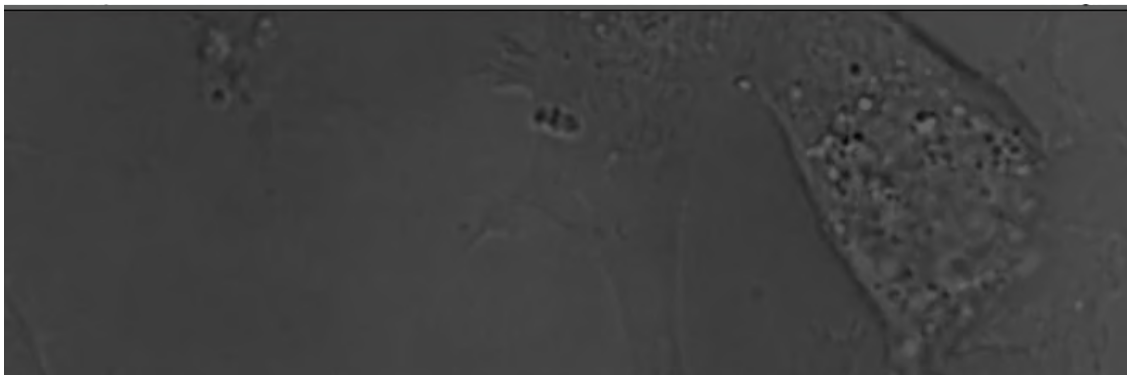
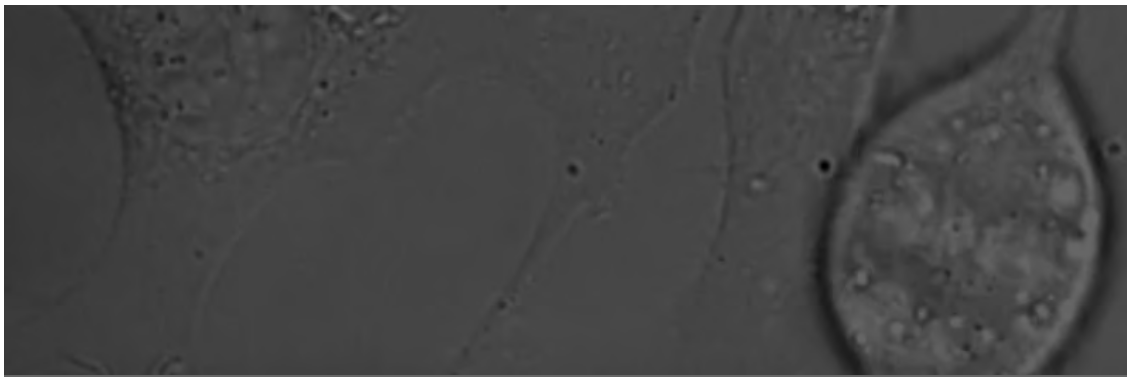
WJ-PURE

www.bioxstem.com



WHERE RESEARCH AND DEVELOPMENT CREATE RESPONSIBLE MANUFACTURING

- We believe research is invaluable.
- We engage in peer, physician, and patient collaboration.
- We respect and uphold regulatory guidelines through a proactive culture.
- We establish and follow rigorous protocols and procedures to ensure high quality products, safety, and consistency.
- We prove our processes with above industry standard testing by third party labs.



PRODUCTS

Vitti Labs specializes in manufacturing minimally manipulated, bio-ethical, cellular and decellularized products for homologous use in clinical settings or cosmetic applications.

BioXstem

WJ-PURE

TABLE OF CONTENTS

WJ-PURE PRODUCT INFORMATION

p.3

SOURCING & TESTING GUIDELINES

p.4

VALIDATION & PRODUCT CHARACTERIZATION

p.5, 6, 7, 8, 9, 10, 11

CONTACT

p.12

BioXstem

WJ-PURE

WHARTON'S JELLY

TISSUE ALLOGRAFT

PRODUCT HIGHLIGHTS

- Minimally Manipulated
- Absent of DMSO
- Absent of Harmful Enzymes
- Concentrated Cytokines, Peptides, and Growth Factors.

PRODUCT SIZE

- WJ-PURE 1mL

PRODUCT TRACKING

- Go to: www.bioxstem.com
- Select the "Tracking" button at the top of the website Complete Form
-

SHIPPING + STORING

- Products are stored in -80° freezers then shipped on dry ice
- Keep frozen in -20° up to 60 days or -80° conditions until use or expiration.

WJ-PURE

WJ-PURE is a minimally manipulated DMSO free Wharton's Jelly allograft for homologous use in clinical settings. Our proprietary process is absent of harmful enzymes and chemicals to preserve structural integrity and potency. WJ-PURE is rich in Medicinal Signaling Cells (MSC's), cytokines, growth factors, natural nano-particles, and proteins which stimulate healing and repair the body.

REGULATIONS

Vitti Labs' WJ-PURE contains live cells but does not claim that it is dependent on the metabolic activity of living cells for its primary function. WJ-PURE contains tissue components such as hyaluronan, elastin, collagen fibers, growth factors, cytokines, and nanoparticles which stimulate cushioning agents, therefore, WJ-PURE is not reliant on the presence or the metabolism of the cells in this allograft to create a therapeutic benefit. WJ-PURE does meet the criteria under 1271.3(d) as an HCT/P, and therefore is regulated under 21 CFR 1271 and Section 361 of the PHS Act.

Vitti Labs is an FDA registered tissue bank. We comply with FDA (Federal Drug Administration) regulations. Additionally, we implement AATB (American Association of Tissue Banking) standards, follow GTP (Good Tissue Practices), GMP (Good Manufacturing Guidelines), and WHO (World Health Organization) protocols and procedures.

SOURCING & TESTING GUIDELINES

SOURCING

Vitti Labs only accepts bio-ethically donated birth tissue from healthy consenting mothers who have passed a comprehensive medical background check, blood screenings, and are full-term, live, C-section births in the United States. In addition, we only work with tissue procurement organizations within the United States who use collection techniques that follow the AATB guidelines, prioritizing the health and safety of the mother and baby above procurement. We do this to have a 100% FDA and AATB compliant supply chain, validated sterility, and the highest quality procurement.

TESTING, STERILITY AND SAFTEY

20% of every lot manufactured is sent for sterility and endotoxin testing by a 3rd party laboratory.

1. USP 71 Sterility Guidelines (All fungus, Mold, Yeast, Bacteria) in accordance with AATB and FDA
2. Endotoxin guidelines in accordance with AATB and FDA
3. Viruses, blood, and tissue borne pathogens in accordance with AATB and FDA
   - Additional Testing: E.Coli, Clostridium Species, Pseudomonas Aeruginosa, Bacillus Subtilis, Aspergillus Brasiliensis, fungus identified to the genus level, yeast identified to species level and MRSA / VRE Isolate testing.
4. All donors are tested for blood borne pathogens for HIV, HBsAg, HCV, HBc Total, HTLV I/II, RPR, HIV/HCV/HBV Ultrio, WNV NAT, CMV Ab, Zika NAT, Lyme Disease and Candida.
5. Each of our processes has multiple safety and validation testing steps to ensure the quality and consistency of each lot. In addition, all of our products are characterized by third party laboratories bi-annually for full process analysis and potency.

WJ-PURE

REPORTS AND ANALYSIS

Summary of Results:

Assay	Criteria
Growth-Cell Density	>30,000 cells/cm^2

GROWTH-CELL DENSITY

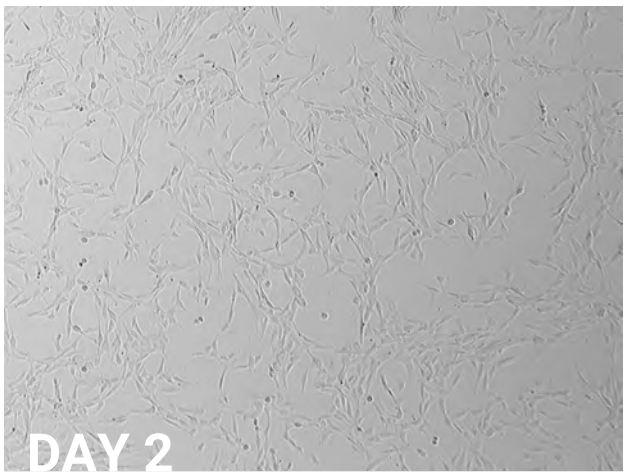


Table 1. CFU and Expansion of the cells

Cells were seeded at different densities and CFU and expansion was calculated in duplicate.

Plating Cell Density (cells/cm ^{2})	Mean CFU	Fold Increase
10	21	48.1
50	71	52.8
100	99	49.9

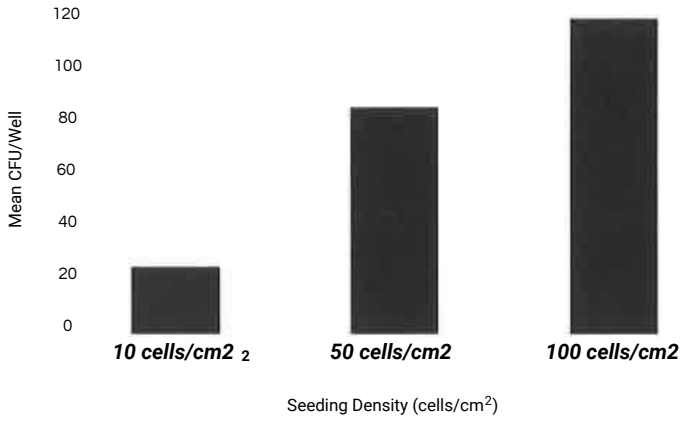


Figure 1. Colony Forming Units

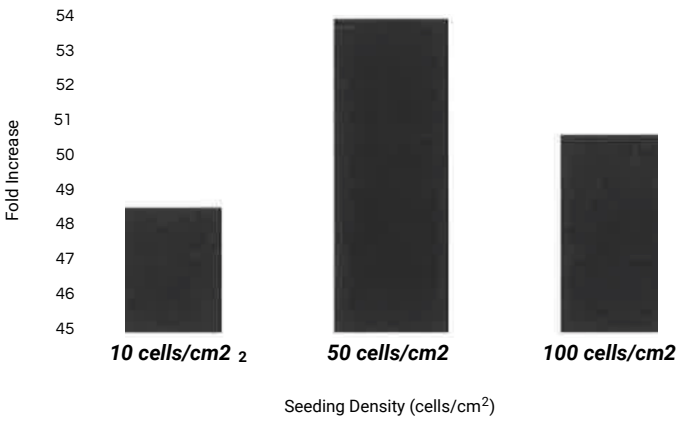


Figure 2. CFU Cell Fold Increase

WJ-PURE

SURFACE MARKER ANALYSIS

Table 2. Summary of Minimal Criteria* to Identify MSC

Phenotype	Positive (>95%+)	Negative (<2%+)
	CD105 CD73 CD90	CD45 CD34 CD79 HLA-DR

**Proposed by International Society for Cellular Therapy (ISCT)*

The cells were stained with anti-CD-73, CD90, CD105, CD34, and CD45, for characterization by flow cytometry.

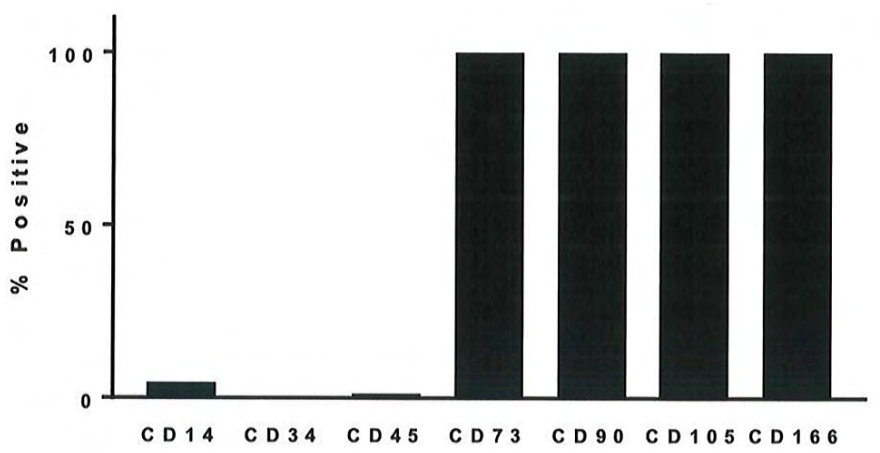
Table 3. Summary of Specific Marker Expression of the Test Sample

Cell Marker	% Positive
CD90	99.5%
CD105	99.3%
CD73	99.7%
CD45	1.6%
CD34	0.1%
CD14	3.1%
CD166	99.2%
CD79	0.0%
HLA-DR	0.0%

WJ-PURE

SURFACE MARKER ANALYSIS

Flow Cytometry Analysis:



- Analysis is based on viable single cells of a co-localized population determined on the bivariate plots.
- Histograms are shown to indicate distribution of expression for the sample population.
- Flow cytometry analysis conducted in house. Reference Supplemental Figures for gating.
- The percentage of positive cells was determined to be:
    - 3.1% CD14, 0.2% CD34, 1.4% CD45, 99.9% CD73, 100.% CD90, 100.% CD105, and 100.% CD166

WJ-PURE

ANGIOGENIC CYTOKINE SECRETION REPORT

Results

Detectable levels for Angiogenic Cytokine Secretion Report as follows.

Table 1. Summary of Angiogenic Cytokine Secretion Report

Cytokine Secretion	Mean
IIL-8ra	1050.12
FGF	86.22
EGF	59.56
VEGF	65.41
PGDF	193.20
SCF	48.52
TIMP-1	348,808.68
TIMP-2	16,154.64

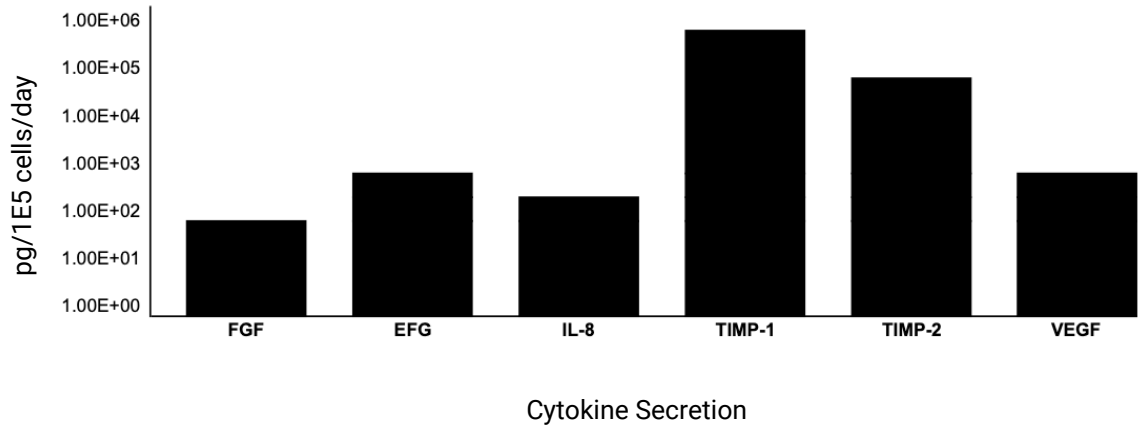


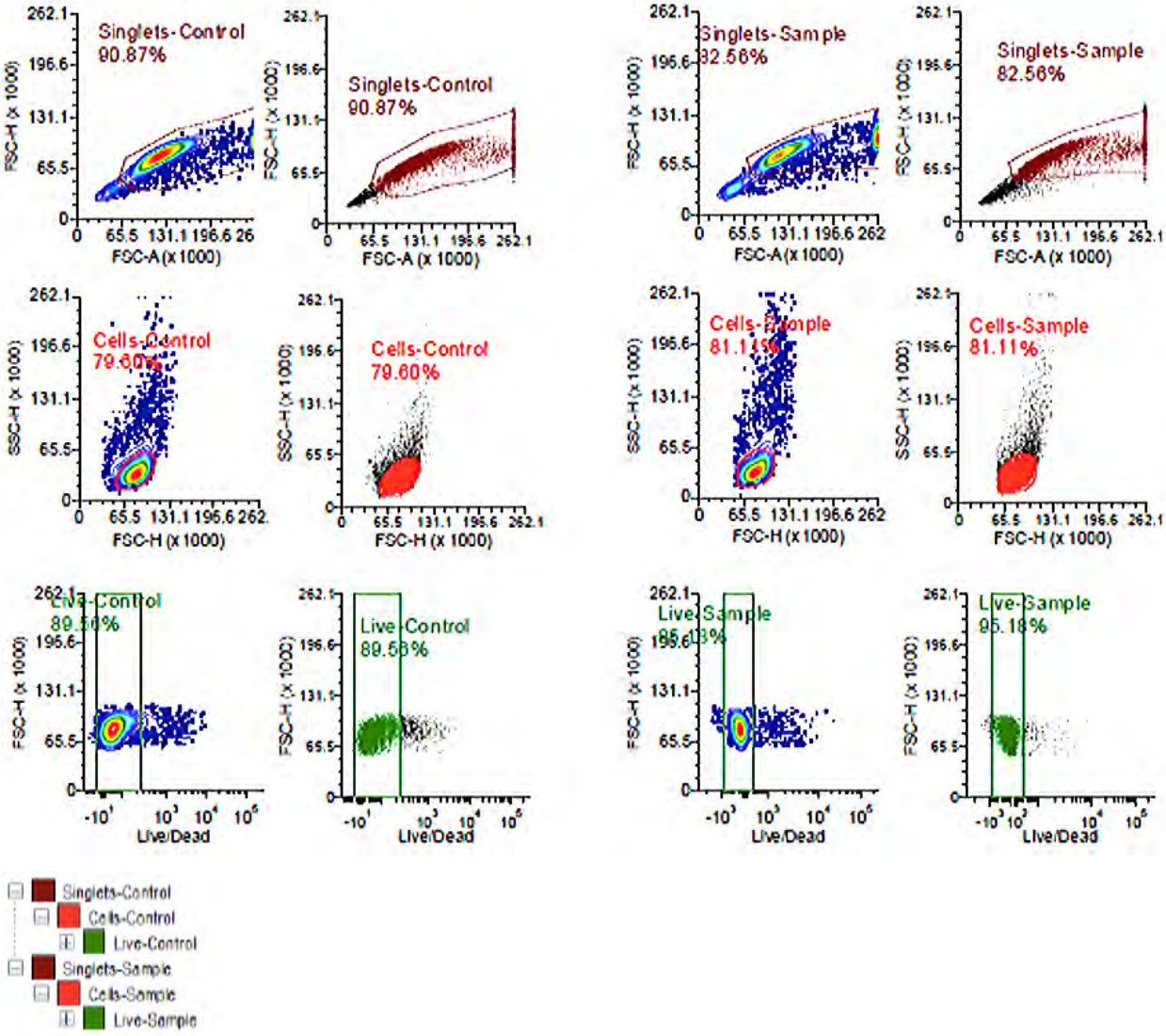
Figure 1. Angiogenic Cytokine Secretion

WJ-PURE

SUPPLEMENTAL FIGURE

CONTROL

SAMPLE



WJ-PURE

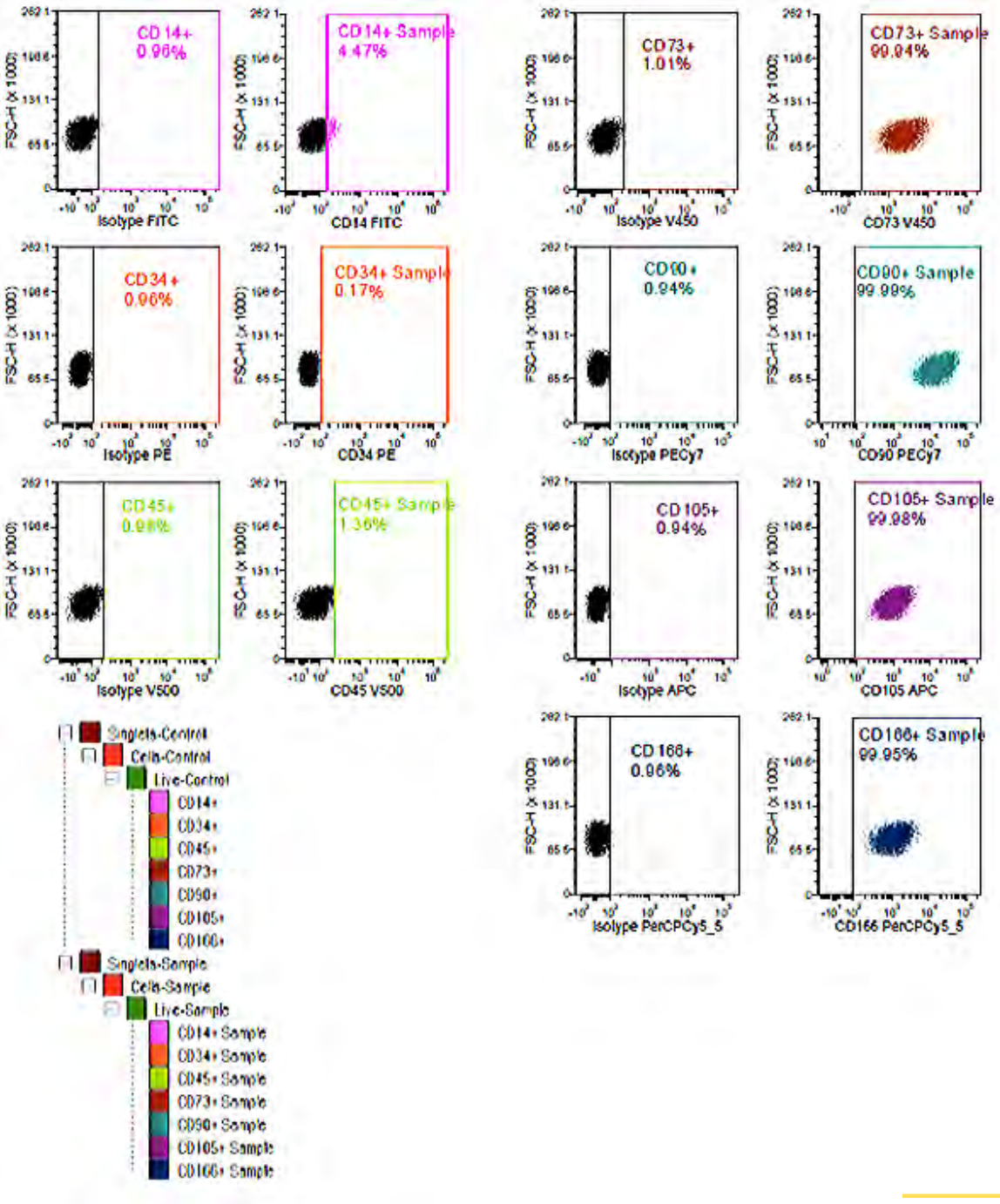
SUPPLEMENTAL FIGURE

Negative Markers

CONTROL **SAMPLE**

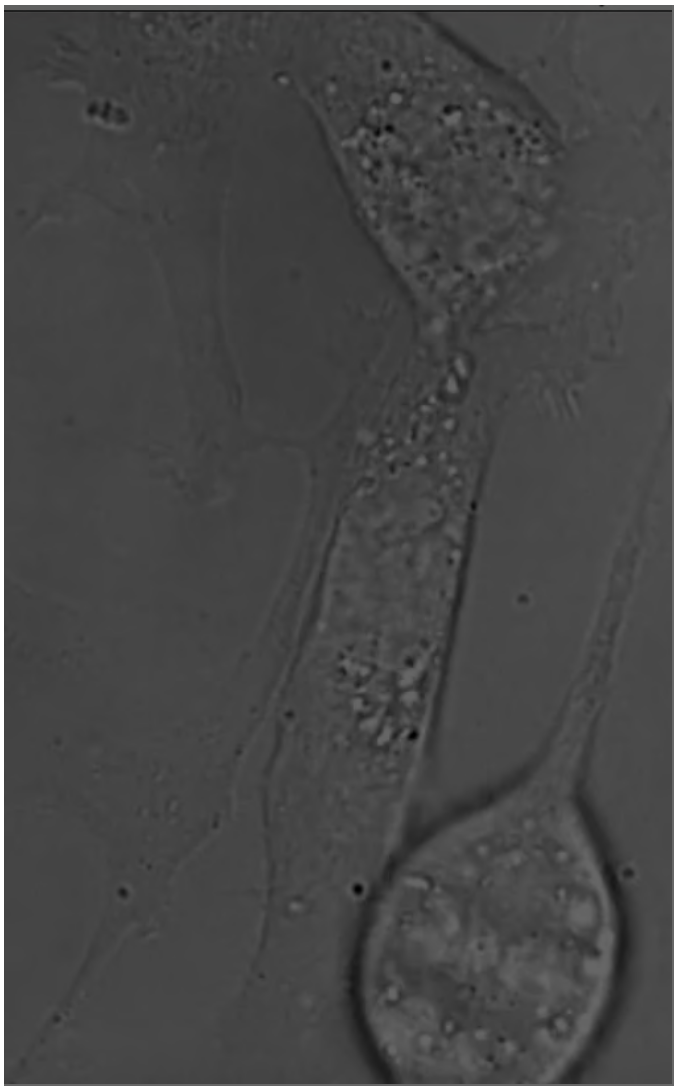
Positive Markers

CONTROL **SAMPLE**



CONTACT

BIOXSTEM



WEBSITE

www.bioxstem.com

EMAIL

info@bioxstem.com

PHONE

224.401.9157

ORDER

www.bioxstem.com

& contact your rep