SARTORIUS

Product Datasheet

MDCK Suspension Platform

Boost Your Vaccine Platform 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 testing, biosafety testing, characterization. We also offer technical support throughout upstream and downstream processing and scale-up.

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, characterization
- Regulatory alignment: Adheres to guidelines on moving away from egg-based processes

Introduction

Relevant Applications

- Virus production for batch and perfusion processes in suspension
- Research & development (Cell line and Medium)
- Commercial manufacturing (Cell line* and Medium)

Relevant Process Steps

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

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]

Sartorius' MDCK Suspension Cell Line 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, on the one hand increasing conformity with regulatory and public health guidance, on the other hand reducing the reliance on egg-based processes and egg supply, which can pose a greater challenge 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]

Sartorius' MDCK Suspension Cell Line 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
The medium formulation plays a key role in cell line performance. 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 requirement.

The tailored combination of the MDCK monoclonal suspension cell line and 4Cell® MDXK chemically defined medium — available in various formats such as bottles, bags, and larger powder forms — significantly enhances platform scalability and supports flexible manufacturing technologies throughout the drug development journey.

Reduced Timelines
According to the World Health Organization (WHO), producing, approving, and distributing vaccines takes approximately 6 – 8 months. Recommendations for the upcoming influenza season are made every year — typically in February for the Northern Hemisphere and in September for the Southern Hemisphere. Responding quickly to the strains recommendation is essential to allow the highest vaccine effectiveness and even more crucial during pandemics to prevent spreading of infectious diseases.

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.

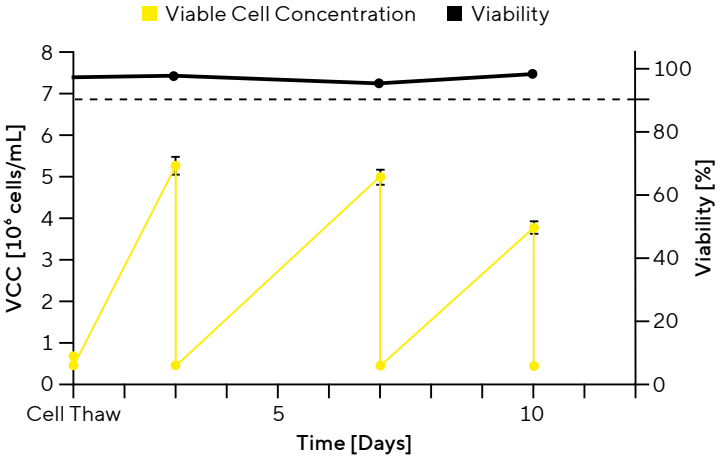
*GMP Cell line coming soon

Performance

The MDCK Suspension Cell Line is Robust and Stable

Sartorius' MDCK Suspension Cell Line has demonstrated excellent viability over >97% during cell thawing (Figure 1). Viability remained constant over three passages and with a very low standard deviation.

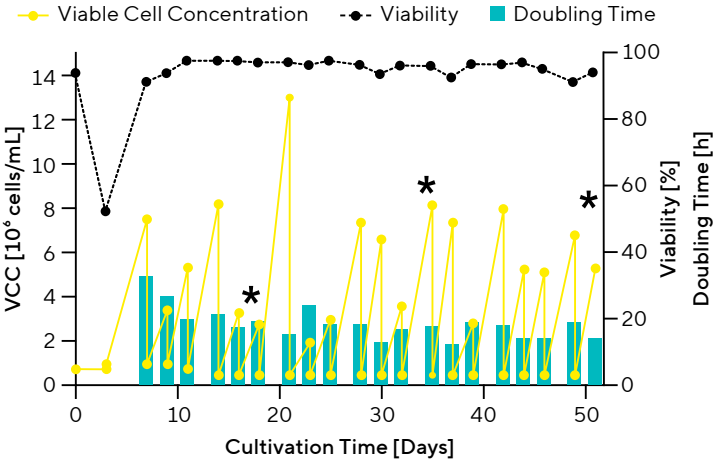
Figure 1: *MDCK Suspension Cell Recovery After Thawing*



Note. VCC = viable cell concentration. Results from three vials.

One cryovial was thawed and subcultured over 50 days to assess the stability of the cell line. Three cell banks were generated at different times (18, 35, and 51 days post-thawing) to mimic the establishment of a research cell bank (RCB), master cell bank (MCB), and working cell bank (WCB). These cell banks were then thawed simultaneously, subcultured for 5 passages, and tested (Figure 2). The MDCK Suspension Cell diameter ranged from 13.7 to 15.2 µm with a mean of 14.5 µm and an average doubling time of 19 h.

Figure 2: *MDCK Suspension Cell Stability*

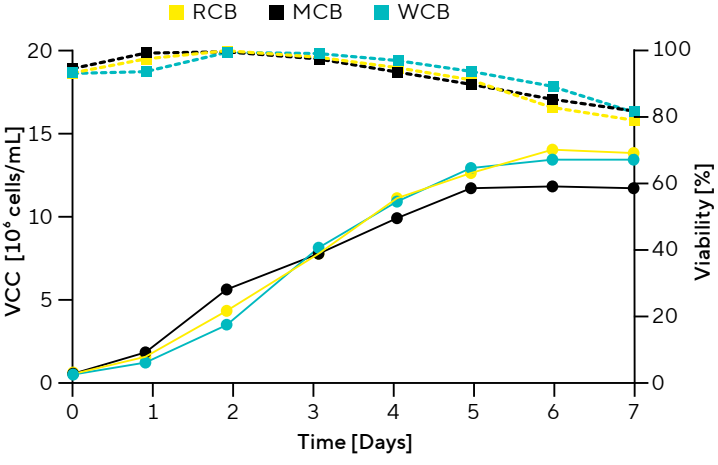


Note. VCC = viable cell concentration.

MDCK Suspension Platform Supports High Cell Growth

Sartorius MDCK Suspension Cell Line was cultured for seven days, reaching a peak of 13.9 × 10⁶ cells/mL at day 6, making it a robust candidate for intensified processes (Figure 3). Comparable results were observed within the three cell banks.

Figure 3: *MDCK Suspension Cell Growth Performance*

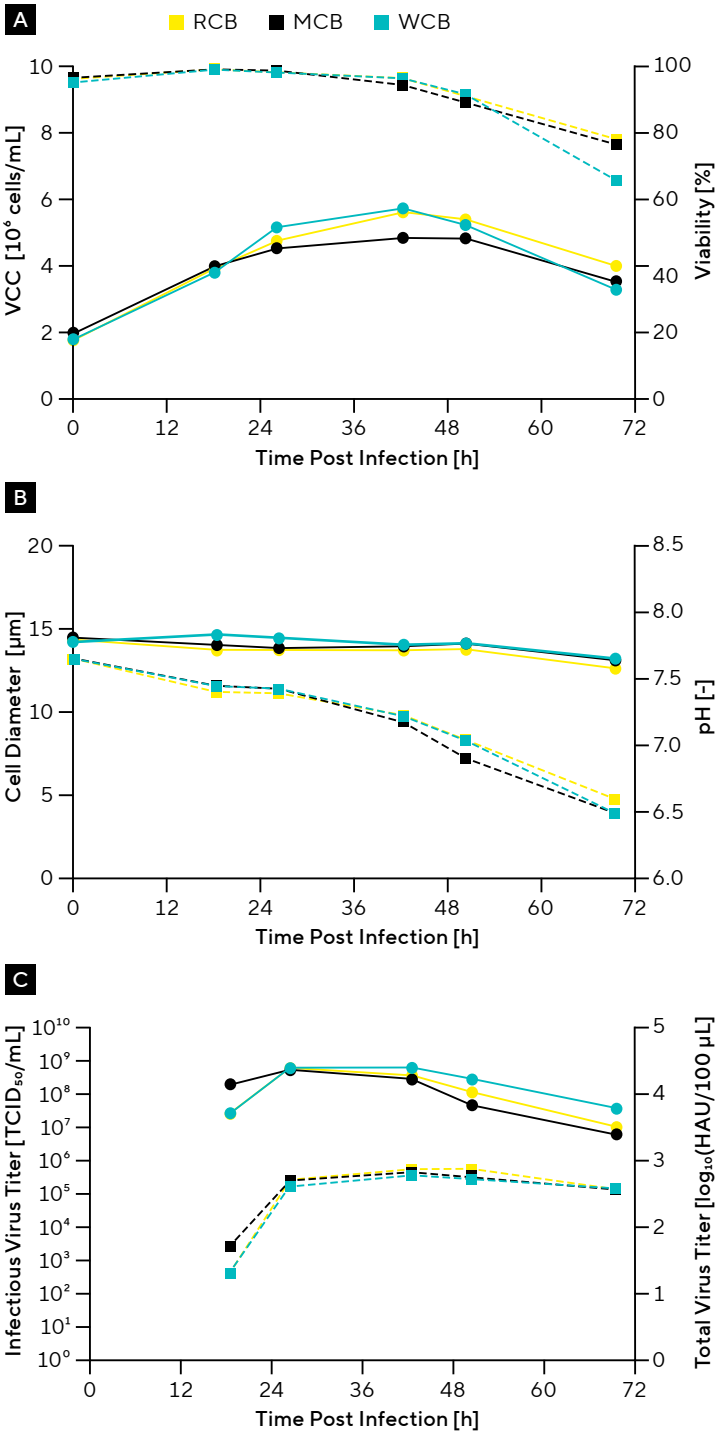


Note. VCC = viable cell concentration. Cells were seeded at 0.5 × 10⁶ cells/mL in 4Cell® MDXK CD medium (+8 mM Gln) into 125 mL non-baffled SF, working volume = 30 mL; 120 rpm (50 mm throw). Sampling was performed once per day.

Figures 4A and B show comparable batch growth characteristics after infection with influenza A (H1N1), with similar growth and cell diameter.

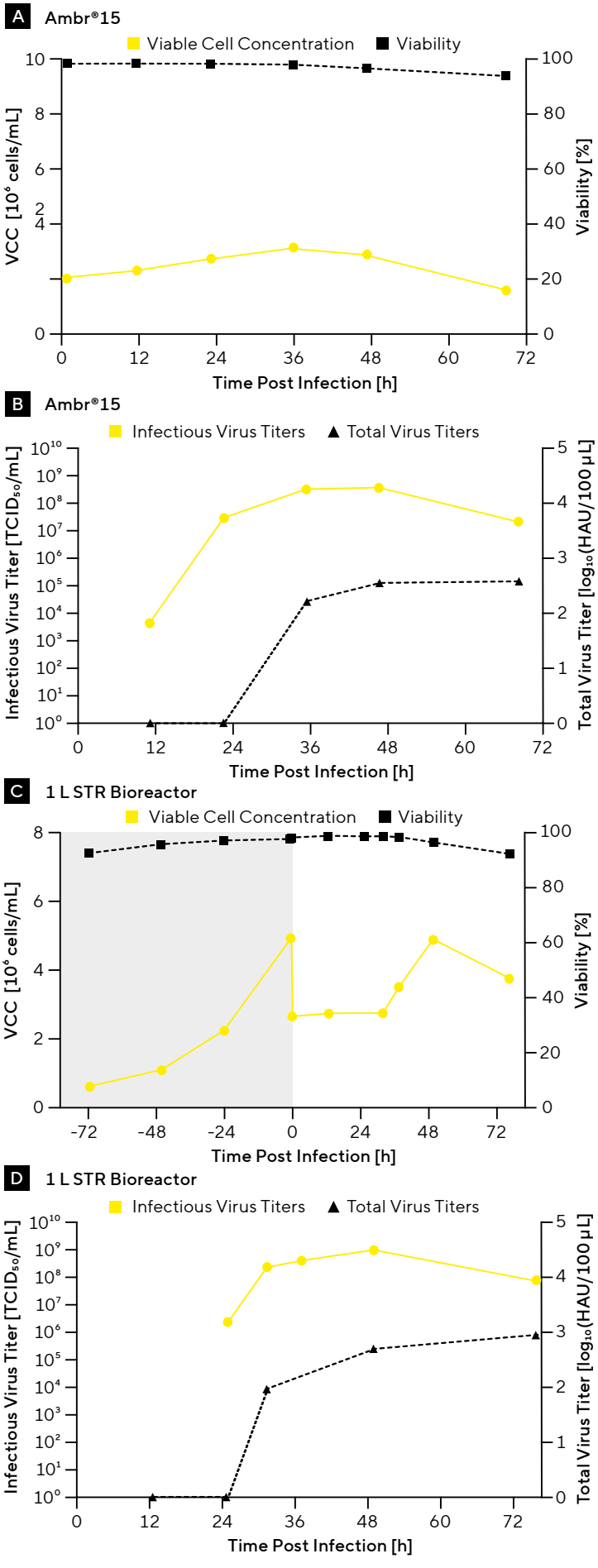
Post-infection (24h), infectious titer reached HA_{max} of 2.82 ± 0.05 and $TCID_{50}$ of 5.15 ± 0.8 × 10^8, highlighting the high productivity (Figure 4C).

Figure 4: *MDCK Suspension Growth Characteristics After Infection*



Note. VCC = viable cell concentration.

Figure 5: *Scale-Up From Shake Flasks to Ambr® 15 to 1 L STR Bioreactor*



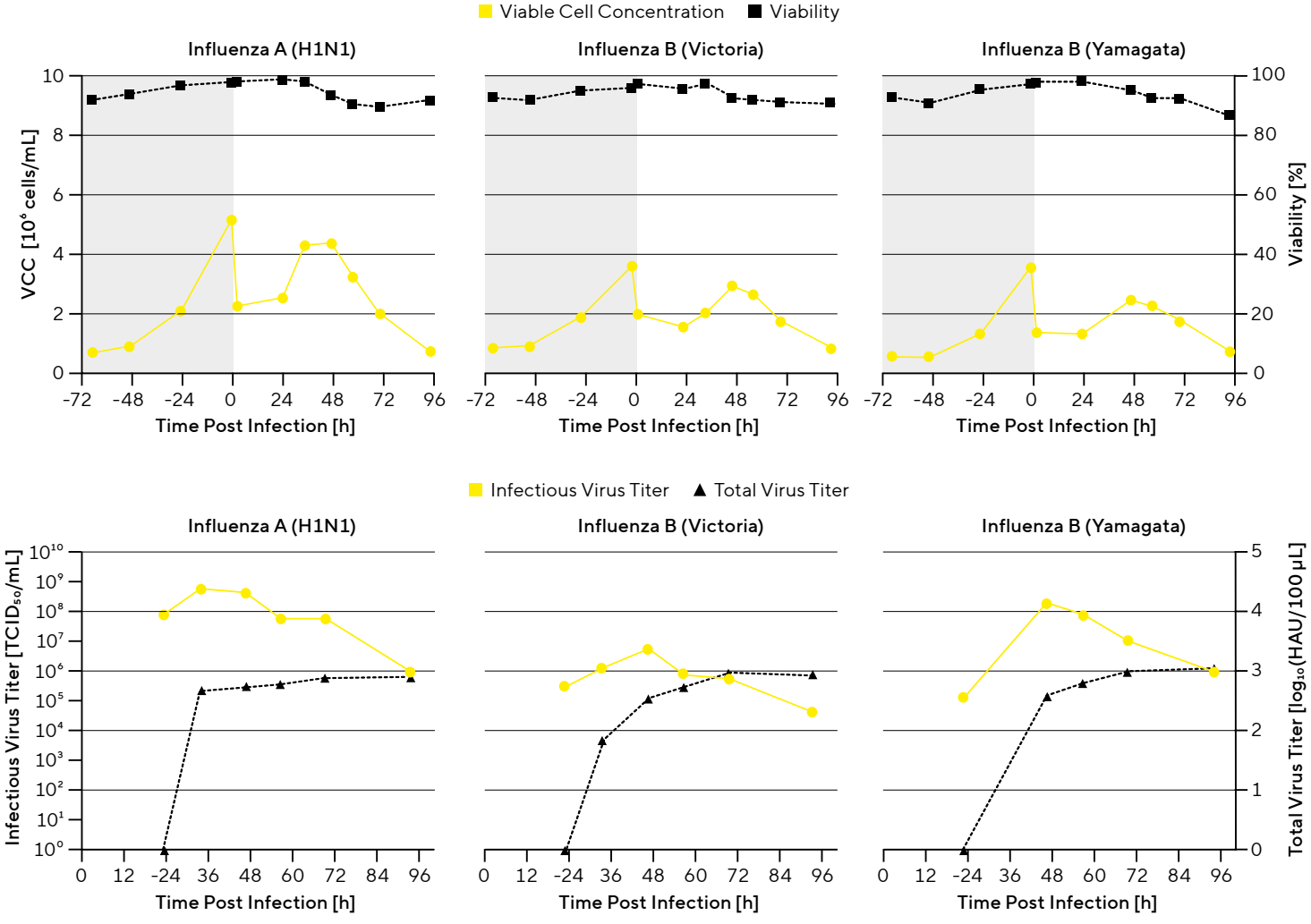
Sartorius' MDCK Suspension Cell Line is Scalable

Cell line performance was also measured in Ambr® 15 Cell Culture Bioreactor System and in 1 L STR Bioreactor. Figures 5A and B show a successful scale-up from shake flasks to Ambr®15, with the MDCK Suspension Cell Line reaching viability and infectious titers comparable to shake flasks: a peak HAmax of 2.55 ± 0.16 log_{10}(HAU/100 µL) was achieved in the Ambr®15, compared to 2.82 in the shake flask, while TCIDmax reached 0.4 ± 0.3 × 10^9 $TCID_{50}$/mL . Figures 5C and D highlight a successful scale-up from Ambr®15 to 1 L STR Bioreactor , with titers reaching HA_{max} of 2.97 and $TCID_{max}$ of 1 × 10^9.

High Performance of the MDCK Suspension Platform Against Several Influenza Strains

We tested our MDCK Suspension Platform against three types of influenza strains recommended by WHO. The MDCK Suspension Platform supported a VCC of 4.3 × 10^6 cells/mL with influenza A (H1N1) and influenza B (Yamagata) and 2.8 × 10^6 cells/mL for influenza B (Victoria). A HAmax of 2.92 was achieved for influenza A (H1N1), 2.98 for influenza B (Victoria), and 3.05 for influenza B (Yamagata).

Figure 6: *MDCK Suspension Platform Performance With Influenza Strains*



Technical Specifications

Application	Vaccines
Media Features	Animal component free, serum-free, chemically-defined
Growth Mode	Suspension
Storage Conditions	Liquid nitrogen for MDCK Cell Line; 2 – 8 °C for 4Cell® MDXK CD Medium

Ordering Information

MDCK Suspension Platform	Format	Product Information	Order Number	Order Description
MDCK Monoclonal Suspension Cell Line	Vial	R&D Grade	TDT66	SSC-CL-MDCK002 (TDT66-CB-CB59)
4Cell® MDXK CD Medium	Liquid	1 L PET bottle	1010-0001	MDXK Medium, liquid, 1,000 mL PET bottle
	Liquid	10 L Bag	1010-0010BAG	MDXK liquid, 10 L Bag
	Liquid	20 L Bag	1010-0020BAG	MDXK liquid, 20 L Bag
	Liquid	50 L Bag	1010-0050BAG	MDXK liquid, 50 L Bag
	Powder	5 L Powder Container	CQV3FB3001	4Cell® MDXK CD Medium 5 L Powder & Supplement*
	Powder	10 L Powder Container	CQV3FB3002	4Cell® MDXK CD Medium 10 L Powder & Supplement*
	Powder	50 L Powder Container	CQV3FB3003	4Cell® MDXK CD Medium 50 L Powder & Supplement*
	Powder	100 L Powder Container	CQV3FB3004	4Cell® MDXK CD Medium 100 L Powder & Supplement*
	Powder	500 L Powder Container	CQV3FB3005	4Cell® MDXK CD Medium 500 L Powder & Supplement*

*This product is composed of 2 components.

References

1. Hegde NR. Cell culture-based influenza vaccines: A necessary and indispensable investment for the future. Hum Vaccin Immunother. 2015;11(5):1223-34. doi: 10.1080/21645515.2015.1016666. PMID: 25875691; PMCID: PMC4514150.

2. Centers for Disease Control and Prevention. (2024). Seasonal influenza vaccine supply for the U.S. 2024-2025 influenza season. https://www.cdc.gov/flu/prevent/vaxsupply.htm

3. Harding, A. T., & Heaton, N. S. (2018). Efforts to improve the seasonal influenza vaccine. Vaccines, 6(2), 19. https://doi.org/10.3390/vaccines6020019

4. World Health Organization. (2020). Recommendations for influenza vaccines in the Southern Hemisphere for the 2021 season. https://www.who.int/docs/default-source/influenza/who-influenza-recommendations/vcm-southern-hemisphere-recommendation-2021/202009-qanda-recommendation.pdf

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