

ARTSMedia In Vitro Culture Medium (AM-IVC Medium)

with Human Serum Albumin

Product No.:

501010

Indications for use

ARTSMedia In Vitro Culture Medium (AM-IVC Medium) is a culture medium intended for in vitro fertilization and in vitro culture of human gametes and embryos from fertilization until the blastocyst stage of development (day 5). The medium can also be used for embryo transfer.

Technical Support

E-mail: support@artsmedia.dk

Tel: + 45 5350 4530

ARTSMedia Denmark

Kongevejen 149, DK-2830 Virum, Denmark

Tel: +45 5350 4530, www.artsmediadenmark.com

Device Description

10 ml glass bottles, single packed, provided sterile. AM-IVC Medium is a bicarbonate-buffered balanced salt solution, with Physiological Salt, Amino Acids, Calcium Lactate Pentahydrate, EDTA, Gentamicin Sulphate 10 µg/ml, Glucose, L-glutamine, Human Serum Albumin (HSA), Insulin, Sodium Hyaluronate, Sodium Pyruvate, Sodium Bicarbonate, and Phenol Red.

Quality Control Specifications

pH: 7,2 – 7,45 (Ph Eur. 2.2.3, USP <791>)

Osmolality: 257-275 mOsm/kg (Ph Eur. 2.2.35, USP <785>)

Appearance: Clear and particulate free

Sterility: No growth (Ph Eur. 2.6.1, USP<71>)

Endotoxins: < 0.05 EU/ml (USP <85>)

1-cell Mouse Embryo Assay (MEA) ≥ 80% embryos developed to expanded blastocysts at 96 hours.

The results of each batch are stated on Certificate of Analysis, which is available at www.artsmediadenmark.com

Storage

Keep away from sunlight at 2-8° C in original container. Do not freeze.

Warnings

- Do not use after expiry date
- Do not use if the product is cloudy or shows any evidence of microbial contamination.
- Do not use if seal of the container is damaged or open upon delivery.
- Do not use medium that shows any evidence of particulate matter or has changed color.
- Do not re-sterilize after opening.
- Discard media that has been warmed and not used.
- Do not reuse
- Single-use only. Discard remaining medium in vials after opening.
- AM-IVC Medium contains gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic (allergic reaction).

Precautions

- Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.
- Media use should be conducted using aseptic techniques.
- Handle all samples as if capable of transmitting HIV or hepatitis.
- Always wear protective clothing when handling samples.
- All blood products should be treated as potentially infectious.
- This product contains albumin, a derivative of human blood. All donors used in its manufacture were individually tested and found to be nonreactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2). Further, the source plasma was tested and found negative for HIV 1/2, hepatitis virus A (HAV), hepatitis virus B (HBV), HCV, and parvovirus B19 by PCR.

General notes before use

AM-IVC Medium is bicarbonate buffered and should pre-equilibrate in a CO₂ incubator set at 37°C and 5-6% CO₂. Note: Adjust incubator settings to a higher CO₂ concentration if the altitude is above sea level.

To maintain pH, temperature, and osmolality, make sure that the medium is completely covered with oil.

Instruction for use

AM-IVC Medium should be used according to the established procedures and protocols optimized for the individual clinic.

AM-IVC Medium must equilibrate for a minimum of 2 hours in 5-6% CO₂ at 37° C prior to use. Equilibration can also be done overnight.














Fertilization: Oocytes and prepared sperm can be handled/incubated in AM-IVC Medium in preparation of, or during fertilization by IVF/ ICSI. The medium does not contain HEPES. Thus, to maintain a physiological pH, CO₂ incubation prior to use is necessary.

Embryo culture: AM-IVC Medium is a medium for continuous one step embryo culture without media change. It does not need to be renewed or exchanged during culture. Embryos can be cultured from day 1 to blastocyst stage (shorter culture times are possible).

Example: Prepare dishes with 40-60 µl droplets of AM-IVC Medium with an oil overlay. Equilibrate a CO₂ incubator at 37° C and 5-6% CO₂ overnight or for a minimum of 2 hours prior to use. Per droplet, 1-4 COCs can be inseminated by incubation with sperm or denudated oocytes injected (ICSI). Culture embryos in freshly CO₂ equilibrated medium drops.

Embryo transfer: The embryos are prepared and transferred to the uterus in 20-30 µl freshly CO₂ equilibrated AM-IVC Medium. Flush the transfer catheter with AM-IVC Medium prior to use.

Glossary of Symbols*

	5.1.6	Catalog Number
	5.1.5	Batch code
	5.2.2	Sterilized using aseptic processing techniques (filtration)
	5.1.4	Use-by date: Year-Month-Day
	5.3.7	Storage Temperature limits 2-8° C
	5.1.1	Manufacturer
	5.2.8	Do not use if package is damaged
	5.4.3	Consult instructions for use
	5.2.6	Do not re-sterilize
	5.3.2	Keep away from sunlight
		Caution: U.S. Federal law restricts this device to sale by or on the order of a physician. (21CFR 801.109)
	5.4.2	Do not re-use
	5.4.6	Contains human blood or plasma derivatives

*Symbol Reference – ISO 15223-1:2021, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements