Gx-IVF™

Vitrolife

Indication for use

Medium for preparation and handling of gametes, for *in vitro* fertilisation and intrauterine insemination.

Contraindications

Gx-IVF™ contains gentamicin and acetylcysteine. Do not use in patients with known hypersensitivity/allergy to any of the components.

Product Description

SUPPLEMENTED WITH HSA

Gx-IVF is a bicarbonate buffered medium containing human serum albumin, acetylcysteine and gentamicin as an antibacterial agent.

Ready to use after equilibration at +37°C and 6 % CO_2 atmosphere at sea level.

The summary of safety and clinical performance can be found at www.vitrolife.com

Storage instructions and stability

Store dark at +2 to +8°C.

Gx-IVF is stable until the expiry date shown on the container labels and the LOT-specific Certificate of Analysis.

Media bottles can be used for up to two weeks after first opening, use aseptic technique and minimize the time outside the refrigerator. Opening of the bottle shall be limited to the time needed to remove the necessary amount of medium. Discard excess media no later than two weeks after first opening.

Directions for use

The product shall be used by an IVF professional.

The patient target group is an adult or reproductive-age population that undergoes fertility treatment.

Record the opening date on the bottle.

Gx-IVF is designed for culture in a CO_2 incubator.

Gx-IVF shall be equilibrated at 6 % CO_2 and +37°C for no less than 6 hours and until correct pH has been attained before use. The dish or tube shall not be kept in incubator for more than 72 hours.

To obtain desired pH, the incubator CO_2 level may have to be adjusted taking into account incubator characteristics and environmental conditions such as altitude.

Sperm preparation - swim-up method
Equilibrate Gx-IVF according to above. Pipette 1 mL semen into a tube, overlay with 2 mL equilibrated Gx-IVF and allow swim-up for 30-60 minutes. Aspirate the top layer and transfer to a clean tube. For washing, add 5 mL Gx-IVF, mix and centrifuge for 5-10 minutes at 300-600 g. Perform a second wash if required. Discard the supernatant and re-suspend the pellet in 0.5-1 mL Gx-IVF.

Sperm preparation - density gradient centrifugation
Equilibrate Gx-IVF according to above. For preparation of density gradients for sperm cell separation, follow the instruction for the applied density gradient solution. After centrifugation, perform one or two wash steps with Gx-IVF as described in the swim-up method above.

Oocyte culture
Prepare dishes with Gx-IVF droplets (≥ 100 µL) under oil for ART procedures, or use a large volume (≥ 500 µL) with or without oil cover. Equilibrate according to above. Following oocyte collection procedure, rinse the cumulus-oocytes complexes at least two times in Gx-IVF, to remove red blood cells and collection medium, before culture.

Fertilisation
For fertilisation, selected sperm cells in Gx-IVF can be added to the oocytes, or oocytes in Gx-IVF can be added to sperm cells. Number of sperm cells used for insemination and exposure time are according to laboratory procedures.

Intrauterine insemination
Process the semen sample by swim-up or density gradient centrifugation as outlined above. Process the fraction of prepared semen in Gx-IVF for IUI according to laboratory procedures.

Specifications

Aseptically filtered	
Mouse Embryo Assay, 1-cell [% embryos developed to expanded blastocyst at 96 hours]	≥80
Bacterial endotoxins (LAL assay) [EU/mL]	< 0.25
Human sperm survival [% motility of control after 24 hours]	≥ 80
pH tested	
Osmolality tested	

LOT specific test results are available on the Certificate of Analysis provided with each delivery.

Precautions

Discard product if bottle integrity is compromised. Do not use Gx-IVF if it appears cloudy.

Gx-IVF contains human serum albumin.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBc, HCV, and HTLV I/II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

To avoid contamination Vitrolife strongly recommends that media should be opened and used only with aseptic technique.

The risk of reproductive and developmental toxicity for IVF media, including Vitrolife´s IVF media, has not been determined and is uncertain.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Not for injection.

Discard the product according to standard clinical practice for medical hazardous waste when the procedure is finished.

Symbols glossary

Symbol	Title of symbol	Reference and symbol ID.
	Consult instructions for use	*Ref. no: 5.4.3
	Caution	*Ref. no: 5.4.4. Consult Instructions for use for important cautionary information.
	Manufacturer	*Ref no: 5.1.1
	Date of manufacture	*Ref no: 5.1.3
	Use-by date	*Ref no: 5.1.4
	Batch code	*Ref no: 5.1.5
	Catalogue number	*Ref no: 5.1.6
	Sterilized using aseptic processing techniques	*Ref no: 5.2.2
	Single sterile barrier system	Graphical symbols for use on equipment — Registered symbols (ISO 7000:2019). Ref no: 3707
	Temperature limit	*Ref no: 5.3.7
	Keep away from sunlight (light sources)	*Ref no: 5.3.2
	Contains a medicinal substance	Graphical symbols for use on equipment — Registered symbols (ISO 7000:2019). Ref no: 3702
	Contains human blood or plasma derivatives	Graphical symbols for use on equipment — Registered symbols (ISO 7000:2019). Ref no: 3701
	Medical Device	Indicates that the device is a medical device as defined in Regulation(EU) 2017/745

*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied (ISO 15223-1:2016).

Caution: Federal (US) law restricts this device to sale by or on the order of a physician or practitioner trained in its use (Rx only).

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Patent No.
Patents pending

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