

SAGE 1-Step™ GM-CSF with HSA

Product No.:

7701

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a CooperSurgical Company

SAGE 1-Step™ GM-CSF with HSA

Indication for use

The product is intended for *in vitro* culture of human embryos following fertilization until Day 5/6 of development. The media can also be used for embryo transfer.

Composition

Amino acids
Calcium lactate
EDTA
Gentamicin sulphate 10 µg/mL
Glucose
L-glutamine (stable form)
Human Serum Albumin (HSA) 5 mg/mL
Leukine (Sargramostim) GM-CSF 2 ng/mL
Sodium Hyaluronate
Sodium bicarbonate
Sodium pyruvate
Phenol red
Physiological salts

Quality control testing

Sterility tested (Ph.Eur., USP<71>)
GM-CSF: ELISA, TF-1 assay
Osmolality tested 257-273 mOsm/kg (Ph.Eur., USP<785>)
pH tested 7.2-7.4 (Ph.Eur., USP<791>)
Endotoxin tested < 0.15 EU/mL (Ph.Eur., USP<85>)
1-cell MEA: ≥80% blastocysts at 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.

The product 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 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.

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

Caution: All blood products should be treated as potentially infectious. Source material used to manufacture this product was tested and found non-reactive for HBsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore source material has 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.

Instructions for use

1. Equilibrate for a minimum of 2 hours in 5-6% CO₂ at 37°C prior to use. It is recommended that the pH of the medium is measured under laboratory working conditions and the level of CO₂ adjusted to attain the desired pH range for optimal embryo development. The desired pH range for SAGE 1-Step™ GM-CSF is 7.3 ± 0.1.
2. After fertilization, transfer zygotes to fresh pre-equilibrated SAGE 1-Step™ GM-CSF and return the dish to the incubator.
3. The SAGE 1-Step™ GM-CSF has been designed for uninterrupted culture, without media change, until the desired developmental stage of the embryo has been reached.

Embryo transfer

1. The embryos are prepared and transferred to the uterus in 20 to 30 µl of fresh pre-equilibrated SAGE 1-Step™ GM-CSF.
2. Flush the transfer catheter with SAGE 1-Step™ GM-CSF prior to use.