



## Instructions for the Use of LifeGlobal Protein Supplement as a Supplement for Human ART Media

### I. General Information

**Intended Use:**  LifeGlobal Protein Supplement is intended for use as a protein supplement for culture media and other solutions that are used in assisted reproductive procedures.

**Composition:**  LifeGlobal Protein Supplement contains a total protein concentration of 50 mg/ml, comprising 44 mg/ml human serum albumin and 6 mg/ml human  $\alpha$ - and  $\beta$ -globulins from therapeutic-grade source material, in a sterile saline solution.

**Storage:** Store at 2-8°C and protected from light.

**Shelf Life:** No more than one (1) year from the date of production when stored unopened at 2–8°C and protected from light. Do not use the product for longer than 30 days after opening the container.


#### Quality Control Specifications



	<u>Specification</u>
<b>Physiochemical tests:</b>	
• pH	7.2-7.4
• Osmolality	250-270 mOsM
<b>Biological Tests</b>	
• LAL Endotoxin	≤1.0 EU/ml
• Sterility	Sterile
• 1-cell Mouse Embryo Assay (% blastocysts at 96h of culture)	≥ 80%

### II. Disclaimer

The procedures described below have been found to be effective for protein supplementation of culture and handling media for human ART. Every laboratory must define and optimize its own procedures.

### III. Protein Replacement Supplementation

Twenty-four hours prior to the use of media for embryo culture or handling, supplement the media with  LifeGlobal Protein Supplement as follows:

- For oocyte retrieval, handling and culture media, sperm handling media, and fertilization media, mix 9.4 ml of medium with 0.6 ml of  LifeGlobal Protein Supplement in an appropriate embryo-safe tube or other container. This will produce a final total protein concentration of 3 mg/ml in the supplemented medium.
- For embryo handling and culture media, mix 9.0 ml of medium with 1.0 ml of  LifeGlobal Protein Supplement in an appropriate embryo-safe tube or other container. This will produce a final total protein concentration of 5 mg/ml in the supplemented medium.

#### IV. Precautions and Warnings

1. Not to be used for injection
2. Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
3. Do not use the product if:
  - the product packaging appears damaged or if the seal is broken
  - the expiry date has been exceeded
  - the product becomes discolored, cloudy, or shows evidence of particulate matter
4. Record on the label: Date Received and Date Opened
5. To avoid problems with contamination, practice aseptic techniques and discard minimal amounts of excess medium remaining in the bottle.
6. Once the bottle is opened, store the product tightly capped at 2-8°C and protected from light. Do not use the product for longer than 30 days after opening the container.

The human serum albumin and globulins used in the preparation of this product have been heated at 60°C for ten hours.

**Caution:** All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBc, HCV, and HTLV I/II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.