



EC REP



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## Certification of Analysis for HTF w/ HEPES

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

**Lot Number:** GMHH-160407C  
**Expiry Date:** 2016-06-16  
yyyy-mm-dd  
**Production Date:** 2016-04-07  
yyyy-mm-dd

**Indications for Use:** HTF w/ HEPES is designed to be used for oocyte retrieval and washing, holding during ICSI procedures, and for embryo holding during assisted hatching at Day 3.

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

HTF w/ HEPES 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 w/ HEPES 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	7.34
Osmolality	280-292	284
<b>Biological Tests</b>		
LAL Endotoxin	≤ 0.5 EU/ml	< 0.01 EU/ml
Sterility Test (Bacterial and fungal screen)	PASS	PASS
<b>Biological Assays</b>		
1-cell Mouse Embryo Assay*	≥ 80%	95%

\*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 exposed to individual lots of HTF w/ HEPES supplemented with 4 mg/ml embryo-tested BSA for 1 hour. The embryos are then cultured in an embryo-tested system for 96 hours and evaluated for development to the expanded blastocyst stage.