



VitaVitro

VitaVitro® 1-Step Culture Medium

With Human Serum Albumin

User Manual



CAUTION

Federal (U.S.) law restricts this device to sale by or on the order of a licensed physician

CAUTION

The user should read and understand the User Manual. Precautions and Warnings, Instructions, and be trained in the correct procedure before using VitaVitro® 1-Step Culture Medium for the culture of human embryos from zygote to blastocyst.

INDICATION FOR USE

This product is intended for the in vitro culture of human embryos following fertilization until Day 5/6 of development.

INTENDED USERS

The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

COMPOSITION

Sodium Chloride, Potassium Chloride, Potassium Phosphate, Magnesium Sulfate, Calcium Chloride, Magnesium Sulfate, Sodium Bicarbonate, Glucose, Na-Lactate, Na-Pyruvate, Essential and non-essential Amino Acids, EDTA, Sodium Citrate, Taurine, Alanine, glutamine, Phenol Red, Gentamicin Sulfate (10 µg/mL), Human serum albumin (5mg/mL).

PERFORMANCE

Each set of VitaVitro® 1-Step Culture Medium is tested for:

- 1) Sterility: Passed (USP <71>)
- 2) Osmolality: maintains between 250-290 mOsm/kg (USP <785>)
- 3) pH (at 37°C, 6 % CO₂): maintains between 7.2-7.6 (USP <791>)
- 4) Endotoxin: < 0.25 EU/mL (USP <85>)
- 5) 1-cell Mouse Embryo Assay (MEA) >80% blastocysts by 96 hours

SHELF LIFE

6 months

STORAGE CONDITIONS

Store in original container at 2-8°C.

Do not freeze.

Do not re-sterilize.

Do not re-use. After vial opening, any remaining medium should be discarded.

Do not use after expiry date shown on the label.

PRECAUTIONS AND WARNINGS









- 1) VitaVitro® 1-Step Culture 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® 1-Step Culture 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.

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 |  | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
| 5.2.2 |  | Sterilized using aseptic processing technique | Indicates a medical device that has been manufactured using accepted aseptic techniques. |

INSTRUCTIONS

- 1) According to general laboratory practices, prepare culture dishes containing 25-100 μL droplets or in larger volumes (0.5-1.0 mL) of VitaVitro® 1-Step Culture Medium, and cover the medium in oil.
- 2) The medium must be equilibrated overnight in a humidified CO_2 -incubator (at 5-6 % CO_2 , 37°C) prior to use. For optimal embryo development, measure the pH of the medium under laboratory working conditions and adjust the CO_2 level for the desired pH range.
- 3) After fertilization, transfer zygotes to fresh pre-equilibrated VitaVitro® 1-Step Culture Medium, and return the dish to the incubator until the desired developmental stage of the embryo has been reached.

ADDITIONAL INFORMATION

The VitaVitro® 1-Step Culture Medium has been designed for uninterrupted culture until the desired developmental stage of the embryo has been reached. It does not require a medium or dish change.

For additional details on the use of these products, each laboratory should consult its own laboratory procedures and protocols which have been specifically developed and optimized for your individual medical program.



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Shenzhen VitaVitro 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@vitavitro.com

www.vitavitro.com