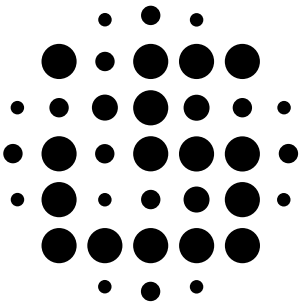
Modified Sperm Washing Medium

Catalog No. 9984 **100 mL, 12 x 12 mL/Box**

For sperm washing procedures.



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INTENDED USE

Modified Sperm Washing Medium is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of this medium for sperm washing.

PRODUCT DESCRIPTION

This medium is a modification of Modified Human Tubal Fluid supplemented with protein and containing the following components:

Sodium Chloride
Potassium Chloride
Magnesium Sulfate, Anhydrous
Potassium Phosphate, Monobasic
Calcium Chloride, Anhydrous
Sodium Bicarbonate
HEPES
Glucose
Sodium Pyruvate
Sodium Lactate
Phenol Red
Bovine Albumin

QUALITY ASSURANCE

Modified Sperm Washing Medium is a culture medium 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 Modified Sperm Washing Medium 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.

BUFFER SYSTEM

Modified Sperm Washing Medium uses a buffering system composed of a

21 mM HEPES (N-2-Hydroxyethylpiperazine-N'-2-ethanesulfonic acid) and 4 mM Sodium Bicarbonate combination. This buffering system provides optimum pH maintenance over the physiologic range (7.2 to 7.4) and does not require the use of a CO_2 incubator.

PROTEIN SUPPLEMENTATION

Modified Sperm Washing Medium contains 5 mg/mL bovine albumin.

DIRECTIONS FOR USE

The following is a general procedure for washing sperm from its surrounding seminal fluid.

1. Bring medium to room temperature or 37°C.

   (NOTE: Modified Sperm Washing Medium should be tightly capped if warmed in a CO_2 incubator to avoid pH levels of 7.0 or less.)

2. Allow the semen to liquefy at room temperature for 20 to 30 minutes.

3. Using aseptic techniques, transfer the liquefied semen to a sterile 10 mL conical centrifuge tube and add 2 to 3 volumes of room temperature Sperm Washing or Modified Sperm Washing Medium (for example, a 2 mL semen sample requires 4 to 6 mL of medium). Should the volume of the sperm medium mixture be greater than 5 mL, divide into two sterile tubes. By minimizing the volume per tube to 4 - 6 mL, the recovery of sperm will be maximized. Samples having high viscosity may require a further processing to ensure total sperm recovery. (See Special Processing Considerations).

4. Centrifuge the tubes at ambient temperature for 10 minutes using a g force of 200 - 300 x g.

5. Using a sterile pipette, remove and discard the supernatant above the "sperm pellet" by aspiration. The sperm should then be resuspended by gently flicking the tube externally with the index finger. The sperm should then be resuspended by gently flicking the tube externally with the index finger. (Note: Do not use a vortex mixer for this step). Resuspend the

sperm in 1 to 2 mL of fresh medium, recap and gently mix by inversion. Samples which were fractionated for the first centrifugation step should now be recombined into one tube.

6. Recentrifuge as in Step 4.

7. Using a sterile pipette, remove and discard the supernatant and resuspend the sperm pellet gently by manual agitation. Add fresh medium to a final volume of 0.5 mL. The sperm are ready for assisted reproductive procedures. (Note: The total volume of the nongravid uterus is 0.25 - 0.50 mL).

SPECIAL PROCESSING CONSIDERATIONS

Processing the highly viscous sample:

Some samples are naturally highly viscous even after liquefaction. These samples have the consistency of heavy syrup and may be among the most difficult to process.

1. After the medium is added to an ejaculate, aspirate and expel the mixture gently using an 18 gauge needle and syringe. This will “shear” some of the viscous mucous.

2. Limit the amount of medium-sperm mixture from Step 1 to 5 mL per centrifuge tube for the first centrifugation step.

3. If after preprocessing the sample with the needle and syringe (Step 1), the sperm do not “pellet” in a normal manner (the sperm will appear as a “cloudy fiber” attached to the bottom of the centrifuge tube), carefully aspirate as much of the supernatant as possible without disrupting the “cloudy sperm fiber” using a sterile needle and syringe. This can be done by keeping the beveled edge of the needle firmly against the wall of the centrifuge tube and slowly start aspiration from the top of the tube downward. When as much of the supernatant as possible has been removed, add 2 or 3 mL of fresh medium. Repeat the process of drawing the mixture through the 18 gauge needle and syringe. Recentrifuge the mixture. The sperm should pellet normally after the second processing.

4. On subsequent sample collections, the patient should be requested to produce a split ejaculate which will minimize the viscosity in the sperm rich portion of the sample.

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 or vials refrigerated at 2º to 8ºC.

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

When stored as directed, Modified Sperm Washing Medium is stable until the expiration date shown on the bottle label.

PRECAUTIONS AND WARNINGS

This device is intended to be used by staff trained in assisted reproductive procedures that include the indicated application for which the device is intended.

Do not use any bottle or vial of medium which shows evidence of particulate matter, cloudiness or is not a pale salmon color. The optical properties of the bovine albumin makes the medium appear much paler in color than our other products.

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

Modified Sperm Washing Medium does not contain antibiotics. Antibiotic supplementation may be added just prior to use. Appropriate precautions should be taken to ensure that the patient is not sensitized to the antibiotic of choice.

Hypersensitivity reactions to BSA have been reported in previously sensitized patient undergoing IUI (Fertil Steril 56:1188, 1991).

The bovine source material in this product is derived from animals of U.S. origin.

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

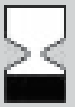
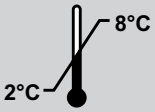
***Human blood derivatives used in the manufacture of this product has been tested by FDA licensed kits, and found to be non-reactive for the Hepatitis B surface antigen (HBsAg), antibodies to Hepatitis C (HCV) and antibodies to Human Immunodeficiency Virus (HIV). However, no test method offers complete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

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

REFERENCES

Quinn, P. et. al.: Successful human in-vitro fertilization using a modified human tubal fluid medium lacking glucose and phosphate ions. Fert Steril 1995; 63: 922-24.

Symbols:

REF	Catalog Number
LOT	Lot Number
STERILE A	Sterilized using aseptic processing techniques (filtration)
	Expiration: Year - Month - Day
	Caution: See instructions for use
	Storage Temperature

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