

VitaVitro® Vitrification Kit User Manual

Specification: See the labels



CAUTION

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

INDICATION FOR USE

VitaVitro® Vitrification Kit is intended for the vitrification of human blastocysts for assisted reproductive technology (ART). This kit is designed for use with VitaVitro® Warming Kit.

PRODUCT DESCRIPTION

This product is used for vitrification of human blastocysts for assisted reproductive technology (ART). It contains three media: Human Holding Medium, Human Vitrification Solution 1, and Human Vitrification Solution 2.

COMPONENTS

Note: The solution contains ethylene glycol(EG) and dimethylsulfoxide (DMSO) as permeating cryoprotectants.

- 1) Human Holding Medium (HHM): M199 HEPES Buffered Medium supplemented with 12 mg/ml Human Serum Albumin (HSA).
- 2) Human Vitrification Solution1 (HV1): same as HHM solution, plus EG and DMSO.
- 3) Human Vitrification Solution2 (HV2): same as HHM solution, plus EG, DMSO, and 0.68 M sucrose.
- 4) The reagent vials are made of two materials: Polypropylene (PP) for the tube body, and silica gel for the seal ring.

PERFORMANCE

Mouse Embryo Assay(1-cell)	≥ 80% development to blastocyst at 96h
Endotoxin	<0.25 EU/mL
pH	7.2-7.6
Sterility	Sterile
Osmolality (HHM)	295-315 mOsm/kg

STERILIZATION METHOD

Aseptic processing (including sterilizing filtration and aseptic filling)

STORAGE CONDITIONS

Store at 2°C to 8°C

SHELF LIFE

12 months

PRECAUTIONS

- 1) The user should be a trained professional (e.g. a doctor or embryologist).
- 2) The user should read and understand the user manual and be trained in the correct procedures before using VitaVitro® Vitrification Kit.

EXPLANATION OF 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 device 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.

WARNING

- 1) The long-term safety of embryo cryopreservation is unknown.
- 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 HTLV-1/HTLV-2 and non-reactive for HBsAg (HBV) and syphilis. However, no known test can guarantee that products derived from humans will not be infectious.
- 3) Not for use in injections.
- 4) Do not use any vials which show evidence of damage, tampering or leaking, or particulate matter and cloudiness.
- 5) To avoid contamination, always use aseptic technique.
- 6) Do not reuse. After vial opening any remaining medium should be discarded.

OTHER MATERIALS THAT ARE REQUIRED BUT NOT INCLUDED

- A cleared storage device for use in vitrification and storage of human blastocysts is needed to complete the procedure. The VitaVibro® Straw Set that is sold separately from this kit is a cleared storage device for vitrification and storage of human blastocyst stage embryos.
- Stereomicroscope
- 1 x 60 mm Petri Dish
- Stopwatch or timer

PREPARATION

- 1) All procedures should be performed at roomtemperature (25-27°C).
- 2) All dishes should be warmed to 25-27°C.
- 3) HHM, HV1 and HV2 should be warmed to 25-27°C.

EQUILIBRATION OF HUMAN BLASTOCYSTS

The methods below are sufficient for the processing of up to three blastocysts. If additional blastocysts are to be processed, please repeat the steps below with new medium drops.

- 1) Pipette a 50 μ L drop of HHM in the lid of the 60 mm Petri Dish (refer to Figure 1), and transfer blastocysts there. Wait for 2 minutes. **2 min**
- 2) Pipette a 100 μ L drop of HV1 in the lid of the 60 mm Petri Dish, transfer the blastocysts there, and wait for approx. 9 minutes. Carefully cover the lid with the inverted bottom of the dish. **9 min**
- 3) After 9 min wait, check the blastocysts under a stereomicroscope. If they are fully recovered (i.e. the perivitelline space is as narrow as before the start of equilibration), proceed to the next step. If not, wait for an additional 3-6 minutes until they are recovered.

- 4) Pipette two 100 μ L HV2 drops far from the existing drops and each other. Transfer the blastocysts into one of the HV2 drops. Mix by pipette for approx. 20 seconds, then transfer them to the other HV2 drop. Mix for another 20 seconds.
- 5) After mixing, load and vitrify blastocysts as described in the Instructions for Use for the vitrification storage device used.



Figure 1. Arrangement of drops in the lid of a 60 mm Petri dish for vitrification of human blastocysts

REFERENCES

- 1) Lopes A.S., Frederickx V., Van Kerkhoven G., Campo R., Puttemans P., Gordts S. Survival, re-expansion and cell survival of human blastocysts following vitrification and warming using two vitrification systems. Journal of Assisted Reproduction and Genetics. 2015; 32(1): 83-90.
- 2) Saragusty J., Arav A. Current progress in oocyte and embryo cryopreservation by slow freezing and vitrification. Reproduction. 2011; 141(1):1-19.
- 3) Varghese A.C., Nagy Z.P., Agarwal A. Current trends, biological foundations and future prospects of oocyte and embryo cryopreservation. Reproductive Biomedicine Online, 2009; 19 (1): 126-140.



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