

MDCK Suspension Platform

Boost vaccine production with a monoclonal, suspension MDCK cell line adapted to a chemically defined medium



Product Information

Our MDCK Suspension Platform is a comprehensive and scalable solution designed for developers and manufacturers of vaccines, especially those targeting influenza. The MDCK Suspension Platform features:

- Monoclonal Suspension MDCK cell line: Cells directly adapted from ATCC MDCK (NBL-2) CCL-34™ without genetic modifications or the use of animal-derived serum.
- 4Cell® MDXK CD Medium: A chemically defined, animal component- and protein-free* medium designed for the growth and infection of MDCK cells.
- Support services: Cell bank, biosafety, and characterization testing, as well as technical support across upstream and downstream processing and scale-up.

* Contains growth factor

Features and Benefits

- Scalability: Robust suspension platform for seamless scale-up
- Versatile: R&D and GMP grade cell lines available
- Chemically-defined media: Animal component-free 4Cell® MDXK CD Medium
- Service portfolio: Tailored banking, testing, and characterization
- Regulatory alignment: Meets guidelines encouraging the replacement of egg-based processes

Introduction

Relevant Applications

Virus production for batch and perfusion processes in suspension cultures:

- Research & development (R&D-grade cell line and medium)
- Commercial manufacturing (GMP-grade cell line and medium)

Relevant Process Steps

Upstream

- Cell culture media preparation
- Seed cultivation
- Bioreactor suspension cell cultivation

Description

Developers and manufacturers worldwide face significant challenges when developing vaccines. From building efficient, scalable platforms to navigating complex regulatory environments, they must balance tight timelines, especially during pandemics, while controlling costs and ensuring safety throughout the process.

The First Characterized Monoclonal MDCK Suspension Cell Line on the Market

MDCK cells were isolated in 1958 from the kidney of an adult female cocker spaniel. MDCK cells are considered the most suitable cultured cell substrates for obtaining primary isolates of influenza viruses. Additionally, they have been shown to be ideal for large-scale influenza virus production, with faster viral replication compared to other cell lines.¹ Still, the Centers for Disease Control and Prevention (CDC) estimates that approximately 80% of influenza vaccines are produced on the ancestral egg-based platform, with the remainder being produced using cell-based or recombinant technology.²

The MDCK Suspension Cell Line from Sartorius is derived from ATCC MDCK (NBL-2) CCL-34™. The cell line was directly adapted to Sartorius 4Cell® MDXK CD medium in a non-animal origin environment and has not been subjected to any genetic modification. It is a monoclonal cell line with an extensive and well-documented history.

Safety & Regulatory Compliance

Cell culture offers several advantages over an egg-based platform: it aligns more closely with regulatory and public health guidance and reduces reliance on egg supply, which can be especially challenging during pandemics. Moreover, using eggs in biologics production creates greater ethical and safety challenges, with some patients experiencing severe allergic responses to egg proteins.³

The MDCK Suspension Cell Line from Sartorius is available as R&D grade for research purposes and GMP grade to ensure regulatory compliance during clinical and commercial manufacturing.

Supported by Highest Quality Media

Medium formulation plays a key role in cell line performance. A chemically-defined medium enables full control over each component, removing batch-to-batch variations and securing platform consistency.

4Cell® MDXK CD medium is optimized for the growth and infection of suspension MDCK cells and is formulated without components of animal origin, serum, or hydrolysates. The medium is manufactured in compliance with ISO 9001 and ISO 13485 quality standards.

Robust Scalability

Egg-based and adherent cell-based platforms are challenging to scale up. Growth is limited by surface area, limiting product yield at large scales. Adherent cell culture requires significant manual labor for set-up, scale-up, and scale-out. Suspension cell lines offer increased flexibility and reduce labor requirements.

The tailored combination of the MDCK monoclonal suspension cell line and 4Cell® MDXK chemically defined medium significantly enhances platform scalability and supports flexible manufacturing technologies throughout the drug development journey.

Reduced Timelines

According to the World Health Organization (WHO), commercializing vaccines takes approximately 6–8 months. Rapid response to these strain recommendations is essential for vaccine effectiveness and becomes even more crucial during pandemics to prevent the spread of infectious disease.

The suspension MDCK cell line and tailored chemically defined media support a fast and easy process set-up and scale-up to meet tight timelines.

Performance

The MDCK Suspension Cell Line is Robust and Stable

The MDCK Suspension Cell Line from Sartorius has demonstrated excellent viability over >98% during cell thawing (Figure 1). Viability remained constant over three passages.

MDCK Suspension Cell Growth Stability

To assess the growth stability of the cell line over time, one GMP vial was thawed and the cells were continuously subcultured over 50 days (Figure 2). The cells showed stable growth over 50 days with high viability and an average viable cell concentration (VCC) of over 8×10^6 cells/mL.

Figure 1: MDCK Suspension Cell Recovery After Thawing (n=3)

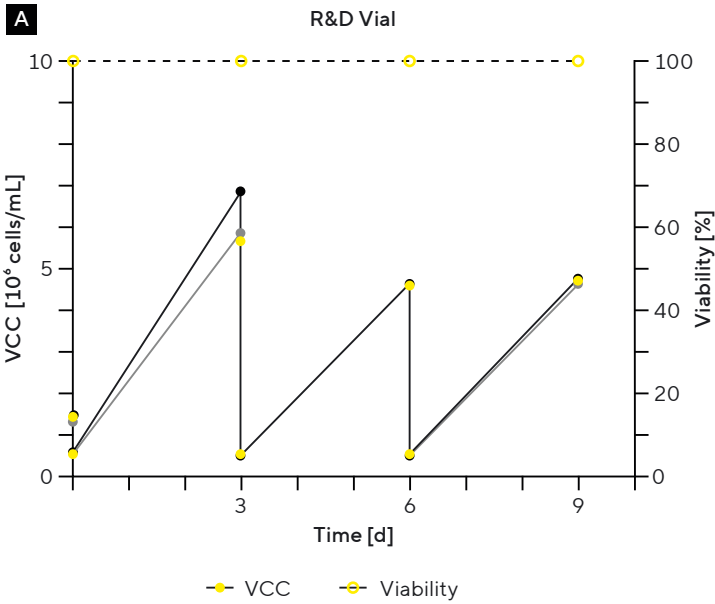
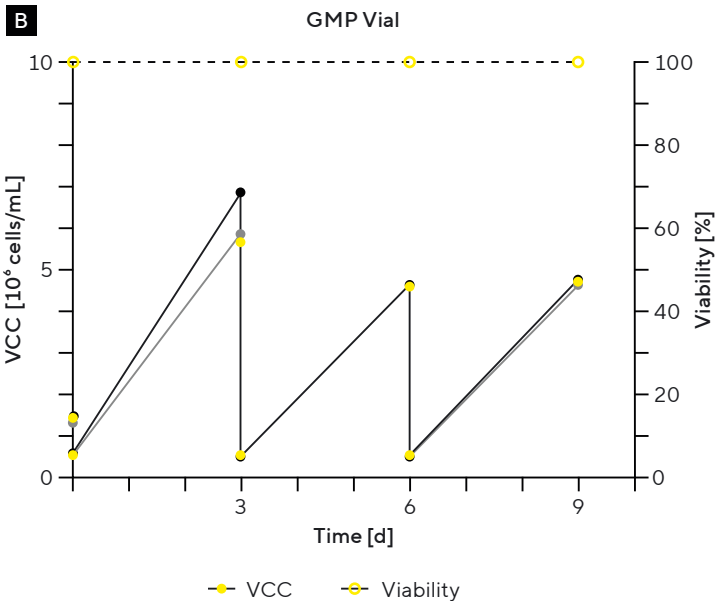
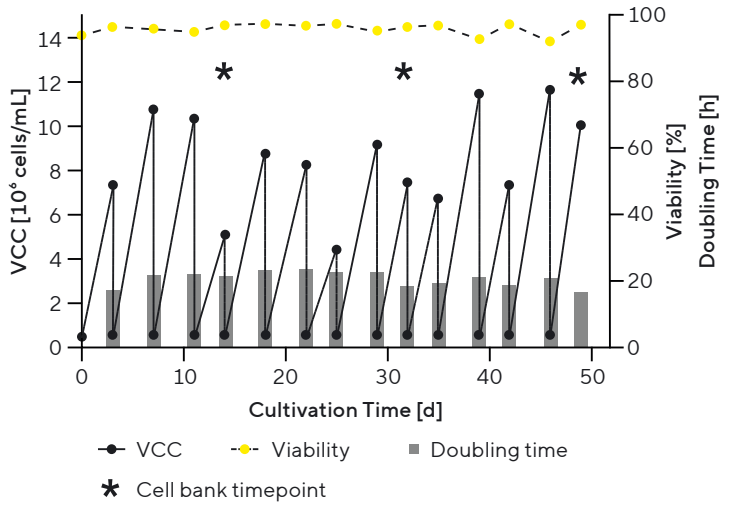


Figure 2: MDCK Suspension Cell Stability



Note. VCC = viable cell concentration. Three independent experiments are shown in black, grey, and yellow.

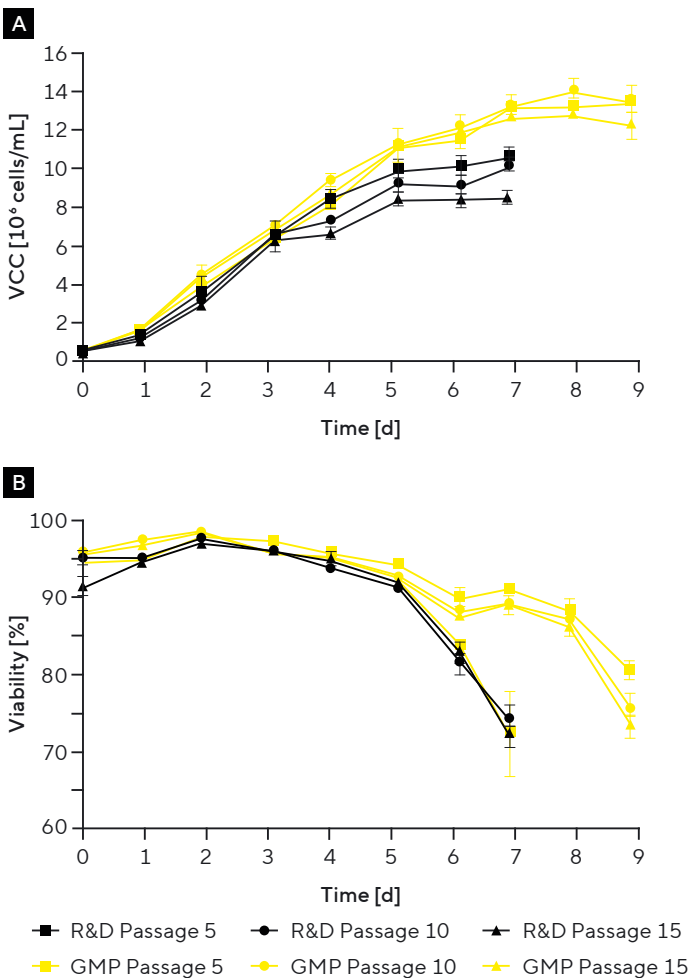
MDCK Suspension Platform Supports High Cell Growth

Both R&D and GMP banks demonstrated stable cell growth and virus production across 15 passages. GMP-derived banks reached higher peak cell densities (up to 12×10^6 cells/mL) and maintained viability longer than R&D banks, confirming their enhanced robustness for intensified production. All R&D and GMP banks showed consistent growth and viability within each series, underscoring the reliability of both banking strategies.

Virus Production in the MDCK Suspension Platform

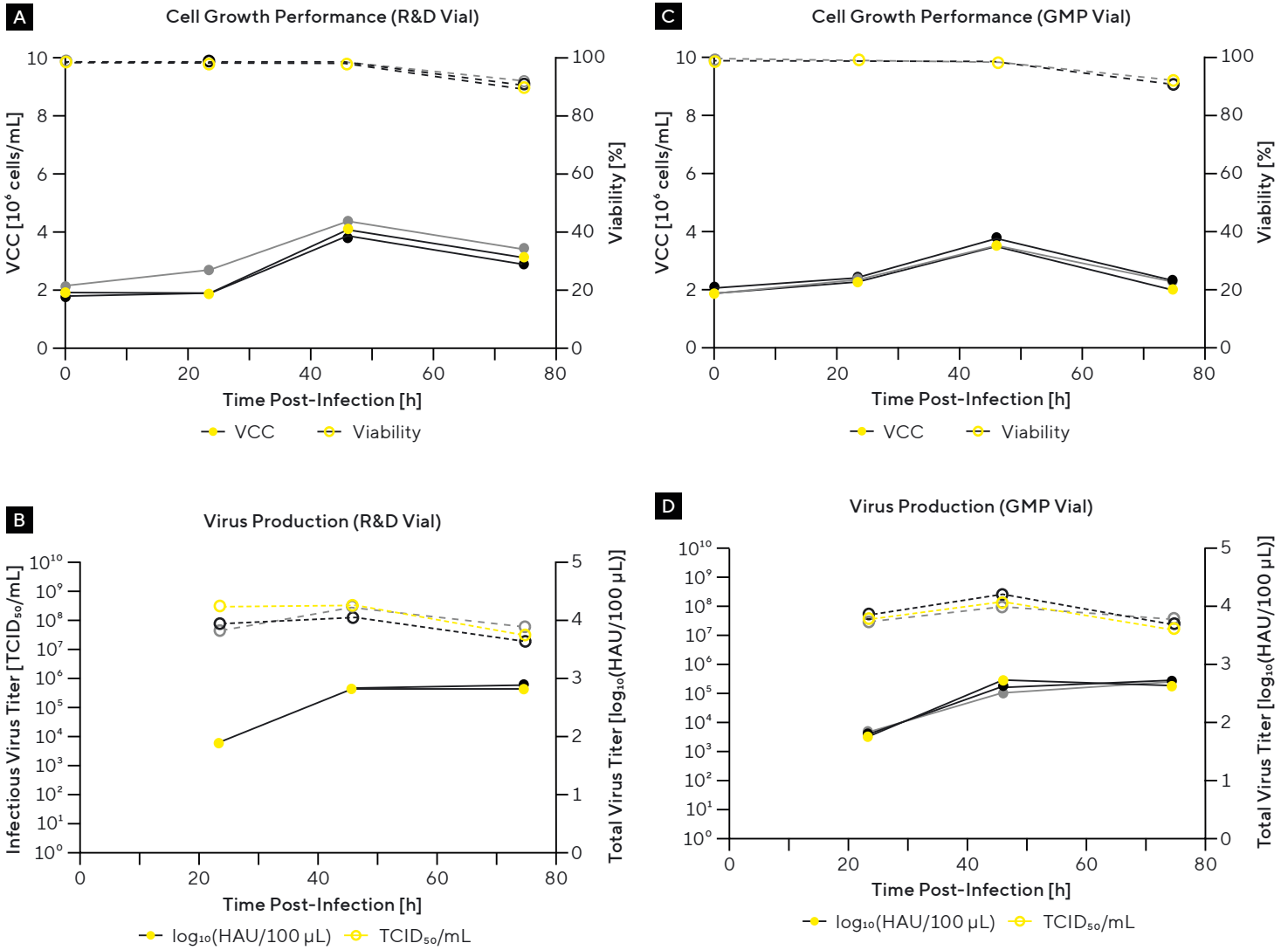
Batch growth characteristics and virus productivity were investigated following infection with influenza A virus (H1N1). Both the R&D and GMP vial-derived cells showed similar VCC and viability after infection (Figure 4A and 4C). The hemagglutination (HA) titer peaked at 2.9, while the infectious titer reached 4.2×10^9 TCID₅₀/mL for the R&D vial-derived cell banks. For the GMP vial-derived cell banks, the HA maximum was 2.7 and the TCID₅₀ was 2.9×10^9 /mL. The high titers observed for both cell banks highlight their robust and strong productivity under batch conditions, suggesting suitability for intensified production processes (Figure 4B and 4D).

Figure 3: MDCK Suspension Cell Growth Performance for Cell Banks Derived From the RCB and MCB Vials (n=3)



Note. Cells were seeded at 0.5×10^6 cells/mL in 4Cell® MDXK CD medium (+8 mM Glc) into 125 mL non-baffled shake flask, working volume= 30 mL. Sampling was performed once per day.

Figure 4: MDCK Suspension Growth Characteristics After Infection of R&D and GMP Vial-Derived Cell Banks

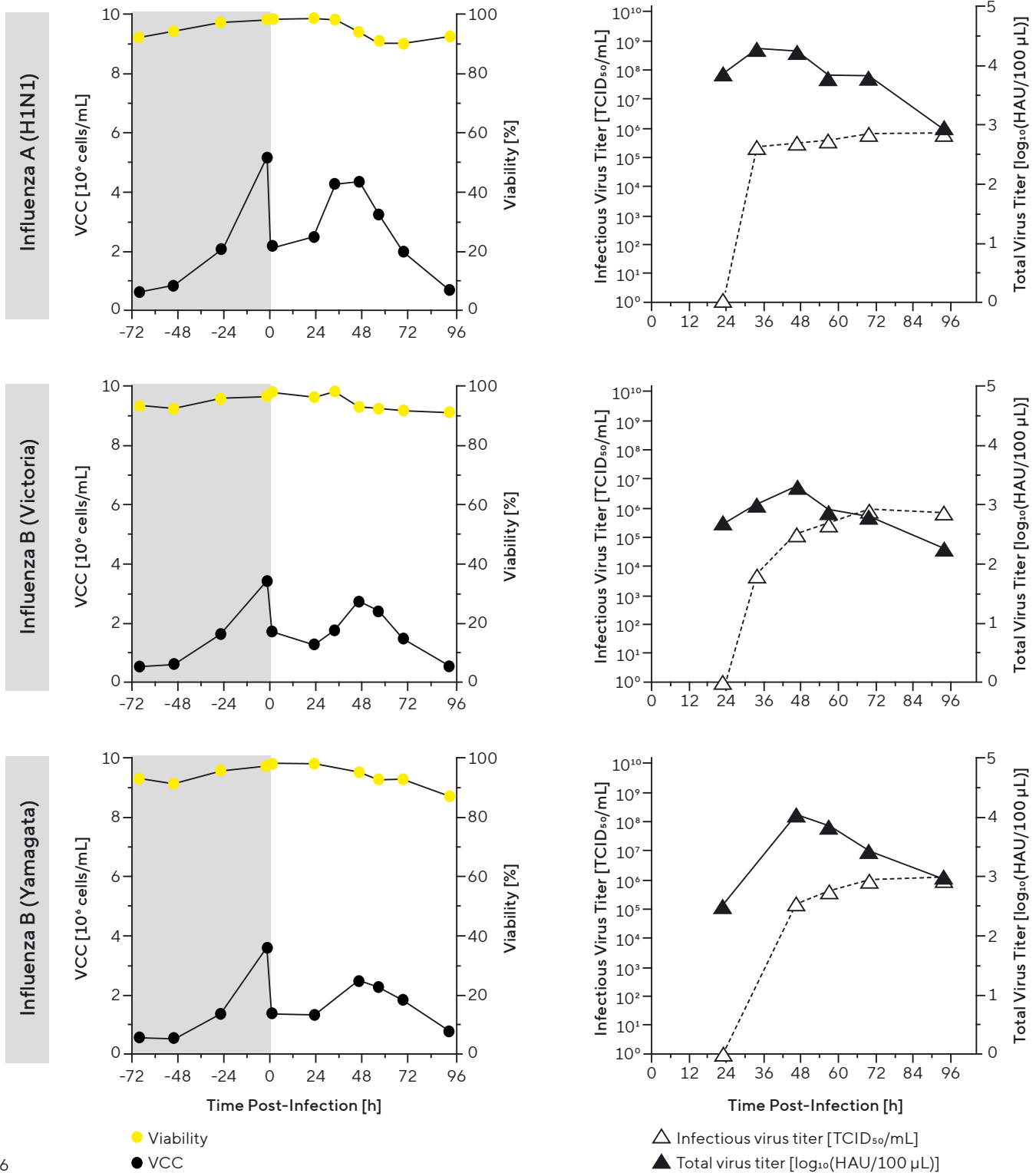


Note. Three independent experiments are shown in black, gray, and yellow.

High Performance of the MDCK Suspension Platform Across Several Influenza Strains

The replication of several WHO-recommended influenza strains was evaluated using the MDCK suspension platform. An HA_{max} of 2.92 was achieved for influenza A (H1N1), 2.98 for influenza B (Victoria), and 3.05 for influenza B (Yamagata) (Figure 5).

Figure 5: MDCK Suspension Platform Performance Following Infection With Multiple Influenza Strains

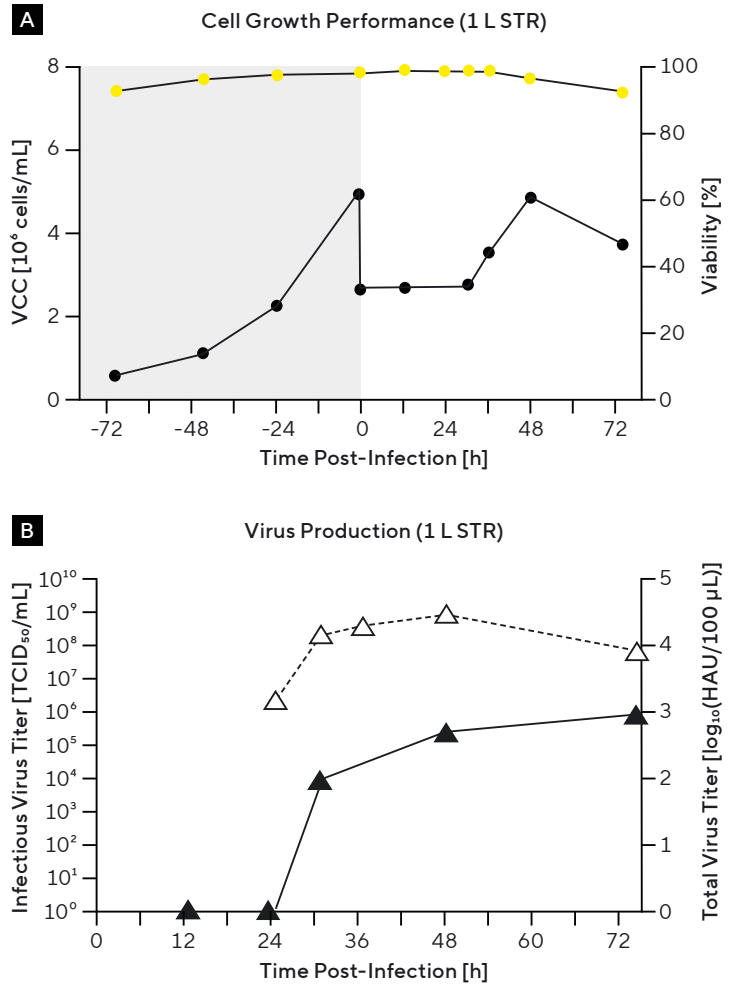


Proven Scalability of the MDCK Suspension Platform

Cell line performance was also measured in a 1 L stirred-tank reactor (STR) using R&D grade cell line. Figures 6A and B show a successful scale-up to 1 L STR, with the MDCK Suspension Cell Line reaching viability and infectious titers comparable to shake flasks: Figure 5 a peak HA_{max} of $2.97 \pm 0.16 \log_{10}$ (HAU/100 μ L) was achieved in the 1 L STR, compared with 2.82 in the shake flask, while $TCID_{50max}$ reached 1×10^9 TCID₅₀/mL.



Figure 6: Scale-Up of an Influenza A Virus Production Process From Shake Flasks to Ambr® 15 to 1 L Bioreactor



Technical Specifications

Application	Influenza vaccines
Media features	Animal component-free, serum-free, chemically defined
Growth mode	Suspension
Storage conditions	Liquid nitrogen (-196 °C) for MDCK Cell Line; 2-8 °C for 4Cell® MDXK CD Medium

Ordering Information

MDCK Suspension Platform	Format	Product Information	Order Description	Order Number
MDCK Monoclonal Suspension Cell Line	Vial	R&D grade	MDCK R&D vial (PCB-N-ER-2022-002)	CL-MDCK-R01
<i>Important Licensing Notice:</i> These products may be subject to one or more Limited Use Label Licenses. By using these products, you agree to comply with all applicable terms and conditions of those licenses.	Vial	GMP grade	MDCK GMP vial (M284-044.01)	CL-MDCK-M01
		Technical licenses		
4Cell® MDXK CD Medium	Liquid	1 L PET bottle	MDXK Medium, liquid, 1,000 mL PET bottle	1010-0001
	Liquid	10 L bag	MDXK liquid, 10 L bag	1010-0010BAG
	Liquid	20 L bag	MDXK liquid, 20 L bag	1010-0020BAG
	Liquid	50 L bag	MDXK liquid, 50 L bag	1010-0050BAG
	Powder	5 L powder container	4Cell® MDXK CD Medium 5 L Powder&Sup*	CQV3FB3001
	Powder	10 L powder container	4Cell® MDXK CD Medium 10 L Powder&Sup*	CQV3FB3002
	Powder	50 L powder container	4Cell® MDXK CD Medium 50 L Powder&Sup*	CQV3FB3003
	Powder	100 L powder container	4Cell® MDXK CD Medium 100 L Powder&Sup*	CQV3FB3004
	Powder	500 L powder container	4Cell® MDXK CD Medium 500 L Powder&Sup*	CQV3FB3005

*This product has two components.

References

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5. Zinnecker, T., et al. (2024). From single-cell cloning to high-yield influenza virus production – implementing advanced technologies in vaccine process development. *Engineering in Life Sciences*, 24(4), 2300245. <https://doi.org/10.1002/elsc.202300245>

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