VitaVitro

# VitaVitro® Sperm Gradient Medium

Supplemented with Gentamycin Sulfate

## User Manual

**CAUTION**

U.S. federal law restricts this device to sale by or on the order of a physician.

### INDICATION FOR USE

VitaVitro® Sperm Gradient Medium is intended for separation of motile sperm from seminal fluid for use in assisted reproduction procedures.

### DEVICE DESCRIPTION

Based on the loading specifications of the package PETG bottles, this device has three specifications, including 12 mL, 30 mL and 125 mL. The bottles are transparent and sterilized, sealed with HDPE closures. The composition and performance of all the three specifications are identical. Each unit of device includes a bottle of Upper Layer Medium (40%) and a bottle of Lower Layer Medium (80%) with the same volume. It is a sterile device which adopts filter sterilization and aseptic filling technology during production. The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

### COMPOSITION

Sodium Chloride, Potassium Chloride, Magnesium Sulfate, Potassium Phosphate, Calcium Chloride, Sodium Bicarbonate, HEPES, HEPES-Na, Glucose, Sodium Lactate, Sodium Pyruvate, Taurine, Alanyl Glutamine, Gentamycin Sulfate*, EDTA, Silane-coated silica particles, and Water.

*from therapeutic-grade source material

### QUALITY CONRTOL TESTING

- Specific gravity per USP <841>:
  - Upper layer 40%: 1.05±0.03 g/mL
  - Lower layer 80%: 1.10±0.03 g/mL
- pH per USP <791>: 7.4 - 7.8
- Osmolality, per USP <785>:
  - Upper layer 40%: 270-330 mOsm/kg
  - Lower layer 80%: 300-360 mOsm/kg
- Endotoxin per USP <85>: < 0.25 EU/mL
- HSSA: ≥ 80% of control motility at 24h
- Sterility per USP <71>: No microbial growth

### CATALOG NUMBER

| Catalog Number | Specification |
|---|---|
| V015012 | 12 mL of Upper Layer Medium (40%, SG-40) |
| | 12 mL of Lower Layer Medium (80%, SG-80) |
| V015030 | 30 mL of Upper Layer Medium (40%, SG-40) |
| | 30 mL of Lower Layer Medium (80%, SG-80) |
| V015125 | 125 mL of Upper Layer Medium (40%, SG-40) |
| | 125 mL of Lower Layer Medium (80%, SG-80) |

### WARNING

1) Do not use the product if:
   - It becomes discolored, cloudy or shows any evidence of microbial contamination.
   - Expiry date has been exceeded.
   - Do not use if packaging is damaged or broken.
2) This product contains the antibiotic Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
3) Always work under strict sterile operation to avoid possible contamination, even if VitaVitro® Sperm Gradient Medium contains gentamicin.
4) Only for the intended use, not for use in injections.
5) Single use only – discard 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 |
|---|---|---|---|
| 5.1.1 |  | Manufacturer | Indicates the medical device manufacturer. |
| 5.1.3 |  | Date of manufacture | Indicates the date when the medical was manufactured. |
| 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. |
| 5.1.6 |  | Catalogue number | Indicates the manufacture's catalogue number so that the medical device can be identified. |
| 5.2.2 |  | Sterilized using aseptic processing techniques | Indicates a medical device that has been manufactured using accepted aseptic techniques. |
| 5.3.2 |  | Keep away from sunlight | Indicates a medical device that needs protection from light sources. |
| 5.3.7 |  | Temperature limit | Indicates the temperature limits to which the medical device can be safely exposed. |
| 5.4.2 |  | Do not re-use | Indicates a medical device that is intended for one single use only. |
| 5.4.3 |  | Consult instructions for use or consult electronic instructions for use | Indicates the need for the user to consult the instructions for use. |

## INSTRUCTIONS

1) Warm all components to room temperature prior to use.
2) A separate gradient formed in a test tube by transferring into 2 mL VitaVitro® Sperm Gradient Medium 40%, undelay with 2 mL VitaVitro® Sperm Gradient medium 80%.

   *NOTE: Use the gradient within 1 hour for optimal results.*
3) Carefully layer 2 mL of liquefied semen on the top of the prepared gradient. Centrifuge at 300-400g for 20 minutes.
4) Discard the supernatant from the pellet and transfer the pellet with a new sterile tip into a clean test tube containing 3 mL of VitaVitro® Sperm Washing Medium. Centrifuge at 200-300g for 4-10 minutes.
5) Aspirate and discard most of the supernatant, add 3 mL of VitaVitro® Sperm Washing Medium. Centrifuge at 200-300g for 4-10 minutes.
6) Assess for sperm concentration and motility, if recommended, store the capped tube at 37˚C until use.
7) Aspirate and discard the supernatant, resuspend the pellet in appropriate volume of VitaVitro® Sperm Washing Medium.

## STORAGE CONDITIONS

- Store in original container at 2-8˚C, protect from (sun) light.
- Do not freeze.
- Discard excess (unused) medium following warming.
- When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.



**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

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