VitaVitro

VitaVitro® Gamete Buffer Medium

With Human Serum Albumin

User Manual

INDICATION FOR USE

VitaVitro® Gamete Buffer Medium is intended for human gamete and embryo short-term handling procedures outside the incubator, including washing and intracyto-plasmic sperm injection (ICSI).

COMPOSITION

Physiological salts, energy (glucose, lactate, pyruvate), buffer system, taurine, sodium citrate, amino acids, glutamine dipeptide, EDTA, phenol red, gentamicin*, HSA*.

*from therapeutic-grade source material

STORAGE CONDITIONS

Store in original container at 2-8˚C.

Do not freeze.

The shelf life is 12 months from time of manufacture.

Keep away from (sun) light.

Do not use after the expiry date shown on the label.

QUALITY CONRTOL TESTING

- Sterility: Sterile (USP <71>)
- Osmolality: 260-290 mOsm/kg (USP <785>)
- pH(at 37˚C, 6 % CO_2): 7.2-7.6 (USP <791>)
- Endotoxin: <0.25EU/mL (USP <85>)
- 1-cell Mouse Embryo Assay (MEA): ≥ 80% expanded blastocyst at 96 hours after a 2-hour exposure to medium

WARNING

1) VitaVitro® Gamete Buffer Medium contains the antibiotic Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
2) All blood products should be treated as potentially infectious. This product contains Human Serum Albumin (HSA). It was found negative when testing for antibodies to HIV-1/HIV-2, HCV and non-reactive for HBsAg. However, no known test can guarantee that products derived from humans will not be infectious.
3) Always work under strict sterile operation to avoid possible contamination, even when VitaVitro® Gamete Buffer Medium contains Gentamicin.
4) Only for the intended use.
5) Not for use in injections.
6) Do not use the product if it becomes discolored, cloudy or shows any evidence of microbial contamination.
7) VitaVitro® Gamete Buffer Medium with HEPES should be tightly capped when used in a CO_2 incubator to avoid downward drifts of pH.
8) For prescription use only.
9) Single Use only – discard medium after opening.

DESCRIPTION OF ISO SYMBOLS

The symbol glossary is in line with the SDO-developed standard ANSI/AAMI/ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General requirements.

Reference number	Symbol	Title of symbol	Description of symbol
5.3.2		Keep away from sunlight	Indicates a medical device that needs protection from light sources.
5.4.2		Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.1.1		Manufacturer	Indicates the medical device manufacturer.
5.1.3		Date of manufacture	Indicates the date when the medical was manufactured.
5.3.7		Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
5.1.4		Use-by date	Indicates the date after which the medical device is not to be used.
5.1.5	LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.2.2	STERILE A	Sterilized using aseptic processing technique	Indicates a medical device that has been manufactured using accepted aseptic techniques.

INSTRUCTIONS

This is the medium for procedures done in an atmosphere of air does not require the use of a CO_2 incubator. Such procedures include oocytes retrieval, gametes or embryos washing, ICSI, embryo transfer.

1) Pre-warm VitaVitro® Gamete Buffer Medium to 37˚C prior to use.
2) Before oocytes and embryos washing and manipulation, prepare culture dishes containing 25-100 µL droplets, or in larger volumes (0.5-1.0 mL) of VitaVitro® Gamete Buffer Medium, under oil, according to general laboratory practice. For washing, pass the oocytes or embryos through several droplets or wells.
3) For ICSI, prepare 5-10 small droplets (5-10 µL) of VitaVitro® Gamete Buffer Medium in the ICSI dish, next to the PVP droplets and cover them with oil, according to general laboratory practice. Transfer the oocytes to the respective droplets just before the ICSI procedure.
4) For transfer, rinse the transfer catheter with VitaVitro® Gamete Buffer Medium first, then wash the embryos according to the above description, and transfer to the uterus in 20-30 µL of VitaVitro® Gamete Buffer Medium.

Each laboratory should define and optimize its own procedures.

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