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For Life is Precious

Transitioning to Animal Free Cell Culture Media in India.

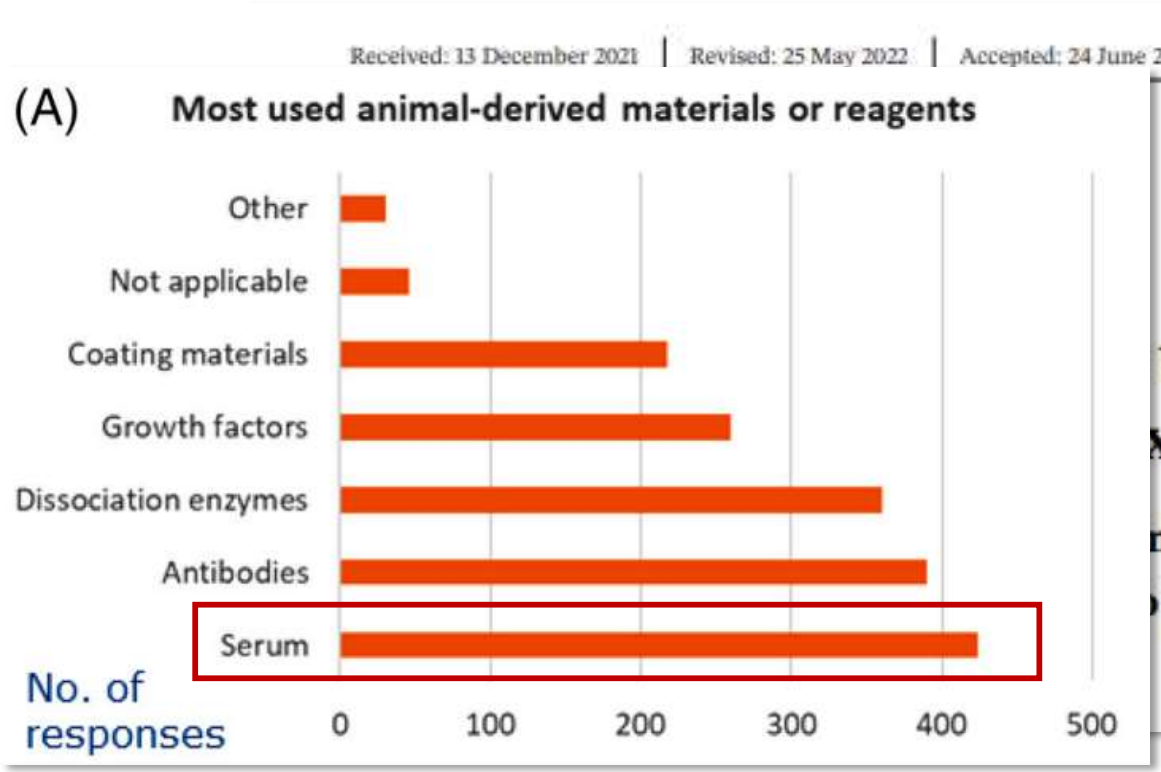
Presented by
Dr Pratiksha Palahe
Project Lead
Cell Biology Division
HiMedia Laboratories Pvt. Ltd, Thane
ppalahe@himedialabs.com

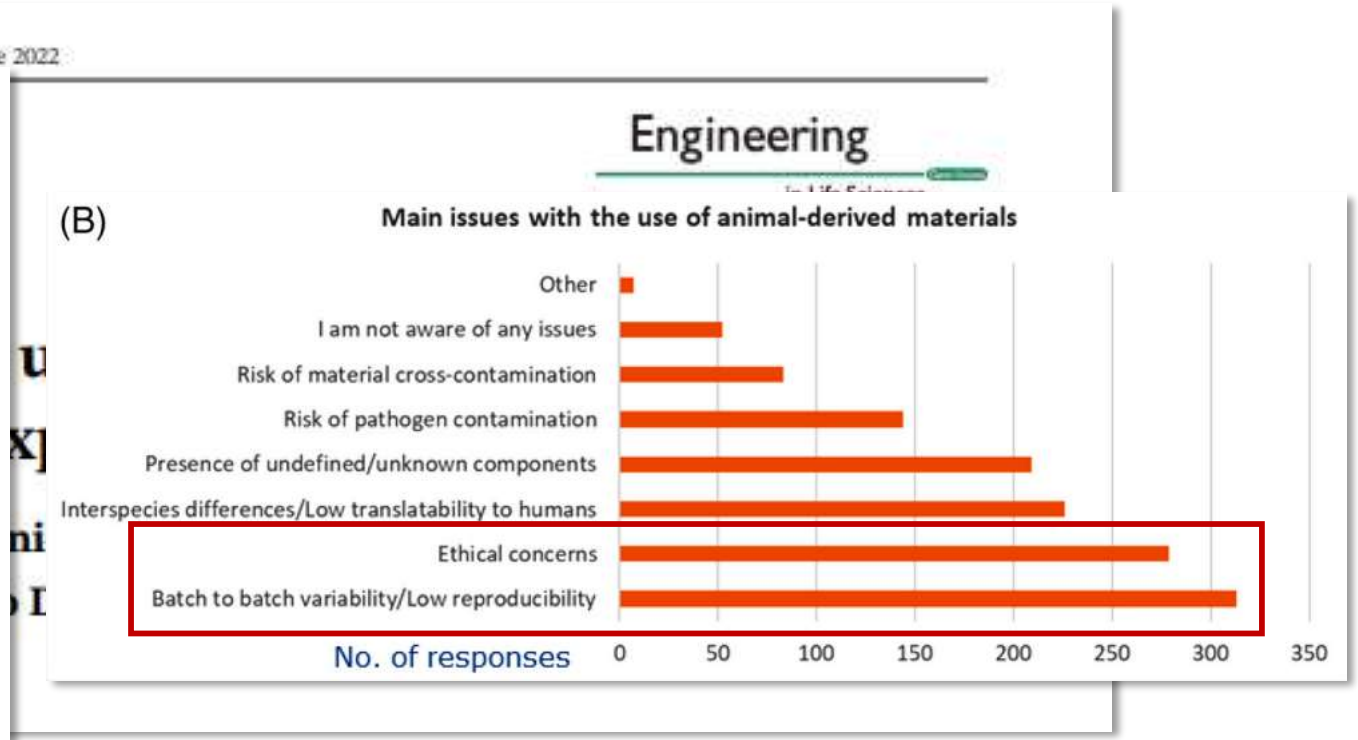
CELLBIO™

Overview

1. Animal derived material
2. FBS composition and function
3. How is it made?
4. Market potential
5. Global demand
6. Balancing ethical and scientific concerns
7. Indian Pharmacopoeia Commission (IPC) amendment
8. Scientific and regulatory challenges
9. Regulatory acceptance
10. NuSera
11. Validation data
12. HiMedia’s animal-free product
13. Conclusion
14. Acknowledgement

Use of animal-derived components in research





551 respondents from 52 countries

Composition and function

Composition

- Hormones
- Transport Proteins
- Growth Factors
- Lipids
- Minerals
- Elements
- Detoxifying Factors

Functions

- Cell Viability
- Cell Metabolism
- Cell Growth
- Cell Proliferation
- Cell Spreading

The FBS on your table!!

Cut from Pregnant Mother

Unborn calves are removed from their mothers

Heart Puncture

A needle is used to puncture the calf's heart

Serum Withdrawal

Serum is extracted from the calf's heart

Jugular Stab

The calf's jugular vein is stabbed

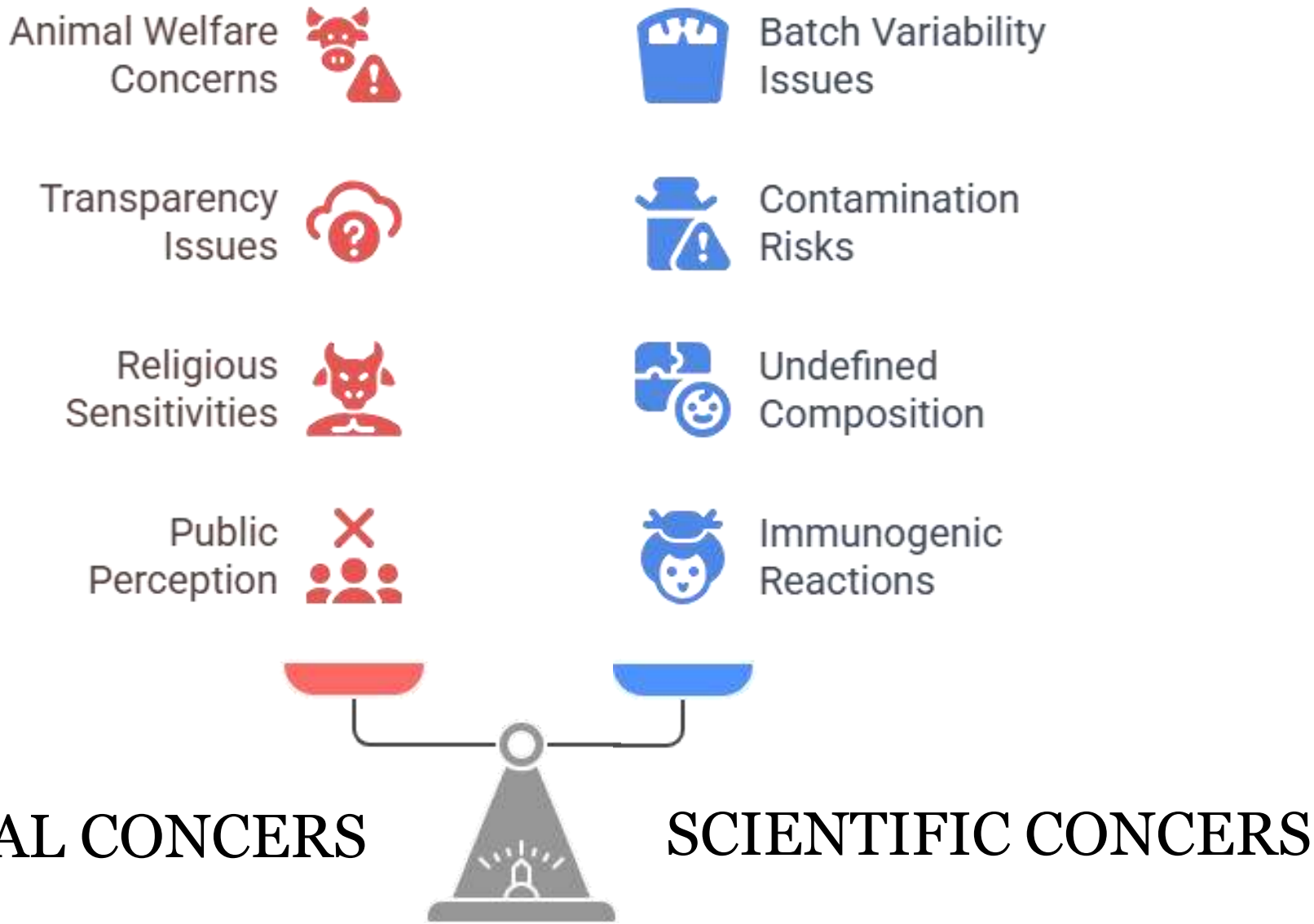
Bleed Out

The calf is left to bleed out and die

600,000 litres of FBS are obtained from up to 1.8 million bovine fetuses WORLDWIDE EVERY YEAR!

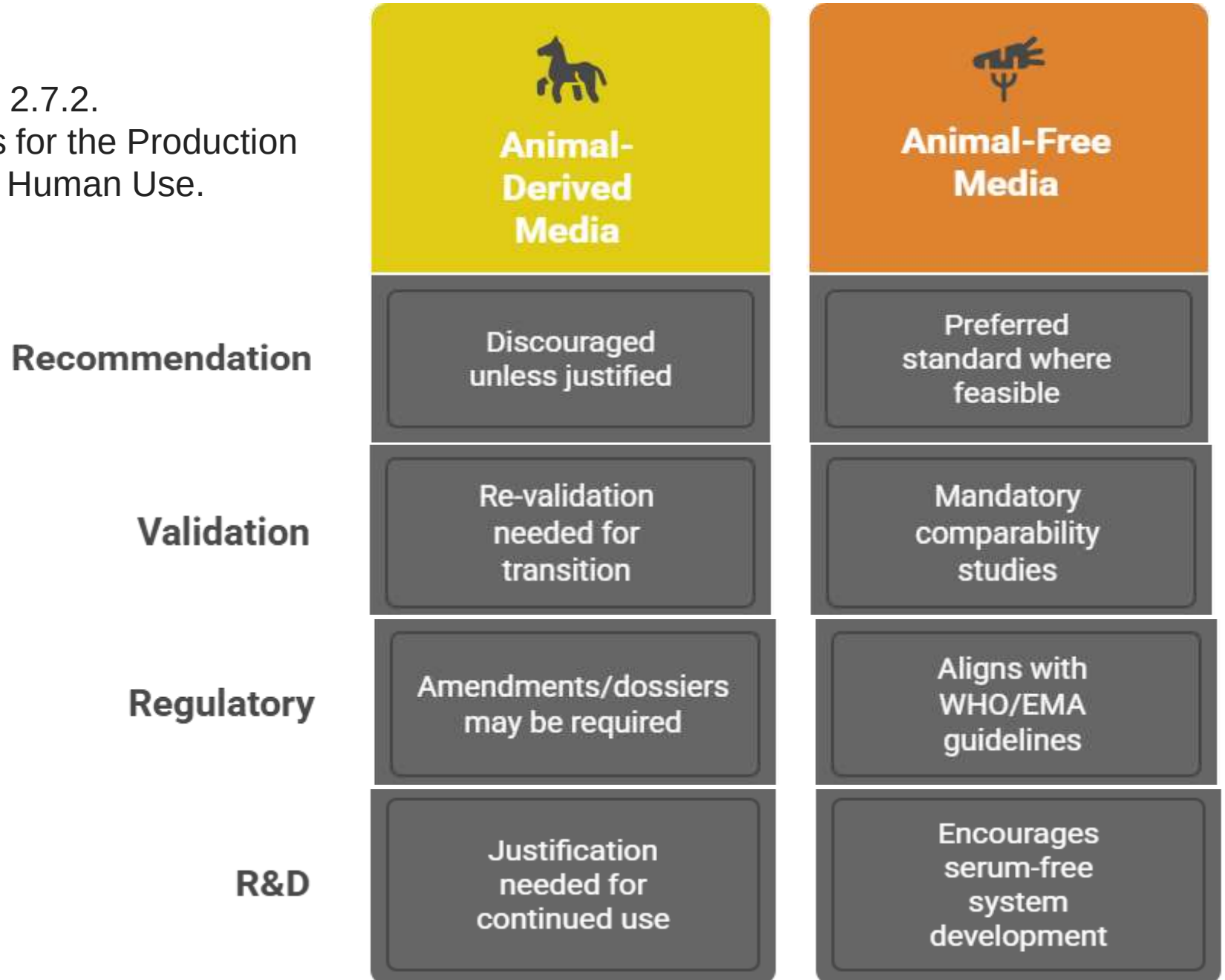
https://www.gminsights.com/industry-analysis/fetal-bovine-serum-market

Balancing ethical and scientific concerns of FBS use



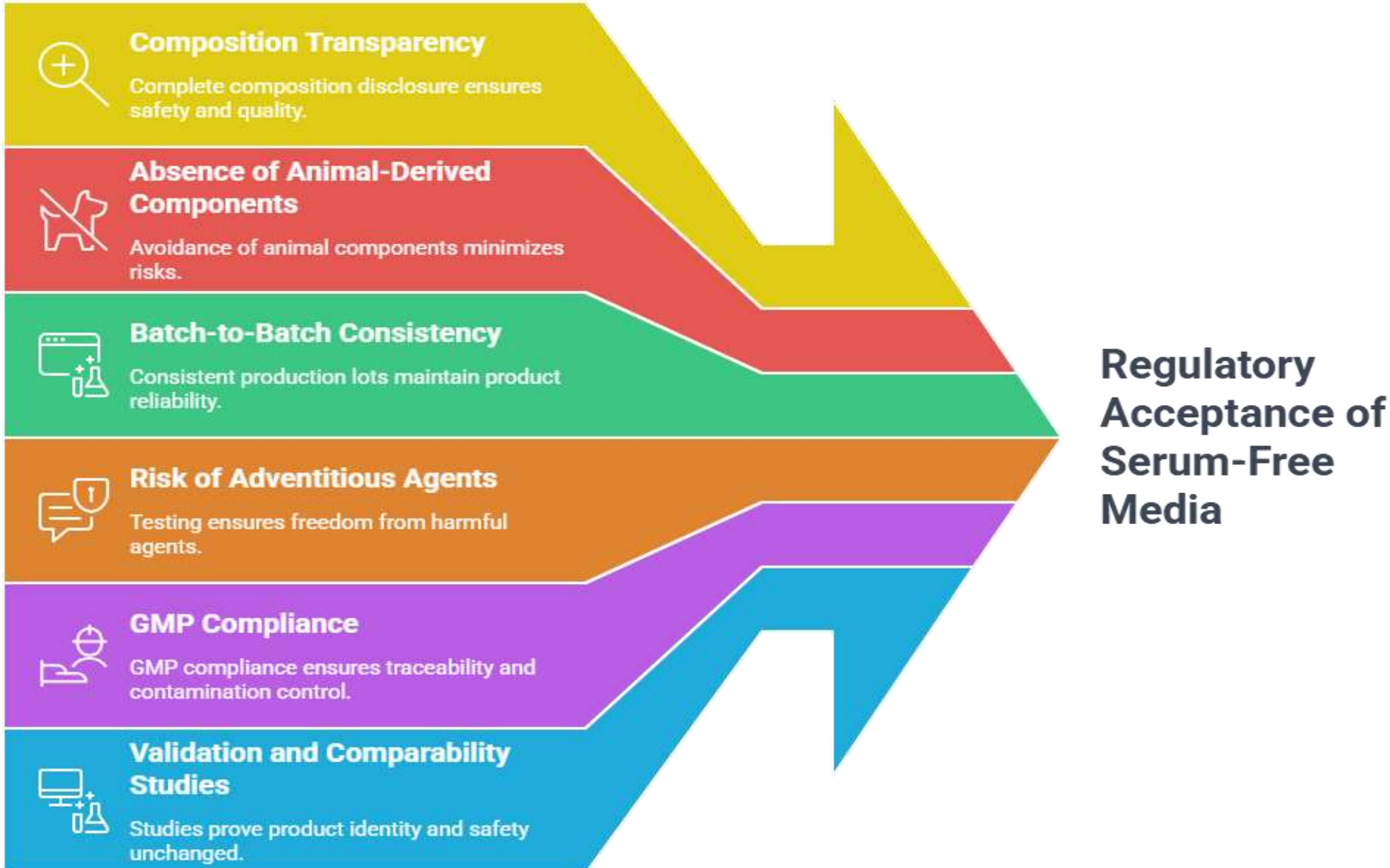
IPC amendment impact on vaccine production

Chapter name: 2.7.2.
Cell Substrates for the Production of Vaccines for Human Use.



Scientific and regulatory challenges for using animal free media

Challenge Type	Scientific	Regulatory
Adaptation Needs	Cell lines need adaptation	Regulatory re-submissions needed
Media Limitations	Media requires customisation	GMP compliance is essential
Process Changes	Optimization requires time	Cost implications are significant
Other Issues	Supplementation or engineering needed	International harmonization is lacking


Composition Transparency
Complete composition disclosure ensures safety and quality.
Absence of Animal-Derived Components
Avoidance of animal components minimizes risks.
Batch-to-Batch Consistency
Consistent production lots maintain product reliability.
Risk of Adventitious Agents
Testing ensures freedom from harmful agents.
GMP Compliance
GMP compliance ensures traceability and contamination control.
Validation and Comparability Studies
Studies prove product identity and safety unchanged.
Regulatory Acceptance of Serum-Free Media

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NuSera™

Advanced Serum Alternative

- Serum replacement solution for both anchorage and suspension-dependent cell cultures.
- Ensures remarkable batch-to-batch consistency and reproducibility, eliminating the need for cell line adaptation.
- Performance equivalent to that of 10% FBS with 30% reduction in cost.
- Supports more ethical research.

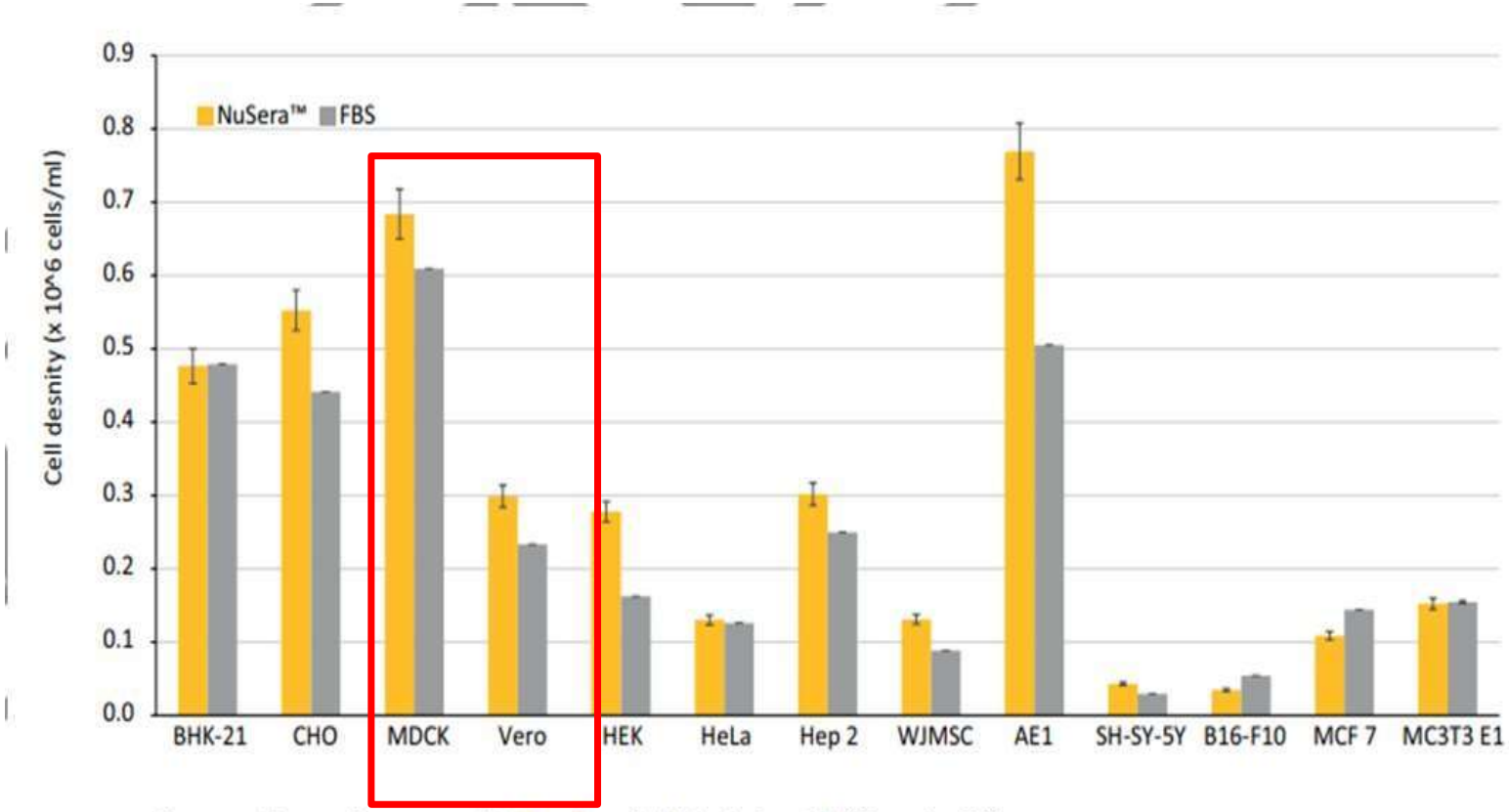
Why NuSera

- **One Bottle of NuSera Saves Two Fetuses**
- Low protein content: facilitates the downstream processing
- Lot to lot consistency
- Compatible with all the basic cell culture media
- Free of biological variability
- No pre-screening & no batch reservation required

Validation study data from Korea

Research Objective

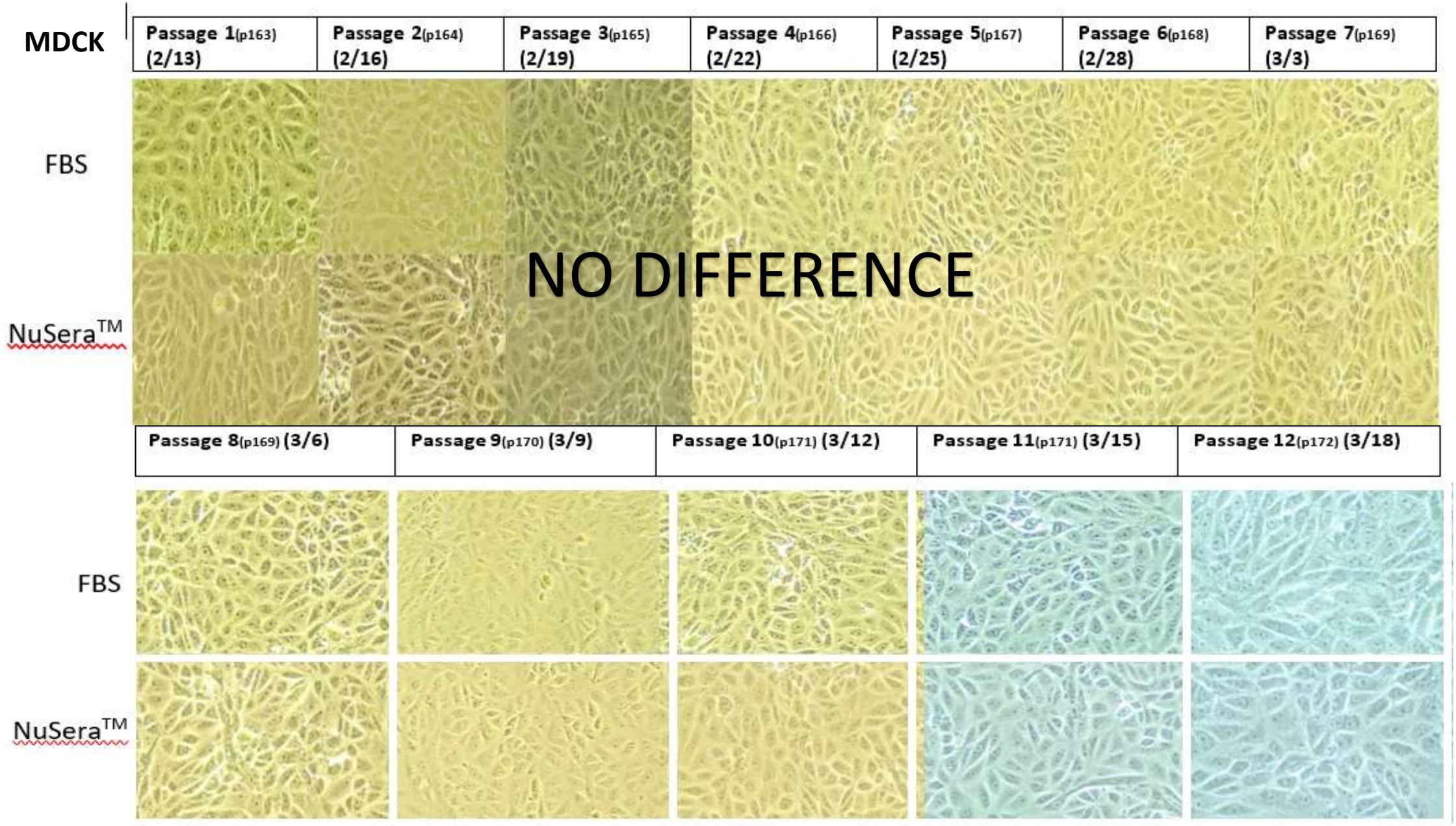
NuSera™ (TCL280) is an artificial FBS alternative developed by HiMedia. This solution aims to replace animal-derived Fetal Bovine Serum (FBS) used in cell culture. The primary objective of the current study was to assess the potential of NuSera™ to replace conventional FBS (SERENA) currently used in laboratories.

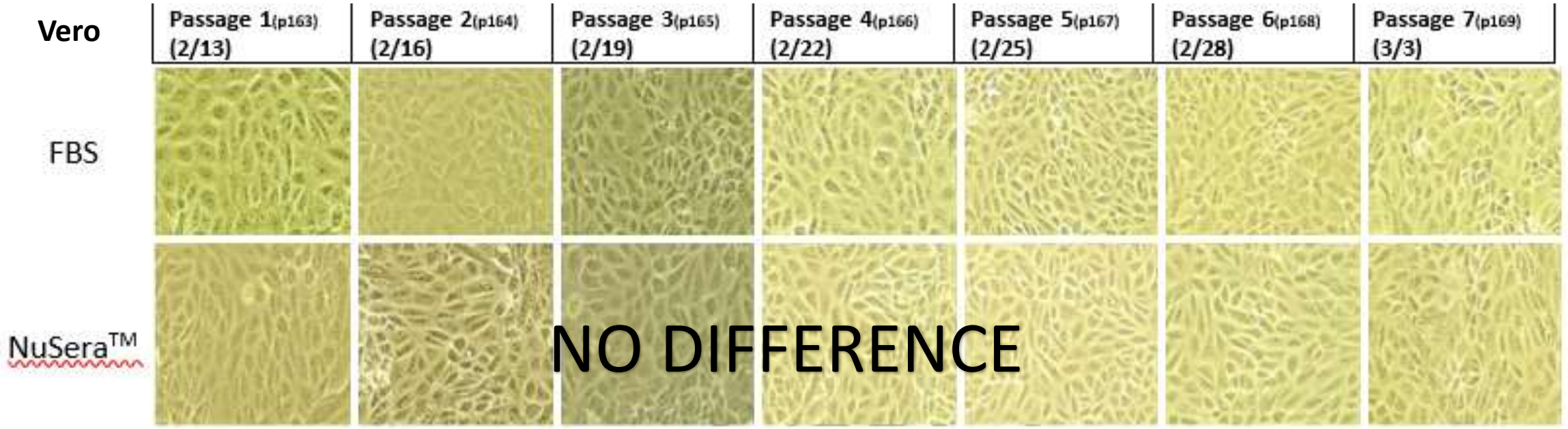


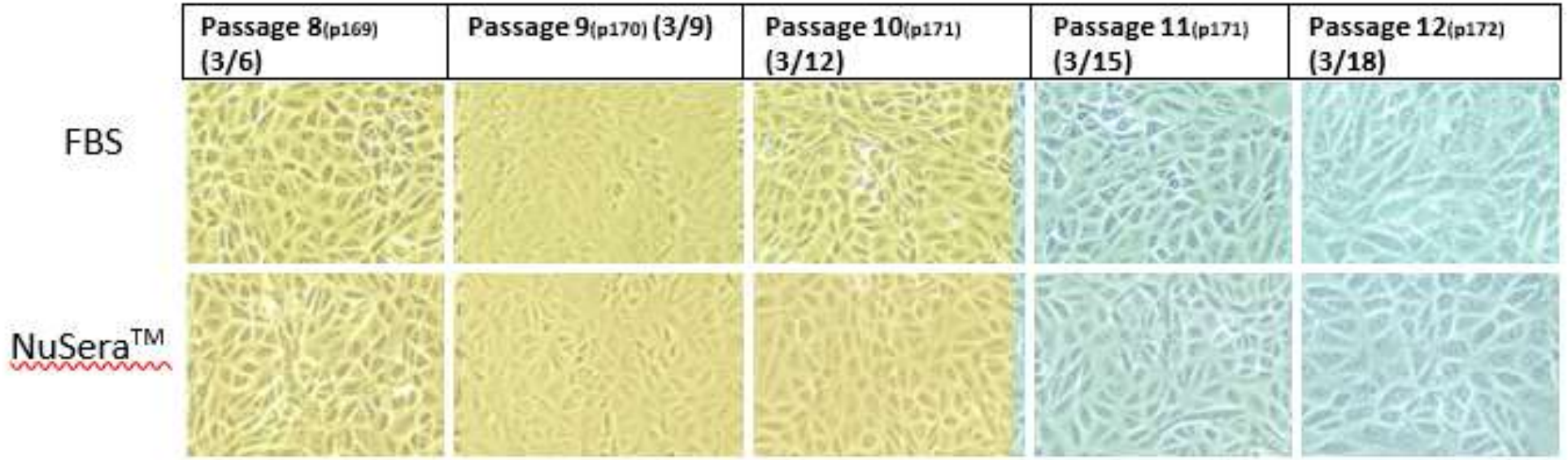
Comparative performance of NuSera™ and FBS tested on 13 different cell lines

Each cell line was seeded in 96 well plates at a fixed cell density and the plates were incubated at 37°C, 5% CO_2 for 96 hours. Cell density was determined after each 24 hours using an automated multimode imaging reader Cytation 5.

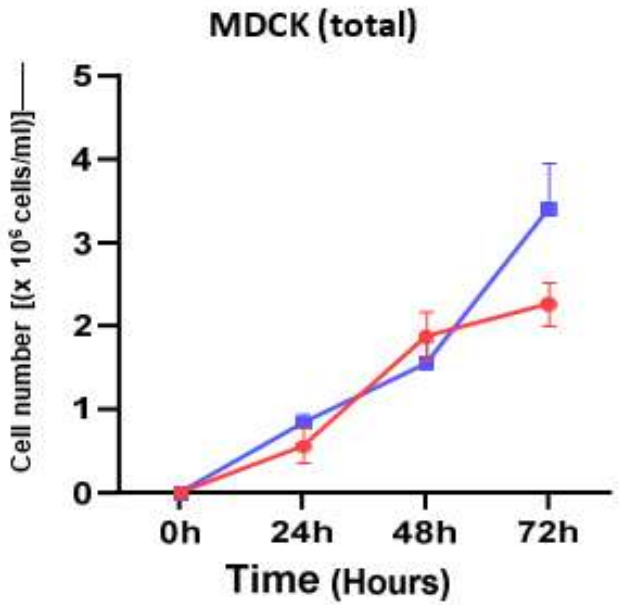
Cell morphology

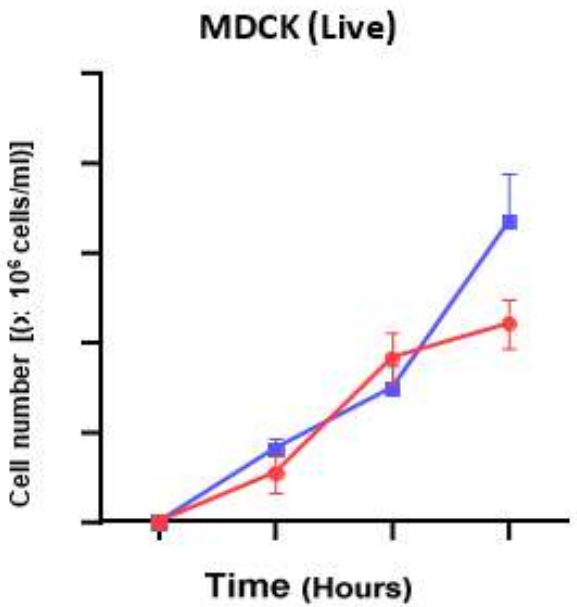



Vero
Passage 1(p163) (2/13)
Passage 2(p164) (2/16)
Passage 3(p165) (2/19)
Passage 4(p166) (2/22)
Passage 5(p167) (2/25)
Passage 6(p168) (2/28)
Passage 7(p169) (3/3)
FBS
NuSera™
NO DIFFERENCE

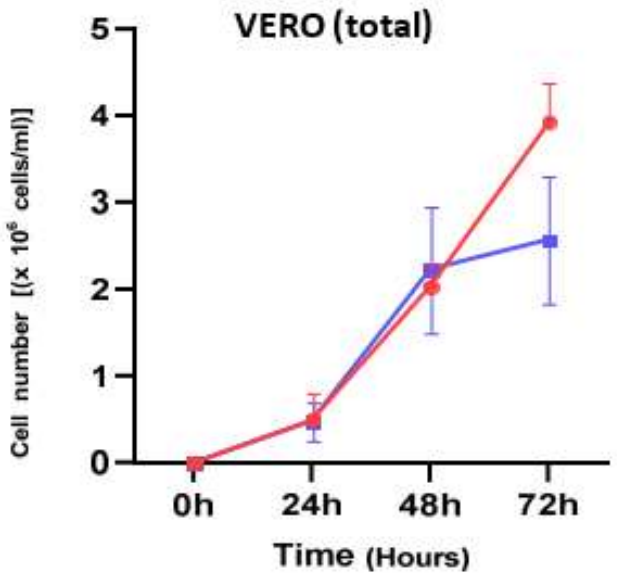

Passage 8(p169) (3/6)
Passage 9(p170) (3/9)
Passage 10(p171) (3/12)
Passage 11(p171) (3/15)
Passage 12(p172) (3/18)
FBS
NuSera™

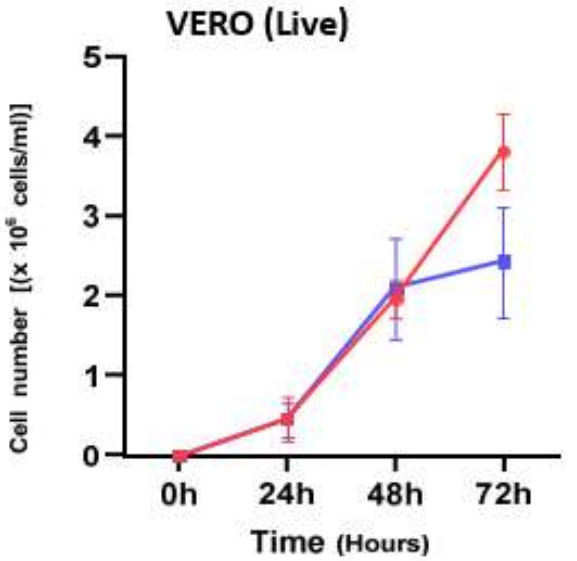
Cell growth and viability





NO DIFFERENCE





*P<0.05
*MDCK P value; 0.4568

MDCK Cell Viability

Time point (hours)	FBS (%)	NuSera™ (%)
24	97.7	97.3
48	97.9	96.2
72	97.9	98.2

Vero cell Viability

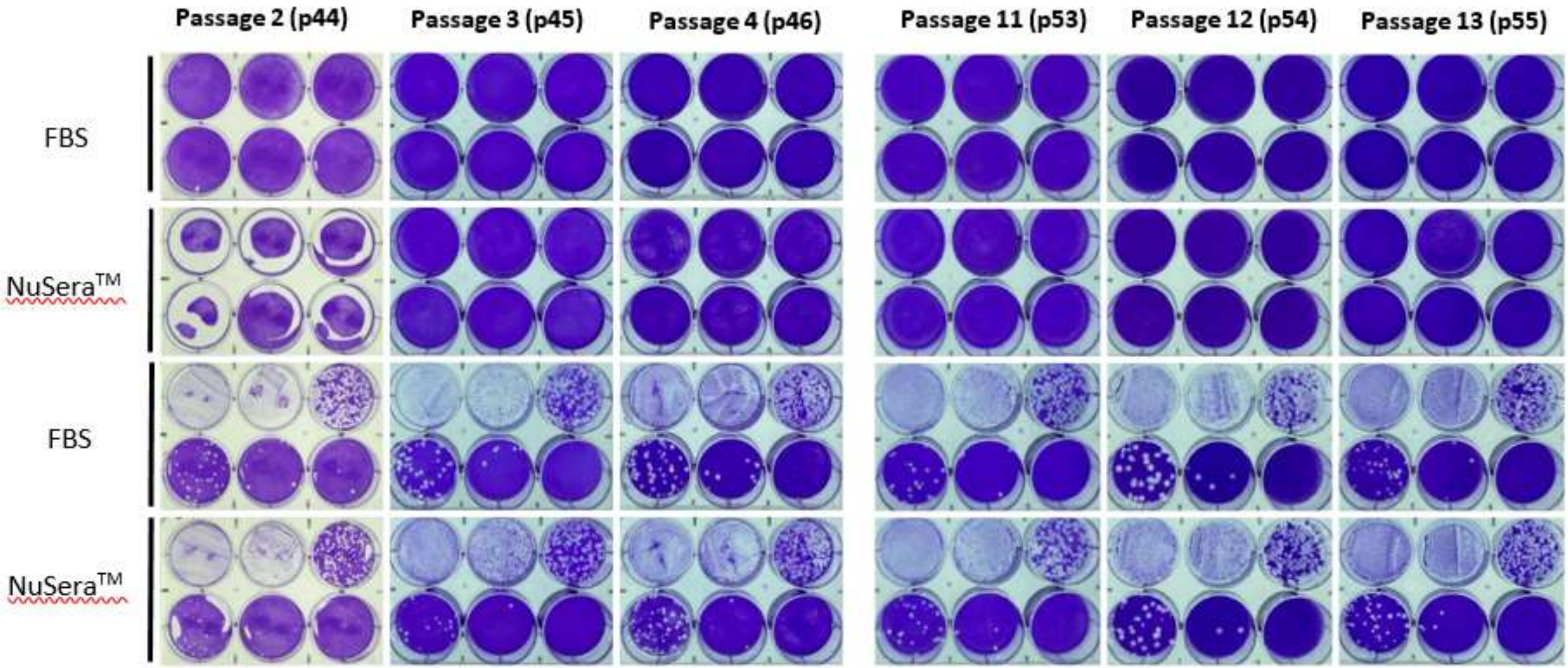
Time point (hours)	FBS (%)	NuSera™ (%)
24	94.8	95.7
48	96.9	95.2
72	97.1	95.1

NO DIFFERENCE

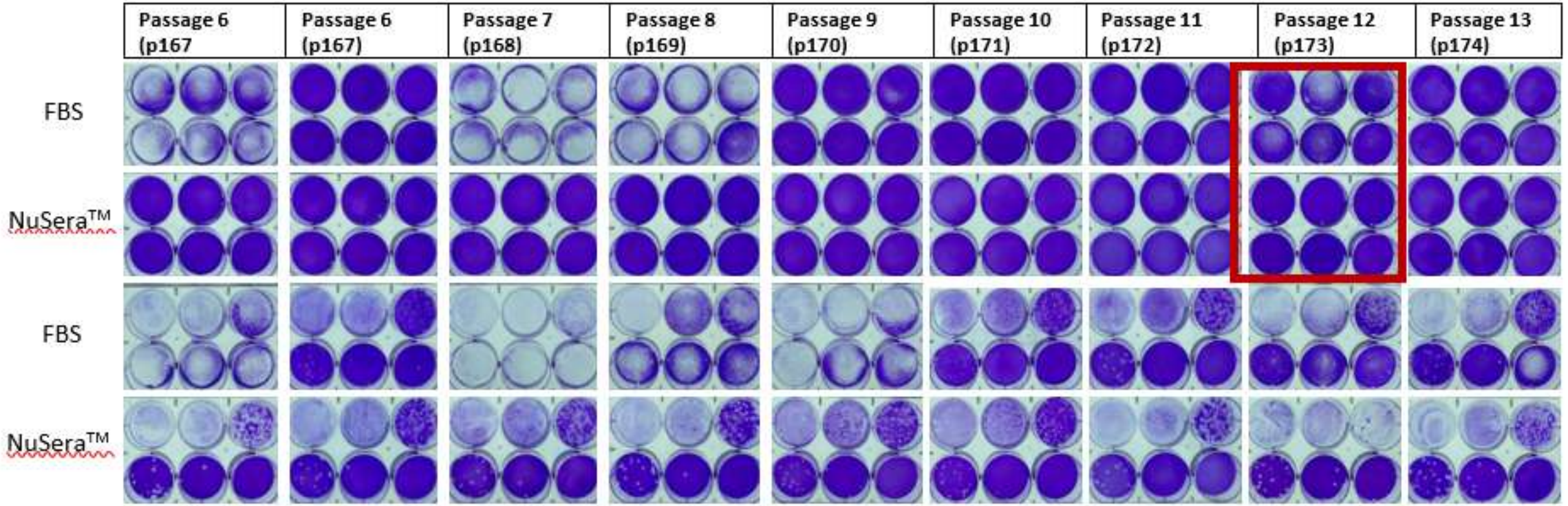
Plaque assay

MDCK

NO SIGNIFICANT DIFFERENCE



VERO

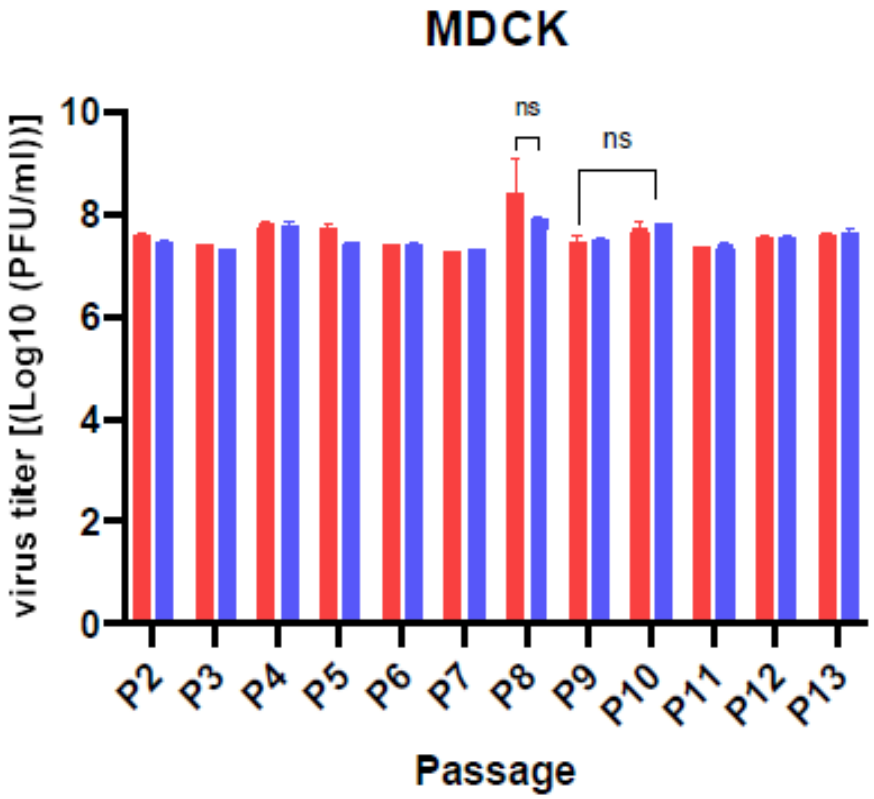


Result:

- In Vero, there was no difference in plaque morphology and titer between FBS and Nusera.
- During long-term subculture, cell loss was observed to the extent that the titer could not be confirmed in some passages of the group using conventional FBS, but it did not occur in cells using Nusera.

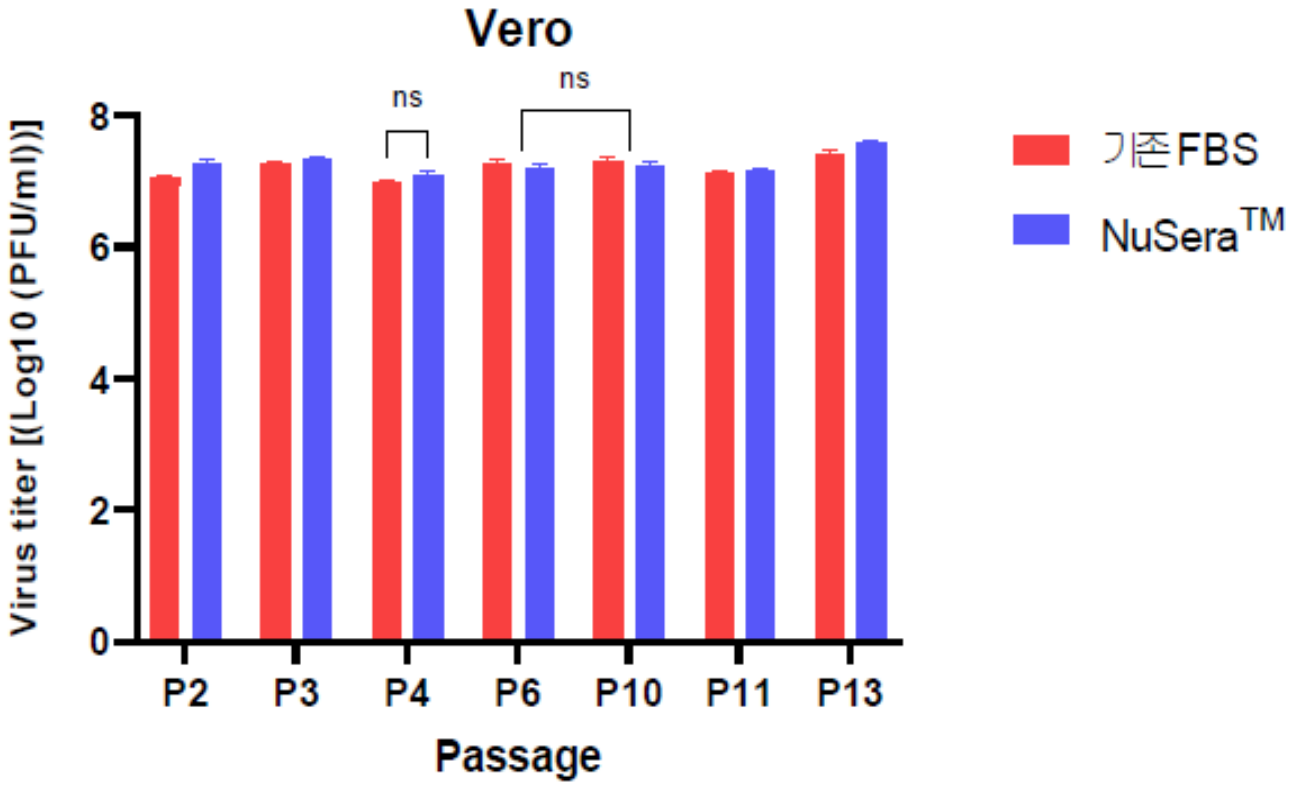
  →The frequency of cell shedding was 5 (41.7%) out of 12 experiments in the FBS group and 0 (0%) in the NuSera group

Titre values



*Definition of statistical significance P<0.05

*P value = 0.2023



*Definition of statistical significance P<0.05

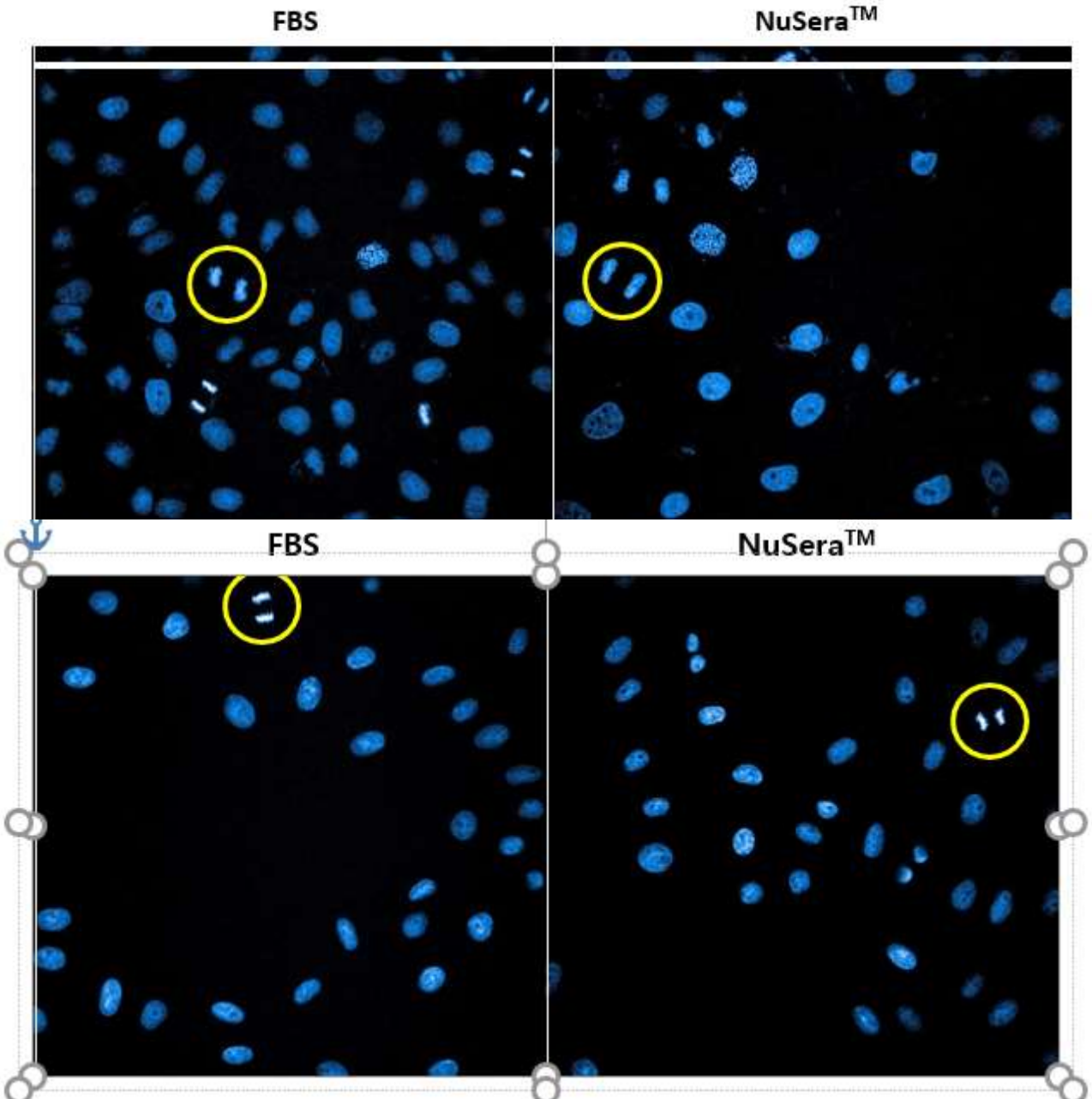
*P value = 0.1039

Result: There was no difference in titer between FBS and **NuSera™** between passages.

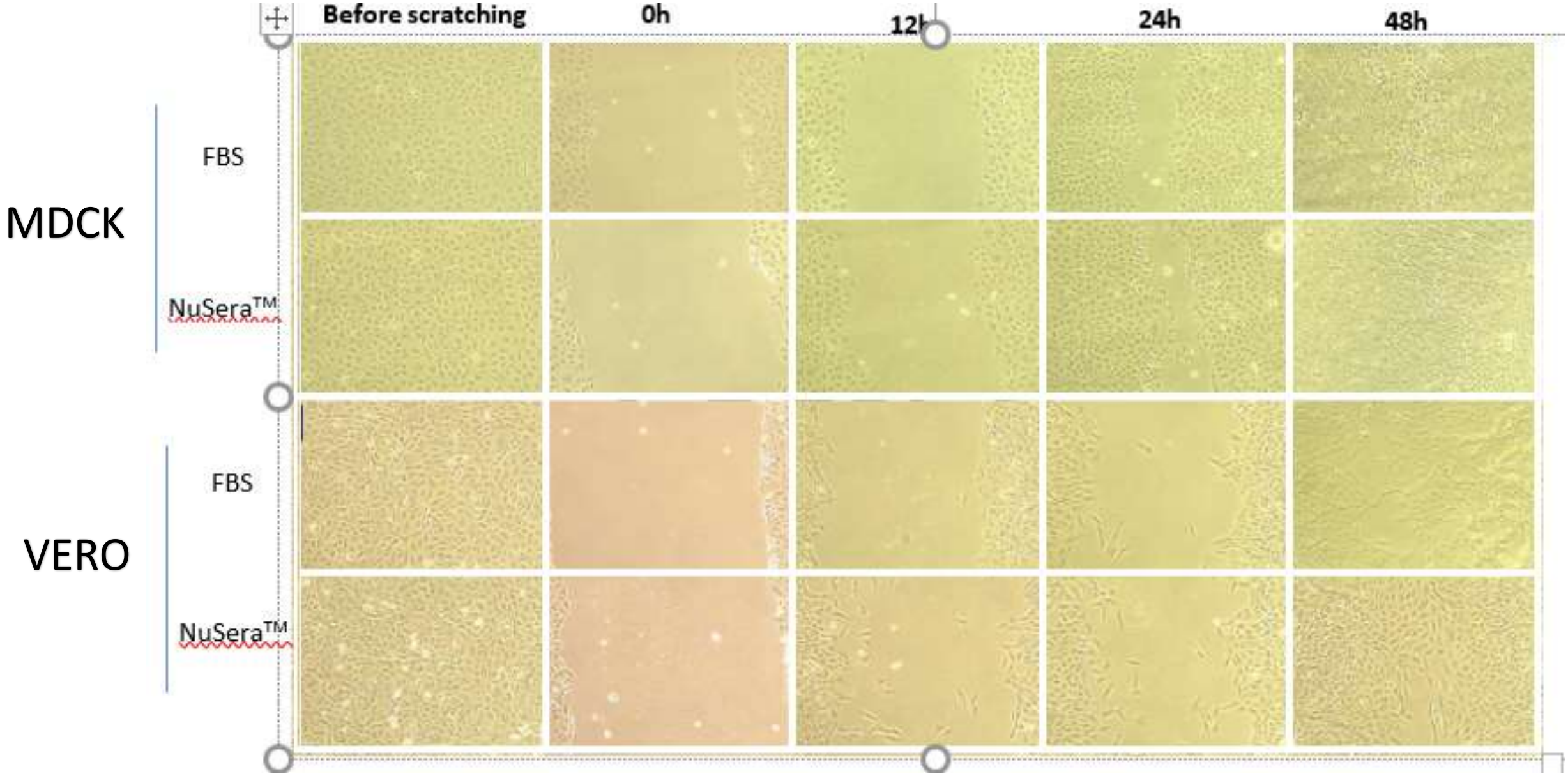
Nuclear staining

MDCK

VERO



Wound healing



HiVeg™ Media

Plant-based media, peptones, and hydrolysates, animal-free. Eliminates contamination risks and ensures consistent growth.

smarT™ Media

Serum-free and xeno-free system for culturing human T cells. Optimized for research and development.

STEMin1™ Media

Defined medium for expanding human mesenchymal stem cells. Serum-free and xeno-free formulation.

Cellin1™ Media

Serum-free culture of Vero, PK-15, MDCK, MDBK cells. Designed for inactivated viral vaccine production.

HEKin1™ Media

Optimized for HEK-cell-based recombinant COVID-19 vaccine production. Supports vaccine manufacturing.

BHKin1™ Media

Formulated for BHK cells in foot-and-mouth disease vaccine production. Supports vaccine manufacturing.

EnVzyme™ Reagents

Animal-component-free alternatives to trypsin for detaching adherent cells. Simplifies cell culture.

HiMedia's Animal Free Products

Conclusion

Embracing a Sustainable & Ethical Future in Cell Culture

◆ The Need is Clear

Traditional serum-based media raises ethical, scientific, and reproducibility concerns.

◆ Animal-Free Media is the Future

- Aligns with 3Rs (Replace, Reduce, Refine) principles
- Reduces variability and risk of contamination
- Enhances reproducibility and standardization

◆ India’s Opportunity

Pioneering the shift can place India at the forefront of ethical biotechnology innovation.

◆ Our Commitment

We support the scientific community with reliable, cost-effective, and regulatory-compliant animal-free solutions.

Acknowledgement

- **PeTA INDIA (DR ANKITA)**
- **VACCINE INNOVATION CENTRE,**

  KOREA UNIVERSITY
- **BUSINESS TEAM – HIMEDIA**
- **RESEARCH TEAM – HI MEDIA**
- **MANAGEMENT – HIMEDIA**
- **TECH AND IT TEAM**


Thank you
everyone!