



VitaVitro

VitaVitro® Sperm Washing Medium

Supplemented with Human Serum Albumin and 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 Washing Medium is intended for the preparation and washing of sperm for use in assisted reproduction procedures. VitaVitro® Sperm Washing Medium is also intended for use in intrauterine insemination procedures.

DEVICE DESCRIPTION

Based on the loading specifications of the package PETG bottles, this device has three specifications including 30mL, 60mL and 125mL. And the bottles are transparent and sterilized, sealed with HDPE closures. The composition and performance of all the three specifications are identical. 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, Human Serum Albumin*, Gentamycin Sulfate*, EDTA and Water.

*from therapeutic-grade source material

CATALOG NUMBER

Catalog Number	Specification
V014030	30 mL
V014060	60 mL
V014125	125 mL

INSTRUCTIONS

Warm to incubator temperature (37°C) prior to use.

Any laboratory procedures described herein are recommendation only. Each laboratory must establish and validate its own procedures for preparations and use.

1) Direct swim up preparation

- Carefully layer 1 mL liquefied semen in a test tube underneath 2 mL VitaVitro® Sperm Washing Medium.
- Cap the tube tightly, place the tube at a 45° angle (to increase the interface between the semen sample and the VitaVitro® Sperm Washing Medium) and incubate for 30-60 minutes at 37°C.
- Transfer the upper layer into a new tube (don't aspirate the interface and the lower layer). Centrifuge at 200-300g for 10 minutes.
- Aspirate and discard the supernatant, resuspend the

supernatant, resuspend the remaining sperm pellet in 5 mL (or another appropriate volume) of VitaVitro® Sperm Washing Medium.

- Assess for sperm concentration and motility, if recommended, store the capped tube at 37°C until use.

2) Indirect swim-up preparation

- Transfer 1.5 mL VitaVitro® Sperm Washing Medium into a test tube.
- Add equal amount of liquefied semen to the test tube and mix well. Centrifuge at 300-500g for 10 min.
- Aspirate and discard the supernatant, overlay the pellet with 2 mL of VitaVitro® Sperm Washing Medium. Centrifuge at 200-400g for 5 min.
- Aspirate and discard the supernatant, resuspend the remaining pellet in 1 mL of VitaVitro® Sperm Washing Medium.
- Cap the tube tightly, place the

tube at a 45° angle and incubate for 30-60 minutes at 37°C.

- Transfer the upper layer into a new tube (don't aspirate the interface and the lower layer).
- Assess for sperm concentration and motility, if recommended, store the capped tube at 37°C until use.

3) Semen preparation for IUI

- After liquefaction, place the semen in a 15 mL conical centrifuge tube.
- Assess for sperm concentration and motility.
- Add VitaVitro® Sperm Washing Medium to the tube to a total volume of 10 mL, and mix.
- Centrifuge at 300 g for 10 minutes, and discard the supernatant.
- Resuspend the pellet with VitaVitro® Sperm Washing Medium to a total volume of 10 mL and centrifuge again at 300g for 10 minutes.

- Determine the concentration and motility.
- Discard the top fraction, resuspend the pellet with 0.5 mL of VitaVibro® Sperm Washing Medium.
- The specimen is ready for IUI.

WARNING

- 1) Do not use the product if:
 - It becomes discolored, cloudy or shows any evidence of microbial contamination.
 - Expiry date has been exceeded.
 - 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 VitaVibro® Sperm Washing 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.

QUALITY CONTROL TESTING

- pH per USP <791>: 7.2 - 7.6
- Osmolality per USP <785>: 270-300 mOsm/Kg
- Endotoxin per USP <85>: < 0.25 EU/mL
- HSSA: ≥80% of control motility at 24h
- Sterility per USP <71>: No microbial growth

STORAGE CONDITIONS

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

PRECAUTION

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.



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