

ENHANCE Sperm Wash Medium with Gentamicin

Reference: 15262, 15261, 15263

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

INTENDED USE

Enhance Sperm Wash Medium with Gentamicin (EWG) was specifically developed for *in vitro* procedures involving sperm washing and incubation, (Seminars Reprod Endocrinol 5:23, 1987). This medium is a modification of HEPES-buffered Human Tubal Fluid (HTF) (Fertil Steril 41:202, 1984; 44:493, 1985). Enhance Sperm Wash Medium with Gentamicin is used for *in vitro* fertilization, intrauterine insemination (IUI) and procedures involving sperm manipulation in an air environment.

DESCRIPTION

Enhance Sperm Wash Medium with Gentamicin is an aqueous, isotonic, complex mixture of organic and inorganic salts and simple carbohydrates, at neutral pH intended for *in vitro* mammalian cell culture. The medium contains 5 mg/mL human serum albumin, 0.010 mg/mL gentamicin and 0.003 mg/mL phenol red as a pH indicator.

Enhance Sperm Wash Medium with Gentamicin uses a buffering system composed of a 21 mM HEPES and a 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 CO₂ incubator. Washed sperm suspended in HEPES-buffered medium have been reported to produce a significantly higher pregnancy rate in IUI than when a bicarbonate-buffered medium was used (Fertil Steril 56:540, 1991).

COMPONENTS

Sodium Chloride	HEPES	Glutamine
Potassium Chloride	Glucose	Alanylglutamine
Magnesium Sulfate	Sodium Pyruvate	Gentamicin
Potassium Phosphate, Anhydrous	Calcium Lactate, Pentahydrate	Non-Essential Amino Acids
Sodium Bicarbonate	EDTA	Phenol Red
		Human Serum Albumin

PRECAUTIONS AND WARNINGS

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

- For external use only, not for injection.
- Do not use the product if:
 - it becomes discolored (if medium contains phenol red), cloudy, or shows any evidence of microbial contamination;
 - seal of the container is opened or defect when the product is delivered;
 - expiry date has been exceeded.
- Do not freeze before use.
- Do not re-sterilize after opening.
- Product which include gentamicin should not be used on a patient that has a known allergy to gentamicin or similar antibiotics.
- Depending on the number of procedures that will be performed on one day, remove the required volume of medium under aseptic conditions in an appropriate sterile recipient. This is in order to avoid multiple openings/ warming cycles of the medium. Discard excess(unused) media.
- Keep in its original packaging until the day of use.

STORAGE / DISPOSAL INSTRUCTIONS

- Store Enhance Sperm Wash Medium with Gentamicin (EWG) medium between 2-25 °C. Once opened: store between 2-8 °C.
- Store EWG medium between 2-8 °C.
- The products can be used up to 7 days after opening, when sterile conditions are maintained, and the products are stored at 2-8 °C.
- Keep away from (sun)light.
- The products are stable after transport (max. 5 days) at elevated temperatures (≤ 37 °C).
- The devices need to be disposed in accordance with local regulations for disposal of medical devices.

DIRECTIONS FOR USE

Each laboratory should make its own determination of suitability for use in each particular procedure. To be used by appropriately trained personnel. This is the preferred medium for procedures performed in an atmosphere of air not involving the use of a CO₂ incubator. Such procedures include gamete washing, oocyte recovery, micromanipulation, embryo transfer and cryopreservation.

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PROTEIN SUPPLEMENTATION

Enhance Sperm Washing Medium contains 5 mg/mL human serum albumin. All donors used in its manufacture were individually tested by approved testing methods and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg) and antibodies to Hepatitis C (HCV) and Human Immunodeficiency Virus (HIV). Experimental evidence (Transfusion 26:210, 1986) has indicated that the cold ethanol fractionation process (Cohn) used in human albumin manufacture effectively inactivates the HIV virus (formerly termed human lymphotropic virus, type III HTLV-III).

PRODUCT SPECIFICATIONS

A complete Certificate of Analysis is provided with every lot of Enhance Sperm Wash Medium with Gentamicin.

RELATED PRODUCTS

Vitrolife has a full line of products for the Reproductive Medical Specialist. For more information or technical support please visit our website at www.vitrolife.com or contact Customer Service at (866) 848-7687. Email contact and information at order.us@vitrolife.com.

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