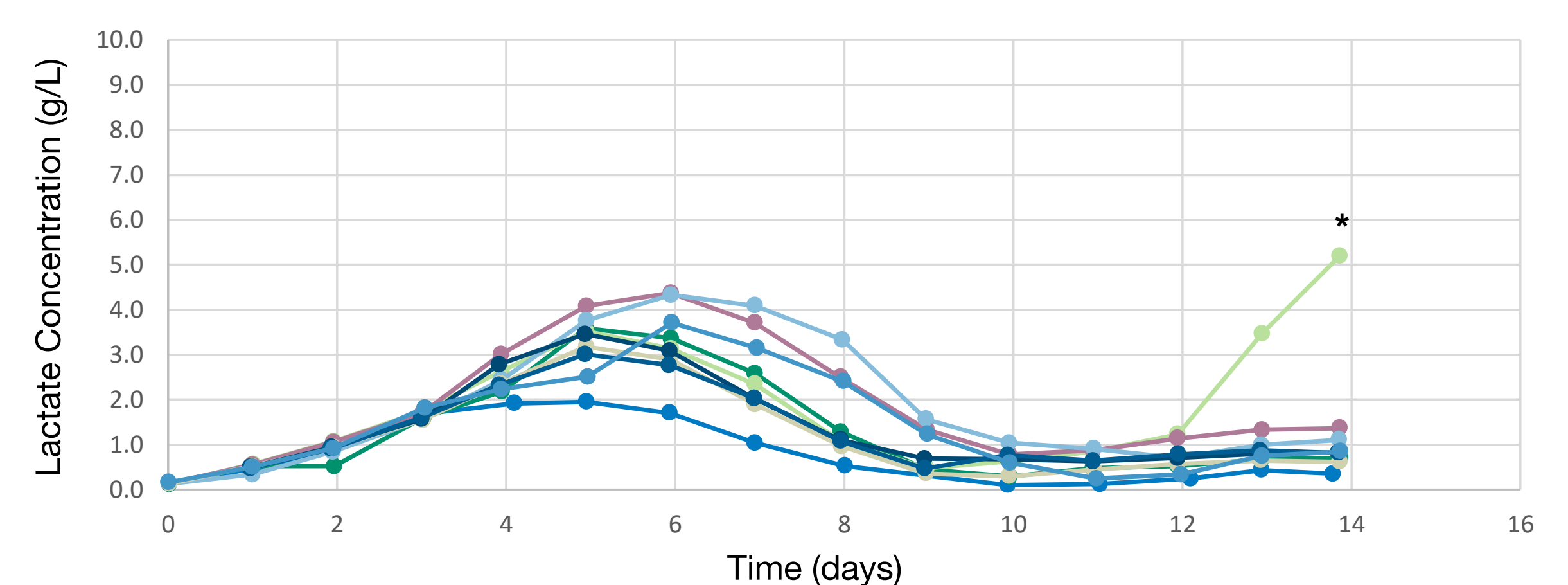
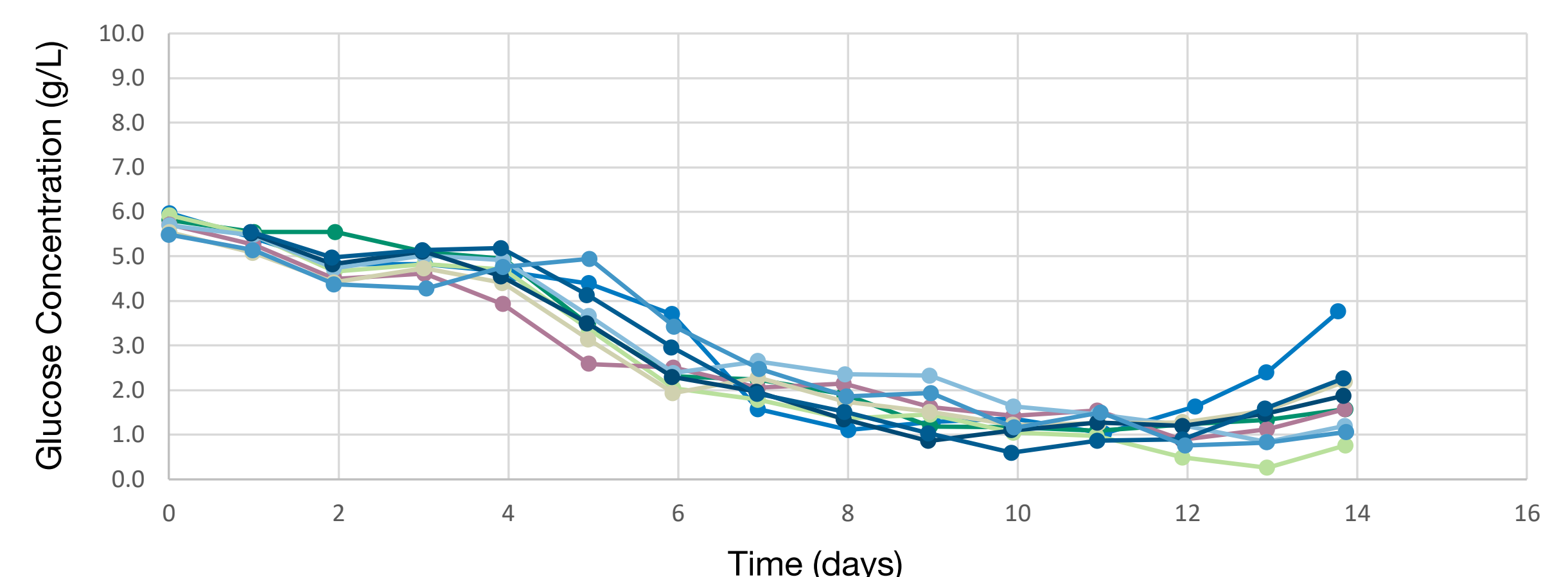
LEGEND:

- Historical Average
- 1F (Powder)
- 2F (Powder)
- 3F (FUJIFILM Irvine Scientific prep'd liquid)
- 4F (FUJIFILM Irvine Scientific prep'd liquid)
- 5F (Oceo Rover Stability 1)
- 6F (Oceo Rover Fresh Lot 1)
- 7F (Oceo Rover Fresh Lot 2)
- 8F (Oceo Rover Stability 2)

CELL GROWTH, VIABILITY, AND TITER ARE EQUIVALENT



NUTRIENTS, METABOLITES, AND OSMOLALITY



*The data for 2F trended consistently up to day 12. The results at day 13 and 14 are due to an in-process sampling error.

1. Powder Culture Media Packaging, Preparation and Market Trends. BioPlan and Associates, Inc. (2014)