



EC REP

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Certification of Analysis for HTF

(Catalogue Numbers: GMHT-100, GMHT-250, GMHT-500)

Lot Number: GMHT-160505C
Expiry Date: 2016-07-14
yyyy-mm-dd
Production Date: 2016-05-05
yyyy-mm-dd

Indications for Use: Culture of cleavage-stage human embryos (Day 1 to Day 3).

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

HTF 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 HTF 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
Physicochemical Tests		
pH (with 5% CO ₂ equilibration)	7.2-7.4	7.30
Osmolality	280-292	285
Biological Tests		
LAL Endotoxin	≤ 0.5 EU/ml	< 0.01 EU/ml
Sterility Test (Bacterial and fungal screen)	PASS	PASS
Biological Assays		
1-cell Mouse Embryo Assay*	≥ 80%	97%

*Mouse Embryo Assay tests are performed by an independent laboratory. One-cell B₆C₃F₁ X B₆D₂F₁ mouse embryos are cultured in individual lots of HTF supplemented with 4 mg/ml embryo-tested BSA for 96 hours. The embryos are then evaluated for development to the expanded blastocyst stage.