

MediCult IVM® System

Product No.:

8221

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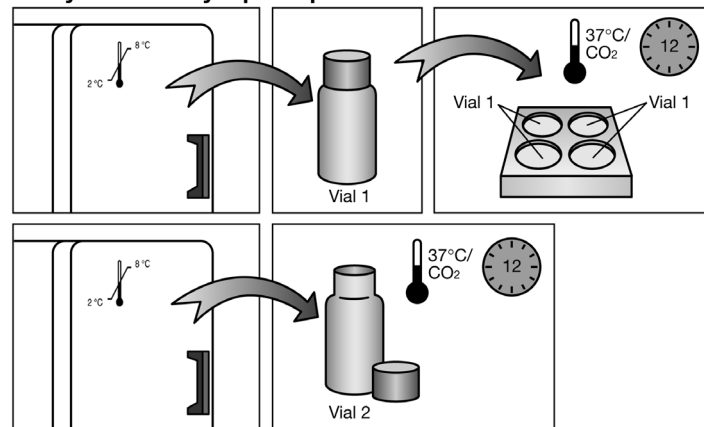
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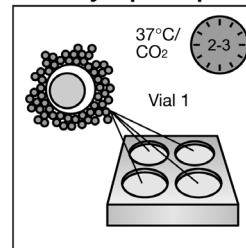
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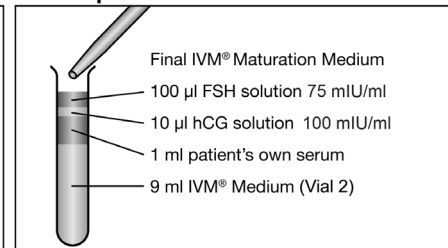
I Day before oocyte pick up



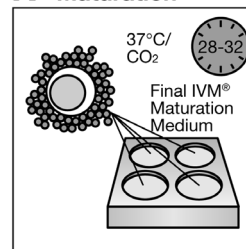
II Oocyte pick up



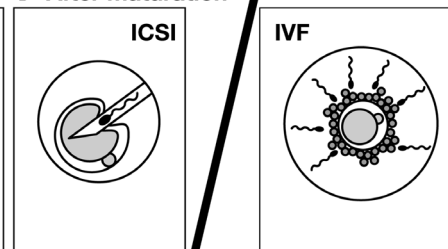
III Preparation



IV Maturation



V After maturation



MediCult IVM® System

Intended use

The LAG Medium (vial 1) is for preincubation of immature oocytes.

The IVM® Medium (vial 2) is a basal medium for maturing immature oocytes.

MediCult IVM® System is for infertile women undergoing in vitro fertilization who for medical reasons can not undergo conventional ovarian stimulation using drugs.

Composition

Vial 1, LAG Medium

Synthetic Serum Replacement (SSR®)* (USA: ART Supplement)

* Contains Recombinant Human Insulin

Human serum albumin (HSA)

Glucose

Sodium pyruvate

Physiological salts

Sodium bicarbonate

Gentamicin sulphate 10µg/mL

Phenol Red

Vial 2, IVM® Medium

Glucose

Sodium pyruvate

Sodium acetate

Physiological salts

Amino acids

Nucleotides

Vitamins

Cholesterol

Sodium bicarbonate

Gentamicin sulphate 10µg/mL

Phenol Red

Quality control testing

Sterility tested (Ph.Eur., USP)

Osmolality tested (Ph.Eur., USP)

pH tested (Ph.Eur., USP)

Endotoxin tested ≤ 0.1 EU/mL (Ph.Eur., USP)

1 cell Mouse Embryo Assay (MEA) ≥ 80%

Blastocysts by 96h

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Storage instructions and stability

Store in original container at 2-8°C, protected from light.

Do not freeze.

Discard excess (unused) media following warming.

IVM® Medium is provided in vial intended for single use.

LAG Medium is to be used within 7 days after opening.

When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Precautions and warnings

Do not use the product if:

1. Product packaging appears damaged or if the seal is broken.
2. Expiry date has been exceeded.

The clinical pregnancy and birth rates are lower for IVF cycles using oocytes matured in vitro compared to conventional IVF cycles.

The clinical benefit of in vitro oocyte maturation in IVF cycles is limited to the ability to harvest (immature) oocytes with little or no hormonal stimulation to the ovary.

Relatively fewer mature oocytes are available for fertilization following in vitro maturation compared to the number of oocytes obtained by aspiration following conventional ovarian stimulation protocols.

The in vitro oocyte maturation involves a significantly lower risk of ovarian hyper stimulation syndrome compared to conventional IVF.

The risk of chromosomal and/or congenital abnormalities in pregnancies and births resulting from in vitro maturation is unknown.

Caution: All blood products should be treated as potentially infectious. Source material used to manufacture this product were tested and found non-reactive for HbsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore source material have been tested for parvovirus B19 and found to be non-elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Caution: US federal law restricts this device to sale by or on the order of a physician (Rx only).

Instructions for use

1. Pre-equilibrate 3 mL LAG Medium (Vial 1) and 10 mL of IVM® Medium (Vial 2) in CO₂ environment at 37°C for a minimum of 12 hours.
2. After oocyte pick up store the immature oocytes in LAG Medium in CO₂ environment at 37°C for 2-3 hours prior to transfer to the final IVM® Maturation Medium.
3. Preparation of final IVM® Maturation Medium:
9 mL IVM® Medium
1 mL patient's own serum
10 µL human chorionic gonadotropin (hCG) solution (100 mIU/mL)
100 µL human follicle stimulating hormone (FSH) solution (75 mIU/mL).
4. Transfer the oocytes to the final IVM® Maturation Medium and incubate in CO₂ environment at 37°C for 28-32 hours.