

Quinn's Advantage™ SPS Serum Protein Substitute

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

Product Description	Catalogue Code	Unit Size
Quinn's Advantage™ SPS Serum Protein Substitute	RM-ART-3010	12 x 12mL
Quinn's Advantage™ SPS Serum Protein Substitute	RM-ART-3011	1 x 100mL

INTENDED USE

A variety of protein supplements have been added to ART media, ranging from maternal serum to preparations of albumin purified to varying degrees to plasma expanders such as Albuminar, Plasmatein and Plasmanate (Weathersbee *et al*, 1995; Adler *et al*, 1993). The routine functions of albumin in tissue culture include trace metal binding, osmotic stability and carrier activity. In addition to these beneficial effects of albumin on cellular physiology, it is thought that the presence of α - and β -globulins in certain preparations of plasma expanders provides additional benefits for the culture of preimplantation mammalian embryos *in vitro* (Pool & Martin, 1994). These additional benefits have been ascribed to the high content of polyhydroxy domains present in the α - and β -globulins producing a weak gel-like environment that enhances embryonic development (Weathersbee *et al*, 1995). A protein supplement and possibly any bound embryotrophic components associated with it is still necessary, however, to enhance blastocyst production *in vitro* (Pool *et al*, 2000). Quinn's Advantage® SPS is a protein supplement that provides the beneficial growth-promoting activities of albumin α - and β -globulins.

DESCRIPTION

Product contains 50mg/mL total protein (weight/volume) in saline solution; the protein is in the form of 88% normal human serum albumin and 12% α - and β -globulins. Each lot is tested for pH (7.4 ± 0.2), osmolality (280 ± 10 mOsm/kg water), sterility (no detectable contamination), and biocompatibility (>80% mouse zygote development to blastocysts). All donors used in its manufacture were individually tested and found to be non-reactive for hepatitis B surface antigen (HB_sAG) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV) by approved testing methods.

STORAGE INSTRUCTIONS AND STABILITY

Store unopened containers refrigerated at 2-8°C. Warm to ambient or incubator (37°C) temperature prior to use. Do not freeze or expose to temperatures greater than 39°C. The product is stable until the expiration date shown on the label or within 30 days of the Date of First Use provided that proper aseptic procedures have been observed by the user:

- Remove desired volume of product using aseptic procedures
- Once product has been removed from the original container, reseal the container to ensure a tight seal. Write the date the product was first opened on the product label. Do not use product longer than 30 days after opening the container.
- Once removed, do not return any volume of product to the original container.
- Once the product has been opened, store the sealed container at 2-8°C
- Do not use if the product becomes discoloured, cloudy, turbid, or shows any evidence of microbial contamination.

One-cell MEA tested and passed with 80% or greater blastocyst. USP Endotoxin gel clot tested and passed with <1 EU/ml. A Certificate of Analysis is available for this product.

DIRECTIONS FOR USE

For sperm preparation and embryo culture: Use at 10% (v/v). For 10mL of medium, add 1.0mL of SPS solution to 9.0mL of bicarbonate-buffered medium (eg, Quinn's Advantage® Fertilization Medium) or Quinn's Advantage® Cleavage Medium. *NOTE:* for washed sperm samples for IUI use QUINN'S™ Sperm Washing Medium which already contains 5mg/mL Human Serum Albumin.

For embryo transfer: Use at 50% (v/v). For 10mL of medium add 5.0mL of SPS solution to 5.0mL of Quinn's Advantage® medium with HEPES.

For embryo cryopreservation: Use at 20% (v/v). For 10mL of medium add 2.0mL of SPS solution to 8.0mL of Quinn's Advantage® medium with HEPES.

For micromanipulation (ICSI and assisted hatching): Use at 10% (v/v). For 10mL of medium, add 1.0mL of SPS solution to 9.0mL of Quinn's Advantage® Medium with HEPES.

Laboratories may establish through appropriate testing that higher or lower concentrations than those suggested above are optimal for specific applications.

NOT INTENDED FOR INJECTION BY USUAL PARENTERAL ROUTES IN HUMANS OR ANIMALS
Each laboratory should make its own determination of which medium and protocol to use for each particular procedure.

Information on specific aspects of IVF, embryo culture, and cryopreservation is available in our publication "IVF Laboratory Policy and Procedure Manual".



PRECAUTIONS AND WARNINGS

Do not use product that shows evidence of particulate matter, cloudiness, or is not rose colored.

To avoid problems with contamination, aseptic technique should be used to remove aliquots of product from the container. Do not mix components of one container with another. Discard minimal amounts of excess product remaining in the bottle.

This product contains albumin, a derivative of human blood. All donors used in its manufacture were individually tested and found to be nonreactive for hepatitis B surface antigen (HB_sAG) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV) by approved testing methods. Donors of the source material have been screened for Creutzfeldt Jakob 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.

RELATED PRODUCTS

SAGE Assisted Reproduction Products™ has a full line of products for the Reproductive Medicine Specialist. Please call or write for specific information, technical questions, customer support, or to receive a copy of our current price list.

Your UK distributor for SAGE products is:

Rochford Medical Ltd, PO Box 1311, Oxford OX4 4WE Tel: 01865 772420 Fax: 01865 715598

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REFERENCES

Adler et al. Plasmanate as a medium supplement for in vitro fertilization. *J Assisted Reprod Genetics*. 1993;10:67-71.

Pool & Martin. High continuing pregnancy rates after in vitro fertilization –embryo transfer using medium supplemented with a plasma protein fraction containing α -and β -globulins. *Fertil Steril*. 1994;61:714-719.

Pool et al. The role of macromolecules in human blastocyst production in vitro. In: *Program of the International Symposium on ART and the Human Blastocyst*; 2000; Dana Point, Calif.

Weathersbee et al. Synthetic Serum Substitute (SSS): a globulin-enriched protein supplement for human embryo culture. *J Assisted Reprod Genetics*. 1995;12:354-360.