



VitaVitro

VitaVitro® Fertilization Medium With Human Serum Albumin User Manual

Specification Catalog No.
30 mL V021030
60 mL V021060

INDICATION FOR USE

VitaVitro® Fertilization Medium is intended for preparation and handling of human gametes and for in vitro fertilization.

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 7 months from time of manufacture.

Keep away from (sun) light.

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

PERFORMANCE

- Sterility: Sterile(USP <71>)
- Osmolality: 260-290 mOsm/kg (USP <785>)
- pH (at 37°C, 6 % CO₂): 7.2-7.6 (USP <791>)
- Endotoxin: <0.25 EU/mL (USP <85>)
- 1-cell Mouse Embryo Assay (MEA): ≥ 80% expanded blastocyst at 96 hours after a 24-hour exposure to media.

WARNING

- 1) VitaVitro® Fertilization 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® Fertilization 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) For prescription use only.
- 8) Single Use only—discard media 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 of symbol	Symbols	Title of symbol
5.3.2		Keep away from sunlight
5.4.2		Do not re-use
5.1.1		Manufacturer
5.1.3		Date of manufacture
5.3.7		Temperature limit
5.1.4		Use-by date
5.1.5		Batch code
5.2.2		Sterilized using aseptic processing technique

INSTRUCTIONS

- 1) Prepare dishes with VitaVibro® Fertilization Medium for oocyte holding or fertilization, containing appropriate-sized droplets under oil or larger volumes (0.5-1 mL) in an open system such as with the Falcon or Nunc dishes (without oil), according to general laboratory practice.
- 2) Place the dishes in a CO₂ incubator at 37°C and 6% CO₂. When using open system, the incubator must be humidified. Ideally the medium should be pre-incubated overnight before use (or at least 4 hours).
- 3) At the conclusion of the retrieval, dissect the oocytes to remove any degenerate or excess cumulus cells, blood clot and debris, and wash the oocytes in flushing buffer medium the lab used, according to your standard laboratory procedures.
- 4) Transfer the oocytes into the oocyte-holding dishes, wash

and evaluate each oocyte according to your standard laboratory protocol.

- 5) After oocyte collection, transfer the oocytes to droplets or wells in fertilization dishes and leave at 37°C and 6 % CO₂ overnight.
- 6) The presence of 2 pronuclei (2PN) is checked 16-20 hours after fertilization, then carefully wash and transfer zygotes to fresh droplets or wells of pre-equilibrated culture medium.

Each laboratory should define and optimize its own procedures.



 **Shenzhen VitaVibro Biotech Co., Ltd.**

R601, Building B, and 301, Area 02,
Building A, Hai Ke Xing Tech Park
Baoshan Road No.16, Pingshan
District, Shenzhen, Guangdong,
518118, China

Phone: +86 755 84511813

e-mail: tech@vitavibro.com

www.vitavibro.com