



## Dextran Serum Supplement (DSS)

Catalog No. 9301

100 mL, 12 x 12 mL Kits

For assisted reproductive procedures.

### Glossary of Symbols\*:



Catalog Number



Lot Number



Sterilized using aseptic processing techniques (filtration)



Expiration:  
Year - Month - Day



Caution, consult accompanying documents



Consult instructions for use



Storage Temperature  
2-8°C



Do not resterilize



Do not use if package is damaged



Manufacturer



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

\*Symbol Reference - EN ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labeling.

## INDICATION FOR USE

Dextran Serum Supplement (DSS) is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of DSS as a supplement for culture medium, not for use as an injectable product.

## DEVICE DESCRIPTION

DSS consists of human serum albumin from therapeutic-grade source material (50 mg/mL) and dextran (20 mg/mL) in a saline solution.

## COMPOSITION

<u>Protein, Hormones, and Growth Factors</u>	<u>Other</u>
Human Serum Albumin	Dextran WFI Quality Water

## QUALITY ASSURANCE

DSS is a protein supplement which 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 DSS Dextran Serum Supplement is tested for:

- Endotoxin by Limulus Amebocyte Lysate (LAL methodology)
- Biocompatibility by Mouse Embryo Assay (one-cell)
- Sterility by the current USP Sterility Test <71>

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

## DIRECTIONS FOR USE

General laboratory practice includes protein supplementation when using various culture media (such as HTF, Modified HTF, P-1, ECM, MultiBlast Medium, etc.) for gamete and embryo procedures. The amount of protein supplementation may vary among laboratories and is dependent on the phase of processing/growing the gametes and embryos. Consult your individual laboratory protocols.

Warm the protein supplemented media to 37°C and equilibrate to desired pH in a CO<sub>2</sub> incubator prior to use.

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

## 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.

DSS is stable until the expiration date shown on the bottle or vial label when stored as directed.

## PRECAUTIONS AND WARNINGS

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

Do not use any bottle of medium which shows evidence of particulate matter or extreme cloudiness.

Do not use any bottle in which the sterile packaging has been compromised.

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

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 Cruetzfeldt-Jakob Disease (CJD).