



# Physiologix™ XF SR

GMP, Xeno-Free Serum Replacement



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## Media Supplement for T Cells and Stem Cells

Physiologix is a GMP, xeno-free media supplement made for T cells and stem cells that replaces FBS or human serum in conventional media formulations.

Many “serum-free” supplements and complete media don’t disclose their origin or contents. Physiologix is extracted from transfusion-grade blood products and brings consistent quality, increases cell performance, and streamlines regulatory as you scale from research and development to the clinic.

### Streamline Regulatory Compliance

GMP and completely xeno-free, Physiologix can simplify your transition from development to commercialization.

### Proven Serum Replacement

Drive desirable CQAs at superior or equivalent levels to FBS and human serum in both T cells and stem cells.

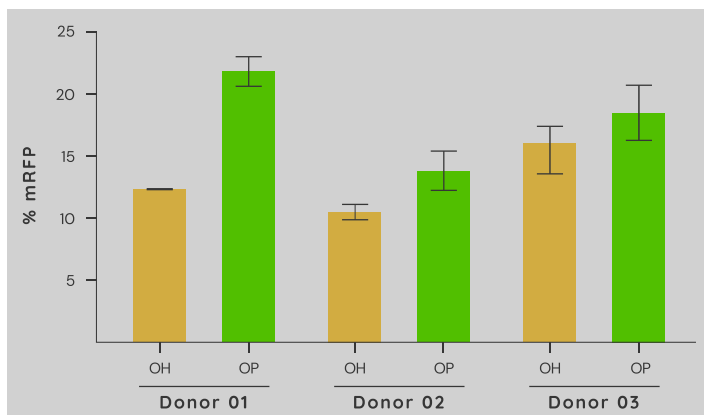
### Consistent Quality

Proprietary manufacturing process and rigorous quality control yield documented consistency across lots.



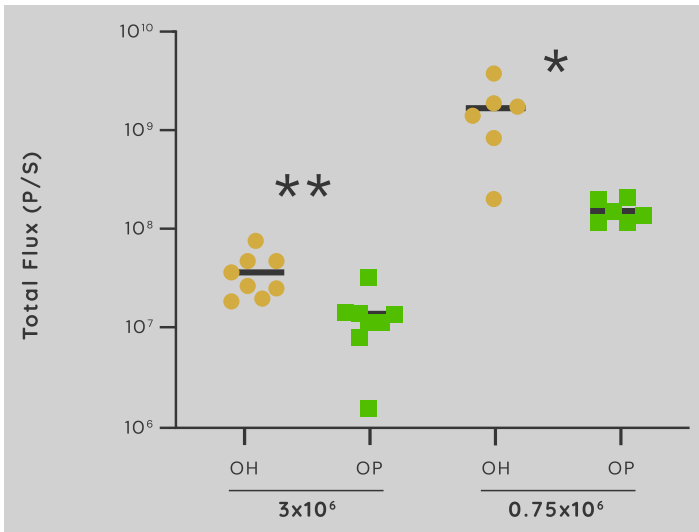
## Take Your Cells Farther

### Enhance Transduction Efficiency



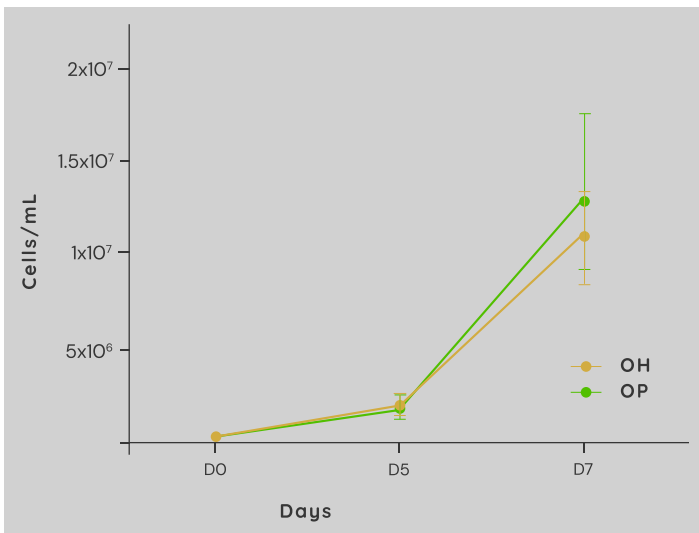
Physiologix promotes viral entry and enhances lentiviral-mediated gene expression. As shown, media supplemented with 2% Physiologix (OP) demonstrate significantly enhanced transduction efficiency measured as % expression of red fluorescent protein (RFP) (compared to 5% human serum (OH)), resulting in a greater proportion of transfected cells and, in turn, a higher potency final product at lower manufacturing costs. Data shown represents 3 donors using Optimizer™ media in a G-Rex® model.

## Greater Efficacy With More CAR+ Cells



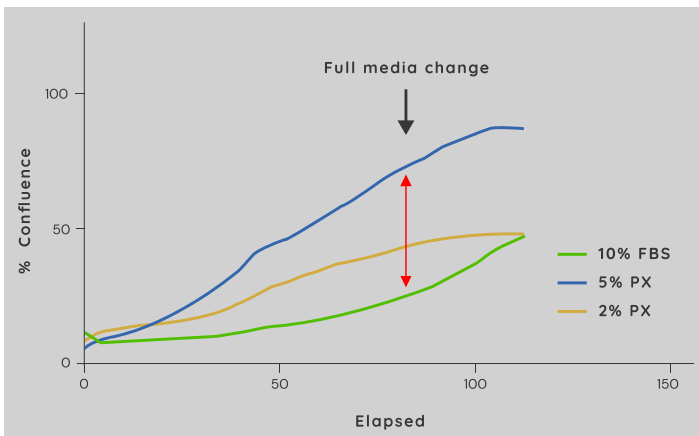
Physiologix can improve the therapeutic potential and *in-vivo* efficacy of CAR T-cell therapy by promoting a more potent antitumor response. In data published by UPenn and Nucleus Biologics, anti-GD2 CAR-T cells expanded in OpTmizer + 2% Physiologix (OP) demonstrated significantly superior tumor killing in an *in-vivo* solid tumor neuroblastoma model when compared to CAR-T cells grown in OpTmizer + 5% human serum (OH). Data shows quantification of tumor burden in total flux (photons/second) by bioluminescence imaging on days 15 ( $3 \times 10^6$  CAR-T cell dose) and 19 ( $0.75 \times 10^6$  CAR-T cell dose).

## Maintain Cell Health and Desirable Characteristics



Physiologix maintains cell health, viability, and desired phenotypes equivalent to human serum. Media supplemented with 2% Physiologix (OP) in a 7-day analysis in a G-Rex model demonstrated strong proliferation and population doubling (data not shown) when compared to media + 5% human serum (OH). Additionally, desired naïve and central memory phenotypes are preferentially maintained as with human serum. Data shown represents average of 3 donors  $\pm$ SD using Optimizer media.

## Applicability in Stem Cell Models



Physiologix can support proliferation in other cell models such as mesenchymal stem cells (MSCs). DMEM/F-12 media supplemented with Physiologix (PX) have increased cell proliferation rates at earlier time points (compared to FBS) resulting in shortened protocols, which could reduce labor and consumable costs, lower energy consumption, and accelerate therapy delivery without affecting the quality of the cells.

# Physiologix™ Xeno-Free Serum Replacement Ordering Information

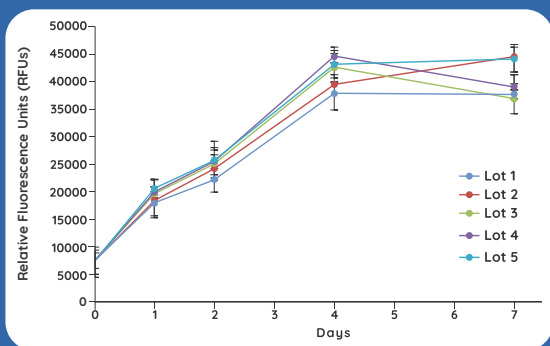
Catalog Number	Product Name	Size	Price
320	Physiologix™ XF SR	10 mL	\$104
322	Physiologix™ XF SR	100 mL	\$1,040

## Product Specifications

<b>Classification</b>	Xeno-free, serum-free	<b>Reactivity</b>	None Known
<b>Source</b>	Transfusion-grade human material	<b>Stability</b>	Stable under normal conditions
<b>Infectious Disease Screening</b>	Not detected	<b>Shipping Conditions</b>	Dry ice
<b>Quality</b>	GMP	<b>Storage Temperature</b>	≤ -80°C
<b>Sterility</b>	Sterile	<b>Shelf Life</b>	2 years
<b>Endotoxin</b>	≤ 0.25 EU/mL	<b>Thawing</b>	Preferred method of thaw is 37°C water bath. Limit freeze thaw cycles of aliquots to less than three. <i>Details available upon request.</i>
<b>Mycoplasma</b>	Negative	<b>Research Category</b>	T cell research, stem cell research
<b>pH</b>	6 to 8		

## Lot-to-Lot Consistency

Functional performance across lots is consistent. Our proprietary manufacturing controls ensures reproducibility of product.



Proliferation of bone marrow MSCs

### Our Commitment to Quality

- Certificate of Compliance or Certificate of Analysis provided at delivery
- Manufactured in a GMP environment
- Manufacturing practices certified to ISO 13485:2016

\*"cGMP/GMP Grade" and "cGMP/GMP" are branding terms Nucleus Biologics uses to describe products manufactured or finished at the Nucleus Biologics San Diego facility. The San Diego facility was designed to manufacture products under more rigorous infrastructure and process controls to achieve more stringent product specifications and customer requirements. Products manufactured at the Nucleus Biologics San Diego facility are manufactured in compliance with ISO 13485 quality management system standards. However, at this time, Nucleus Biologics does not manufacture or sell products known as Active Pharmaceutical Ingredients (APIs) and/or Medical Devices, nor is Nucleus Biologics registered with or inspected to cGMP guidelines by the FDA.

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