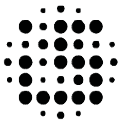


Complete Early Cleavage Medium[®] (ECM[®]) with SSS[™]

Catalog No. 90140

2 x 20 mL

For assisted reproductive procedures.



Irvine**Scientific**[®]

INTENDED USE

Complete Early Cleavage Medium® (ECM®) with SSS™ is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of Complete ECM as a culture medium through day 3 of development.

PRODUCT DESCRIPTION

Complete Early Cleavage Medium with SSS consists of ECM supplemented with 10% Serum Substitute Supplement (SSS), for a total protein concentration of 6 mg/mL. The protein component consists of 5 mg/mL therapeutic grade Human Serum Albumin and 1 mg/mL alpha globulins. This medium contains the antibiotic gentamicin sulfate.

QUALITY ASSURANCE

Complete Early Cleavage Medium with SSS is membrane filtered and aseptically processed according to manufacturing procedures which have been validated to meet a sterility assurance level (SAL) of 10^{-3} .

Each lot of Complete Early Cleavage Medium is tested for:

- Endotoxin by LAL methodology
- Biocompatibility by Mouse Embryo Assay
- Sterility by the current USP Sterility Test <71>

All results are reported on a lot-specific Certificate of Analysis which is available upon request.

BUFFER SYSTEM

Complete Early Cleavage Medium uses Sodium Bicarbonate as a buffering system. This is specifically designed for use in a CO₂ incubator.

DIRECTIONS FOR USE

EQUILIBRATION

Complete Early Cleavage Medium should be warmed to 37°C and equilibrated to the desired pH in a CO₂ incubator prior to use.

Fertilization may be performed by standard *in vitro* fertilization (IVF) in a culture dish containing pre-equilibrated Complete ECM, or by ICSI according to the laboratory's standard procedures. Once fertilization is confirmed, the reproductive specialist should transfer the zygote/embryo into a new dish with pre-warmed equilibrated Complete Early Cleavage Medium for the growth phase. Allow embryo to grow until desired developmental stage (up to 3 days).

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

STORAGE INSTRUCTIONS AND STABILITY

Store the unopened bottles refrigerated at 2° to 8° C.

Do not freeze or expose to temperatures greater than 39°C.

Duration Following Bottle Opening:

The shelf life of the product remains as the expiration date stated on bottle when stored under the recommended conditions of 2° to 8° C.

PRECAUTIONS AND WARNINGS

Do not use any bottle of medium which shows evidence of particulate matter, cloudiness or is not pale orange in color.

CAUTION: Ammonium has been shown to induce retarded embryo development *in vitro*, specifically in the development of the inner cell mass.

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

Not for injection use.

Complete Early Cleavage Medium with SSS contains the antibiotic Gentamicin. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

*Human source material used in the manufacture of this product has been tested by FDA-licensed kits and found to be non-reactive to the antibodies for Hepatitis B surface antigen (HBsAg), antibodies to Hepatitis C (HCV), and antibodies to Human Immunodeficiency Virus (HIV). However, no test method offers complete assurance that products derived from human sources are noninfectious. Handle all human source material as if it were capable of transmitting infection, using universal precautions. Donors of the source material have also been screened for CJD.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

REFERENCES

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