FUJIFILM IrvineScientific

Human Tubal Fluid (HTF) Medium

with Gentamicin

Catalog No. 90125 **100 mL**

For assisted reproductive technology (ART) procedures.

INDICATION FOR USE

Human Tubal Fluid (HTF) is intended for use in assisted reproductive procedures which include human gamete and embryo manipulation. These procedures include the use of HTF as a culture medium through day 3 of development.

DEVICE DESCRIPTION

HTF is a synthetic, defined solution for use as a culture media through Day 3 of human embryo development as well as the processing of gametes. HTF is bicarbonate-based and is designed for use in a CO_2 incubator. HTF contains the antibiotic Gentamicin Sulfate (10 µg/mL).

COMPOSITION

Salts and Ions
Sodium Chloride
Postassium Chloride
Magnesium Sulfate
Potassium Phosphate
Calcium Chloride

Buffers
Sodium Bicarbonate

Energy Sources
Glucose
Sodium Pyruvate
Sodium Lactate

Antibiotic
Gentamicin Sulfate

pH Indicator
Phenol Red

Water
WFI Quality

QUALITY ASSURANCE

HTF is a culture medium which is membrane filtered and aseptically processed according to manufacturing procedures which have been validated to meet a sterility assurance level (SAL) of 10^{-3}.

Each lot of HTF is tested for:

- Endotoxin by Limulus Amebocyte Lysate (LAL) methodology
- Biocompatibility by Mouse Embryo Assay
- Sterility by the current USP Sterility Test <71>

All results are reported on a lot specific Certificate of Analysis which is available upon request.

BUFFER SYSTEM

HTF uses sodium bicarbonate as a buffering system. This is specifically designed for use in a CO_2 incubator.

PROTEIN SUPPLEMENTATION

HTF does not contain protein components. General laboratory practice includes supplementation when using this medium. The amount of protein supplementation may vary among laboratories and is dependent on the phase of processing/growing the gametes and embryos. Consult your individual laboratory protocols.

DIRECTIONS FOR USE

HTF Medium should be supplemented with protein, as appropriate, and pre-equilibrated to 37°C and desired pH in a CO_2 incubator prior to use. When equilibrating in a CO_2 incubator, the bottle of HTF should be loosely capped to allow for the exchange of gas and pH equilibration.

After the medium has been pre-warmed and equilibrated in a CO_2 incubator, allow fertilization to occur in a culture dish that contains HTF supplemented with protein. Once fertilization occurs, the reproductive specialist should transfer the zygote/embryo into a new dish with pre-warmed equilibrated HTF containing the desired concentration of protein for the growth phase. Allow embryo to grow until desired developmental stage (up to 3 days).

For additional details on the use of these products, each laboratory should consult its own laboratory procedures and protocols which have been specifically developed and optimized for your individual medical program.

STORAGE INSTRUCTIONS AND STABILITY

Store the unopened bottles refrigerated at 2° to 8°C.

Do not freeze or expose to temperatures greater than 39°C.

Duration Following Bottle Opening:
Product should be used within four (4) weeks from opening when stored under the recommended conditions of 2° to 8°C.

PRECAUTIONS AND WARNINGS

This device is intended to be used by staff trained in assisted reproductive procedures. These procedures include the intended application for which this device is intended.

The user facility of this device is responsible for maintaining traceability of the product and must comply with national regulation regarding traceability, where applicable.

Do not use any bottle of medium which shows evidence of particulate matter, cloudiness or is not reddish-orange in color.

To avoid problems with contamination, handle using aseptic techniques and discard any excess medium that shows any evidence of contamination after opening.

CONTRAINDICATION

Product contains Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

Glossary of Symbols*:

REF	Catalog Number
LOT	Lot Number
STERILE A	Sterilized using aseptic processing techniques (filtration)
	Expiration: Year - Month - Day
irvinesci.com	Consult instructions for use or consult electronic instruction for use
8°C 2°C	Storage Temperature 2-8°C
2 STERILIZE	Do not resterilize
	Do not use if package is damaged and consult instruction for use
UDI	Unique device identifier
MD	Medical device
	Contains a medical substance
	Date of manufacture
	Manufacturer
Rx Only	U.S. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

*Symbol Reference - **EN ISO 15223-1,** Medical devices – Symbols to be used with medical device labels, labeling.

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