



## Certification of Analysis for HSA

(Catalogue Numbers: GHSA-125)

**Lot Number:** GHSA-160223E  
**Expiry Date:** 2017-02-22  
 yyyy-mm-dd  
**Production Date:** 2016-02-23  
 yyyy-mm-dd

**Indications for Use:** For use as a protein supplement for culture media and other solutions that are used in assisted reproductive procedures.

**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

This product contains human serum albumin, a derivative of human blood. The human serum albumin used in the preparation of this product has 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.

Each vial of HSA is intended for **single use only**. Discard any unused product after opening.

**Instructions for Use:** See HSA Instructions for Use.

**Storage Requirements:** Store at 2-8°C and protected from light. When stored unopened at 2-8°C and protected from light, the product is stable until the expiration date shown on the bottle label.

### Raw Materials

Chemicals used by LifeGlobal meet ASC, USP, or NF standards.

We certify that this product has been manufactured according to current Good Manufacturing Practice (cGMP). The quality of this particular batch was tested and evaluated by stringent quality control procedures. On the basis of superior test results, the batch was considered suitable for the use intended.

| Assay (Performed for each batch)             | Specification | Results      |
|--|---------------|--------------|
| <b>Physicochemical Tests</b>                 |               |              |
| pH   | 7.2-7.4       | 7.25         |
| Osmolality                                   | 265-285       | 268          |
| <b>Biological Tests</b>                      |               |              |
| LAL Endotoxin                                | ≤ 1.0 EU/ml   | < 0.06 EU/ml |
| Sterility Test (Bacterial and fungal screen) | PASS          | PASS         |
| <b>Biological Assays</b>                     |               |              |
| 1-cell Mouse Embryo Assay*                   | ≥ 80%         | 97%          |

\*Mouse Embryo Assay tests are performed by an independent laboratory. One-cell B<sub>6</sub>C<sub>3</sub>F<sub>1</sub> X B<sub>6</sub>D<sub>2</sub>F<sub>1</sub> mouse embryos are cultured in embryo-tested culture medium supplemented with HSA for 96 hours. The embryos are then evaluated for development to the expanded blastocyst stage.