Gx-TL™

Vitrolife

Indication for use

Medium for culture of embryos from fertilisation to the blastocyst stage and for embryo transfer.

Contraindications

Gx-TL™ contains gentamicin. Do not use in patients with known hypersensitivity/allergy to the component.

Product Description

SUPPLEMENTED WITH HSA

Gx-TL is a bicarbonate buffered medium containing human serum albumin, hyaluronan, 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-TL 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-TL is designed for culture in a CO_2 incubator.

Gx-TL 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 shall not be kept in incubator for more than 7 days.

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.

To minimize evaporation, immediately cover droplets of Gx-TL with oil for ART procedures. Culturing without oil requires humidified environment.

Culture
Prepare dishes with droplets of Gx-TL (≥ 25 µL) under oil, or use a large volume (≥ 500 µL) with or without oil cover. For group culture, a minimum of 10 µL Gx-TL per embryo shall be used, to minimize risk of depletion of nutrients. Equilibrate according to above.

For time-lapse devices, prepare dishes with Gx-TL medium volumes as recommended by the manufacturer.

Following two washing steps in Gx-TL, transfer the fertilized oocytes or embryos to the Gx-TL culture medium and return the dish to the incubator immediately.

Embryo transfer
Prepare and equilibrate a dish with Gx-TL and perform embryo transfer according to laboratory procedures. Rinsing of the embryo transfer catheter with Gx-TL before aspiration of one or more embryos is recommended. Following the embryo transfer procedure, make a final microscopic examination of the catheter.

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
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-TL if it appears cloudy.

Gx-TL contains human serum albumin and acetylcysteine.

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.

Not for injection.

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

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.

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
LOT	Batch code	*Ref no: 5.1.5
REF	Catalogue number	*Ref no: 5.1.6
STERILE A	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
+2°C +8°C	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
MD	Medical Device	Indicates that the device is a medical device as defined in MDR 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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