



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 μ g/mL).

COMPOSITION

Salts and Ions Energy Sources
Sodium Chloride Glucose
Postassium Chloride Sodium Pyruvate
Magnesium Sulfate Sodium Lactate

Potassium Phosphate

Calcium Chloride Antibiotic
Gentamicin Sulfate

Buffers

Sodium Bicarbonate <u>pH Indicator</u> 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 10³.

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 ${\rm CO_2}$ 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 CO₂ incubator prior to use. When equilibrating in a CO₂ 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 CO₂ 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 protucols 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.

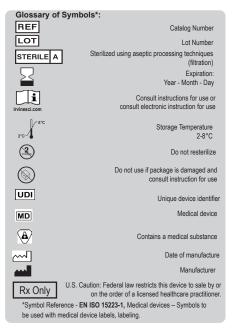
The user facility of this device is responsible for maintaining traceability of the product and must comply with national regulation regarding traceability, where applicable.

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.



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