Distributor

HTF - IVF Basics®
HTF HEPES - IVF Basics®
with or without 0.4% HSA
Culture media

PRODUCT INFORMATION

General
HTF and HTF HEPES have been developed for handling, conditioning and culturing of human gametes and embryos.

Intended use
IVF Basics® HTF (0.4% HSA) and IVF Basics® HTF HEPES (0.4% HSA) are designed for washing and handling of human gametes, and for handling and conditioning of human embryos. Also to be used for embryo transfer.
For professional use only.

The media can be used for the following procedures:
- Flushing for oocyte collection
- Washing/handling of human ova
- Washing/handling of spermatozoa
- Swim-up of spermatozoa
- Production of density gradient media
- Washing/handling for human embryos
- Embryo transfer
- IUI, IVF, ICSI

In addition, IVF Basics® HTF (0.4% HSA) can also be used for embryo culture from day 1 to blastocyst stage.

Composition
IVF Basics® HTF and IVF Basics® HTF HEPES are cell culture media consisting of a balanced physiologic salt solution supplemented with carbohydrate energy sources such as bicarbonate, glucose, pyruvate, lactate and gentamicin sulphate (10mg/liter) which support gamete/embryo development during the procedures used for assisted reproduction.

Component	IVF Basics® HTF Bic mg/L	IVF Basics® HTF HEPES mg/L
Sodium Chloride (NaCl)	5600	5930
Potassium Chloride (KCl)	350	350
Glucose Monohydrate (Glucose x H_2O)	550	550
Potassium Dihydrogen (Phosphate KH_2PO_4)	50	50
Magnesium Sulphate Heptahydrate ($MgSO_4$ x $7H_2O$)	51	51
Calcium Chloride Dihydrate ($CaCl_2$ x $2H_2O$)	300	300
Sodium Lactate solution 50% (D-L-Na Lactate)	3,563 (ml)	3,563 (ml)
Gentamicin Sulphate	10	10
Sodium Pyruvate (Na Pyruvate)	37	37
Sodium Bicarbonate ($NaHCO_3$)	2100	330
HEPES	-	4766
Phenol Red	5	-
With HSA Without HSA	4000 -	4000 -

IVF Basics® HTF and IVF Basics® HTF HEPES supplemented with 0.4% HSA (4g/liter) are ready-to-use.
It is strongly suggested by Gynotec B.V. to supplement IVF Basics® HTF and IVF Basics® HTF HEPES without HSA with 4g/liter HSA before use.

Material not included
- IVF Basics® HTF (with HSA): CO_2 incubator (5% CO_2, 37°C)
- IVF Basics® HTF HEPES (with HSA): Incubator at 37°C
- IVF Basics® HTF and IVF Basics® HTF HEPES (without HSA): Pharmaceutical grade Human Albumin Solution with registered Plasma Master File
- Syringe
- Catheter (for embryo transfer)
- Petri dishes
- Test tubes
- Microscope
- LAF Bench (ISO 5 environment)

Quality Control
- pH: 7,20 – 7,60 (At 5% CO_2 for IVF Basics® HTF (with HSA))
- Osmolality: 270 – 290 mOsm/kg
- Endotoxin: < 0.25 EU/ml
- Sterility: sterile, SAL 10^{-3}
- Mouse Embryo Assay (blastocysts after 96h): ≥ 80%
- Chemical composition
- Use of Ph Eur or USP grade products if applicable
- Certificate of Analysis and MSDS are available upon request

Sterility
Sterilized by using aseptic processing techniques.
STERILE A

Precautions and Warnings
Always work under hygienic conditions (LAF-bench, ISO Class 5) to avoid possible contamination.
Always wear protective clothing when working with specimens.
Handle specimens as if capable of transmitting HIV or hepatitis.
Ensure that the patient is not sensitized to the antibiotic gentamicin.
Only for the intended use.

Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of proven virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes.

Contra indications
Unknown.

Pre-use checks
Do not use if the seal on the bottle is broken or open when the product is delivered.
Do not use if the product shows any signs of microbial contamination, has changed colour or cloudy.

Storage Conditions
Store refrigerated (2° - 8°C).
Do not use after expiry date.
Do no freeze before use.
Keep away from (sun)light.
Shelf life is 18 months from date of manufacture.
Product can be used safely up to 7 days after opening, when sterile conditions are maintained and product is stored at 2° - 8° C.
Stable after transport (up to 5 days) at elevated temperatures (≤ 37°C).

Technical Support

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CE 0344

Instructions for use
(Suggested procedures)

Distributor

SYMBOL	MEANING
REF	Catalogue number
LOT	Batch code
	Use by (expiry date)
	Temperature limitations
	Sterile medical device processed using aseptic technique
	Consult instructions for use
CE 0344	CE mark

IVF Basics® HTF (0.4% HSA)
Designed for the use in a CO_2 incubator in a humified atmosphere.

Pre-Equilibration of IVF Basics® HTF (0.4% HSA):
Preincubate the media (in culture dishes or flasks with loosened screw caps) overnight or at least for a minimum of 4 hours before use at 37ºC and 5% CO_2.

In case pre-equilibration is performed in culture dishes make sure the droplets are covered with suitable oil or alternatively, use an open system according to general laboratory practice.

IVF Basics® HTF HEPES (0.4% HSA)
Contains a HEPES buffer to maintain stable pH during procedures performed outside a CO_2 incubator.

Before use, IVF Basics® HTF HEPES (0.4% HSA) can be preheated to room temperature or 37°C.

Washing / handling instructions
- Recover oocytes and prepare sperm according to your standard laboratory procedures.
- After collection check the oocytes and rewash if necessary before placing them in fresh droplets/wells for overnight culture. Carry out fertilization in IVF Basics® HTF (0.4% HSA) media.
- Where ICSI is required perform the sperm injection in IVF Basics® HTF HEPES (0.4% HSA) media.
- Place the fertilization dishes into a CO_2 incubator and culture according to your standard laboratory procedures.
- Evaluate the oocytes for evidence of fertilization (generally performed within 16-20 hours after fertilization).
- For embryo transfer at day 2 or 3 transfer the embryos to the uterus in fresh equilibrated IVF Basics® medium.
- Flush the Embryo Transfer catheter with IVF Basics® medium prior to use.
- For further instructions, please refer to the procedures and protocols established in your laboratory.

Swim-up
(According to WHO, 2010)
- Carefully layer 1,5ml IVF Basics® medium on top of 1ml washed semen in a conical based centrifuge tube.
- Place the tube in the incubator at a 45° angle for 1 hour at 37°C.
- Place the tube carefully in an upright position and remove 1,0ml of the top layer.
- Dilute the aliquot of motile cells with 8 volumes of IVF Basics® medium. Centrifuge for 15 minutes at 300g.
- Carefully aspirate the supernatant and resuspend the sperm pellet in 0,5ml IVF Basics® medium.

Embryo transfer
(According to Brinsden, 2005)
- Take a sterile syringe, fill it with IVF Basics® medium and eject air bubbles. Place the syringe onto a catheter and eject the medium.
- Suck up the IVF Basics® medium into the syringe and push down the piston to the 10µl calibration mark.
- Suck up the embryo(s) into the catheter in such a way that the volume is approximately 20-30µl.
- Hand over catheter and syringe to the clinician for insertion and transfer into the uterus.

Used Abbreviations

ICSI	Intracytoplasmatic Sperm Injection
IVF	In Vitro Fertilization
IUI	Intra Uterine Insemination
HSA	Human Serum Albumin

Catalogue numbers

IVF Basics® HTF

HTF-B-10	10 ml
HTF-B-30	30 ml
HTF-B-60	60 ml
HTF-B-120	120 ml
HTF-B-250	250ml
HTF-B-500	500ml

IVF Basics® HTF with 0.4% HSA

HTF-B-0.4A-10	10 ml
HTF-B-0.4A-30	30 ml
HTF-B-0.4A-60	60 ml
HTF-B-0.4A-120	120 ml
HTF-B-0.4A-250	250ml
HTF-B-0.4A-500	500ml

IVF Basics® HTF HEPES

HTF-H-10	10 ml
HTF-H-30	30 ml
HTF-H-60	60 ml
HTF-H-120	120 ml
HTF-H-250	250ml
HTF-H-500	500ml

IVF Basics® HTF HEPES with 0.4% HSA

HTF-H-0.4A-10	10 ml
HTF-H-0.4A-30	30 ml
HTF-H-0.4A-60	60 ml
HTF-H-0.4A-120	120 ml
HTF-H-0.4A-250	250ml
HTF-H-0.4A-500	500ml