

BlastGen™

Product No.:

1205

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a CooperSurgical Company

BlastGen™

Indication for use

BlastGen™ is for the culture of embryos from the 4-8 cell stage through to the blastocyst stage.

BlastGen™ can also be used for embryo transfer.

Composition

Leukine (sargramostim) GM-CSF 2 ng/mL
Synthetic Serum Replacement (SSR®) (USA:
ART Supplement) (contains Recombinant
Human Insulin)

Human serum albumin (HSA) 5 mg/mL

Gentamicin sulphate 10 µg/mL

Glucose

Sodium pyruvate

Calcium lactate

Physiological salts

Amino Acids

L-glutamine (stable form)

Vitamins

EDTA

Sodium hyaluronate

Sodium bicarbonate

Quality control testing

Leukine (sargramostim) GM-CSF
concentration (ELISA) and potency (TF-1
bioassay)

Sterility tested (Ph.Eur., USP)

Osmolality tested 272-288 mOsm/kg (Ph.
Eur., USP)

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pH tested 7.25-7.45 (Ph.Eur., USP)

Endotoxin tested < 0.15 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.

The product is to be used within 7 days after opening.

Discard excess (unused) media following warming.

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.

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 BlastGen™ for a minimum of 2 hours in 5-6% CO₂ at 37°C prior to use. The time required to achieve full equilibration depends on volume of medium and oil overlay.
2. Following initial culture in EmbryoGen®, wash and transfer embryos to fresh microdrops or wells of BlastGen™. Dishes should be returned to the incubator until blastocyst formation on day 5/6.

Embryo transfer

1. The embryos are prepared and transferred to the uterus in 20 - 30µL pre-equilibrated BlastGen™.
2. Flush the transfer catheter with BlastGen™ or other protein-containing medium prior to use.

It should be determined within individual laboratories as to which medium best suits which procedure.