

Gx-TL™



Indication for use

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

Contraindications

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

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 % CO₂ 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 CO₂ incubator.

Gx-TL shall be equilibrated at 6 % CO₂ 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 CO₂ 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.

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).

For technical support:

Americas

Tel: + 1-866-848-7677

E-mail: support.us.fertility@vitrolife.com

Europe, Middle East, Asia, Pacific, Africa

Tel: +46-31-721 80 20

E-mail: support.fertility@vitrolife.com

Vitrolife Sweden AB, Gustaf Werners gata 2, SE-421 32 Västra

Frölunda, Sweden (visiting address). Box 9080, SE-400 92

Göteborg, Sweden (postal address).

Vitrolife Inc., 3601 South Inca Street, Englewood CO 80110, USA.

Vitrolife Pty. Ltd., Level 10, 68 Pitt Street, Sydney NSW 2000,

Australia.

China/中国

注册申请人/生产企业名称、住所、生产地址、生产许可证编号和联系方式

名称: Vitrolife Sweden AB 瑞利英瑞典有限公司

注册人住所、生产地址: Gustaf Werners gata 2, SE-421 32 Västra Frölunda, Sweden (visiting address). Box 9080, SE-400 92 Göteborg, Sweden (postal address)

生产许可证编号: 556546-6298

联系方式: +46-31-721 80 20

代理人/售后服务单位名称、住所和联系方式

名称: 瑞利英(北京)技术服务有限公司

住所: 北京市朝阳区阜通东大街6号院3号楼20层(17)2006室

邮编: 100102

电话: 010-64036613

传真: 010-64036613

E-mail: support.asia@vitrolife.com

www.vitrolife.com

Manufactured by
Vitrolife Sweden AB
V.Frölunda, Sweden

Patent No.

Patents pending