

DESCRIPTION

InVitroCare® IVC-ONE™ is a sodium bicarbonate buffered culture medium for fertilization of embryos through day 5/6 of development.

COMPOSITION

Sodium Chloride	Cystine
Magnesium Sulfate	Glutamic Acid
Potassium Chloride	Glycine
Potassium Phosphate	Histidine
Calcium Chloride	Isoleucine
Sodium Bicarbonate	Leucine
Dextrose	Lysine
Sodium Lactate	Methionine
Sodium Pyruvate	Phenylalanine
EDTA	Proline
Sodium Citrate	Serine
Alanyl Glutamine	Threonine
Gentamicin	Tryptophan
Alanine	Tyrosine
Arginine	Valine
Asparagine	Vitamins
Aspartic Acid	Pantothenic Acid

INTENDED USE

InVitroCare® IVC-ONE™ is for use as a culture medium for seamless extended culture of embryos from Day 1 through expanded Blastocyst (Day 5/6)

BUFFER SYSTEM

InVitroCare® IVC-ONE™ uses a sodium bicarbonate buffering system designed for a CO₂ incubator.

STORAGE & CONSERVATION

Store unopened bottles at 2-8°C. Do not freeze or expose to temperatures greater than 39°C. InVitroCare® IVC-ONE™ should be used within 4 weeks of opening when stored at 2-8°C (without protein supplementation).

PRECAUTIONS & WARNINGS

InVitroCare® IVC-ONE™ is intended to be used by reproductive specialists and staff trained in assisted reproductive procedures.

To avoid problems with contamination, handle using aseptic techniques and discard any excess medium that remains in the bottle after the procedure is completed.

Do not use any bottle of InVitroCare® IVC-ONE™ which shows evidence of damage, particulate matter, cloudiness or is not reddish-orange in color. Discard the product in accordance with applicable regulations.

InVitroCare® IVC-ONE™ contains the antibiotic Gentamicin Sulfate. Appropriate precautions should be taken by the physician or medical personnel to ensure that the patient is not sensitized to this antibiotic (patient history). This could lead to an allergic reaction.

CONTRAINDICATION

IVC-ONE™ contains Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic

INSTRUCTIONS FOR USE

InVitroCare® IVC-ONE™ requires protein supplementation, as appropriate, dependent on the phase of processing/growing the gametes and embryos, and pre-equilibration at 37°C in 5-6% CO₂. Loosely cap the bottle of IVC-ONE™ when equilibrating in a CO₂ incubator. Consult your individual laboratory protocols.

The following are recommendations and general procedures for the indications of use for InVitroCare® IVC-ONE™:

Protein Supplementation

When using InVitroCare® Human Serum Albumin (HSA Cat # 2101) a 100 mg/ml solution, use at 5mg/ml. For 10ml of medium, add 0.5ml of HSA solution to 9.5ml of the medium.

Equilibration

InVitroCare® IVC-ONE™ (supplemented with protein) should be pre-warmed to 37°C and equilibrated to the desired pH overnight in a 5-6% CO₂ incubator prior to use. A sufficient volume of protein supplemented medium is required so that oocyte recovery, insemination and embryo culture dishes can be prepared.

FERTILIZATION:

On the day before oocyte retrieval, prepare oocyte collection and insemination dishes with pre-supplemented InVitroCare HTF (Cat # 2001) overlaid with oil and pre-equilibrate overnight to 37°C in a CO₂ incubator. Immediately upon oocyte collection and identification, place oocytes into the oocyte collection dish with pre-equilibrated medium and return to the incubator for the desired period (1-4 hours) prior to insemination by conventional IVF or ICSI.

Conventional IVF (use insemination dishes):

1. It is recommended to aseptically dispense 50,000-100,000/ml motile sperm per micro-droplet containing 1-3 oocytes.
2. Return the insemination dish to the incubator and check for normal fertilization 16-20 hours post insemination. (Appearance of two pronuclei and two polar bodies.)

Intracytoplasmic Sperm Injection (ICSI):

1. Following at least 1 hour post oocyte denuding (and no more than 4 hours following oocyte retrieval), remove denuded oocytes from incubator and inseminate with sperm per standard ICSI protocol for your individual laboratory.
2. Immediately following insemination, place 1-3 inseminated oocytes into a pre-equilibrated insemination dish containing a micro-droplet of pre-supplemented InVitroCare HTF (Cat # 2001). Return the dish to the incubator and check for normal fertilization 16-20 hours post insemination. (Appearance of two pronuclei and two polar bodies.)

EMBRYO CULTURE:

On the day of fertilization (one day prior to fertilization assessment), prepare embryo culture dishes with pre-supplemented IVC-ONE™ overlaid with oil and pre-equilibrate overnight to 37°C in a 5-6% CO₂ incubator.

Following fertilization assessments with the identification of the presence of normal fertilization (two pronuclei and two polar bodies), transfer 2PN zygotes into the pre-equilibrated culture dish containing pre-supplemented IVC-ONE™ previously prepared. It is recommended to allow the embryos to grow in a continuous, uninterrupted culture system without changing medium, until the desired developmental stage is reached (up to day 5/6 of development). If medium change is desired for embryo culture beyond day 3, after 48 hours of embryo culture (of the fertilized embryos), the embryos should be transferred into a new dish of fresh pre-equilibrated IVC-ONE™ (pre-supplemented with protein).

For additional details on the use of these products, each laboratory should consult its own laboratory procedures and protocols which have been specifically developed and optimized for your individual medical program.