# EV-OPTI

# WWW.VITTILABS.COM

# **PRODUCT OPTIONS**

EV-OPTI 0.5mL - 10 Day Supply

## PLACING ORDERS

For more information call: (443)-504-7143 sales@advantagebiologics.com

#### **PRODUCT TRACKING**

- Go to: www.vittilabs.com
- Select the "Product Tracking Form" button at the bottom of the website
- Complete Form

# SHIPPING + STORING

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

# WHERE RESEARCH

AND DEVELOPMENT

CREATE RESPONSIBLE

# MANUFACTURING



#### **EV-OPTI** LUBRICATING GROWTH FACTOR DROPS

EV-OPTI DROPS consist of a placental derived matrix providing growth factors, cytokines, trophoblasts, nanoparticles, and nucleic acids. They also contain a lubricant made from high-molecular weighted hyaluronic acid and antimicrobials along with potent concentrations of anti-inflammatory properties that promote wound healing and anti-scarring effects on the surface of the eye.

## VITTI LABS VALUES + PRACTICES

- 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.

## 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 + VALIDATION**

20% of every lot manufactured is sent for sterility and endotoxin testing by a 3rd party laboratory. In addition, Vitti Labs requires biannual Characterization Reports produced by external laboratories for transparency and validation.

# REGULATIONS

Vitti Labs' EV-OPTI contains live cells but does not claim that it is dependent on the metabolic activity of living cells for its primary function. EV-OPTI contains tissue components such as hyaluronan, elastin, collagen fibers, growth factors, cytokines, and nanoparticles which stimulate cushioning agents, therefore, it is not reliant on the presence nor on the metabolism of the cells in this allograft to create a therapeutic benefit. EV-OPTI 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.