



Quinn's Advantage™ Protein Plus Blastocyst Medium

For laboratory procedures only; other uses must be qualified by the end user.

| Product Description | REF | |
|--|----------|-----------|
| | Number | Unit Size |
| Quinn's Advantage™ ProteinPlus Blastocyst Medium | ART-1529 | 20 mL |

INTENDED USE

This product is intended for in vitro procedures involving the culture of fertilized human embryos from Day 3 to Day 5/6.

PRODUCT DESCRIPTION

This medium is a modification of Human Tubal Fluid (HTF) that was first described by Quinn and colleagues (Fertil Steril. 1984;41:202, 1985;44:493). Modifications to the original formulation include the addition of selected nonessential and essential amino acids, taurine, sodium citrate, MEM vitamins, and the presence of lactate in the form of calcium lactate.

This product contains 10 mg/L of gentamicin, an aminoglycoside antibiotic.

PRECAUTIONS AND WARNINGS

Do not use medium that shows evidence of particulate matter, cloudiness, or is not rose colored. To avoid problems with contamination, handle using aseptic techniques and discard any excess product that remains in the bottle or vial after procedure is completed.

This product contains 5 mg/mL serum protein substitute.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when testing for antibodies to HIV-1/HIV-2, HCV and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents. Donors of the source material have been screened for Creutzfeldt-Jacobs disease (CJD). Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of CJD is also considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

Note: Embryo is considered a general term. More precisely, SAGE™ considers the period of time initiating when a single diploid cell results from the fusion of male and female genome resulting in zygote formation with subsequent development from repeated mitotic divisions forming a solid mass or morula (typically day 4-5) and after which a fluid-filled cavity develops resulting in blastocyst formation (typically day 5-6) ending with embryo implantation that begins the end of the first week and is completed by the end of the second week post conception.

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

This product contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

QUALITY ASSURANCE

One-cell MEA tested and passed with 80% or greater blastocyst. USP Endotoxin tested and passed with <1 EU/mL.

A Certificate of Analysis is available upon request.

DIRECTIONS FOR USE

This is the preferred medium for in vitro procedures involving the culture of fertilized human embryos from Day 3 to Day 5/6. We also recommend the use of Quinn's Advantage™ Protein Plus Fertilization (HTF) Medium (REF #1520) for fertilization of oocytes, and Quinn's Advantage™ Protein Plus Cleavage Medium (REF #1526) for culture from Day 1 to Day 3. The media require no protein supplement.

Each laboratory should make its own determination of which medium to use for each particular procedure.

STORAGE INSTRUCTIONS AND STABILITY

Store unopened containers refrigerated at 2 °C to 8 °C. Warm to incubator (37 °C) temperature and equilibrate with desired atmosphere containing 5% to 6% CO₂ prior to use. Do not freeze or expose to temperatures greater than 39 °C.

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

In order to ensure optimal performance, we strongly recommend measuring the pH of the medium under laboratory working conditions and adjusting the level of CO₂ used to attain the desired pH range for optimal embryo development. The desired pH range for Quinn's Advantage™ Protein Plus Blastocyst Medium is 7.3 ± 0.1. Reports from some users recommend using an atmosphere containing approximately

6% CO₂ to attain a pH close to 7.25.

The product is stable until the expiration date shown on the label.

- Remove desired volume of product using aseptic procedures.
- Once removed, do not return any volume of product to the original container.
- Do not use if the product becomes discolored, cloudy, turbid, or shows any evidence of microbial contamination.

RELATED PRODUCTS

ART-1520 Quinn's Advantage™ Protein Plus Fertilization Medium









ART-1526 Quinn's Advantage™ Cleavage Medium

SAGE™ In Vitro Fertilization™ has a full line of products for the Reproductive Medicine Specialist. Please call or write for specific information or to receive a copy of our current catalog. For technical questions, or to reach our Customer Service Department, call the SAGE™ Support Line.

Quinn's Advantage™ Protein Plus is a trademark of CooperSurgical, Inc.

**Call the SAGE™ SUPPORT LINE:
In the U.S.: (800) 243-2974
International: (203) 601-9818**

EXPLANATION OF SYMBOLS

-  REF Catalog Number
-  LOT Batch Code
-  Use By (year, month, day)
-  Do Not Reuse
-  Temperature Limitation
-  Aseptic Technique Sterilization Membrane Filtered (SAL 10⁻³)
-  **ATTENTION:** See instructions for use.
-  Manufacturer

RX ONLY U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

 CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611 USA

Customer Service:
E-mail: customer.service@origio.com
Tel: +45 46 79 02 02 Fax: +45 46 79 03 02