



EC REP



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Certification of Analysis for global[®] total[®] for Fertilization w/ HSA

(Catalogue Numbers: HGTF-020, HGTF-050, HGTF-100)

Lot Number: HGTF- 180311U
Expiry Date: 2018-05-20
 yyyy-mm-dd
Production Date: 2018-03-11
 yyyy-mm-dd

Indications for Use: Human oocyte culture and fertilization.

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.

global[®] total[®] for Fertilization w/ HSA contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

Discard unused medium within 7 days of opening. Do not use after expiry date. Devices are not intended for resterilization.

Instructions for Use: See global[®] total[®] for Fertilization w/ HSA Instructions for Use at: www.lifeglobalgroup.com/ifus.shtml

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
Physicochemical Tests		
pH (with 5% CO ₂)	7.2-7.4	7.28
Osmolality	260-270 mOsM	264 mOsM
Biological Tests		
Endotoxin (LAL)	≤ 0.5 EU/ml	< 0.03 EU/ml
Sterility Test (bacterial and fungal screen, SAL 10 ⁻³)	PASS	PASS
Biological Assays		
1-cell Mouse Embryo Assay (% expanded blastocysts at 96 h of culture)	≥ 80%	97 %