Quinn's Advantage® SPS
Serum Protein Substitute

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

<table>
<thead>
<tr>
<th>Product Description</th>
<th>REF Number</th>
<th>Unit Size</th>
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<tbody>
<tr>
<td>Quinn's Advantage® SPS</td>
<td>ART-3010</td>
<td>12 X 12 mL</td>
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<tr>
<td>Quinn's Advantage® SPS</td>
<td>ART-3011</td>
<td>100 mL</td>
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</tbody>
</table>

INTENDED USE
A variety of protein supplements have been added to ART media, ranging from maternal serum 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 and α- and β-globulins.

DESCRIPTION
Product contains 50 mg/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 nonreactive for hepatitis B surface antigen (HBsAg) 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°C to 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.

A. Remove desired volume of product using aseptic procedures.
B. Once product has been removed from the original container, resell 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.
C. Once removed, do not return any volume of product to the original container.
D. Once the product has been opened, store the sealed container at 2°C to 8°C.

E. Do not use if the product becomes discolored, 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 10 mL of medium, add 1.0 mL of SPS solution to 9.0 mL of bicarbonate-buffered medium (eg, Quinn's Advantage® Fertilization Medium (REF #1020/1021) or Quinn’s Advantage® Cleavage Medium (REF #1026/1027). Use at 50% (v/v). For 10 mL of medium, add 5.0 mL of SPS solution to 5.0 mL of Quinn’s Advantage® Medium with HEPES (REF #1023/1024).

For embryo transfer: Use at 50% (v/v). For 10 mL of medium, add 2.0 mL of SPS solution to 8.0 mL of Quinn’s Advantage® Medium with HEPES (REF #1023/1024).

For embryo cryopreservation: Use at 20% (v/v). For 10 mL of medium, add 2.0 mL of SPS solution to 8.0 mL of Quinn’s Advantage® Medium with HEPES (REF #1023/1024).

For micromanipulation (ICSI and Assisted Hatching): Use at 10% (v/v). For 10 mL of medium, add 1.0 mL of SPS solution to 9.0 mL of Quinn’s Advantage® Medium with HEPES (REF #1023/1024).

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

NOT INTENDED FOR INJECTION 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 Product Catalog (REF #80572).

PRECAUTIONS AND WARNINGS
Do not use product that shows evidence of particulate material.

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 (HBsAg) 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.

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


Call the SAGE SUPPORT LINE at: 1-800-243-2974 or 1-203-601-5200