

FUJIFILM



Irvine**Scientific**

**Refrigeration Medium -
Test Yolk Buffer (TYB)
with Gentamicin**

Catalog No. 90129

20 x 5 mL Kits

For assisted reproductive technology (ART) procedures.

INDICATION FOR USE

Refrigeration Medium is intended for refrigeration of human semen for use in assisted reproductive procedures.

DEVICE DESCRIPTION

Component Specification

TES.....	176 mM
Tris.....	80 mM
Dextrose.....	9 mM
Gentamicin Sulfate.....	10 µg/mL
Heat-inactivated egg yolk obtained from specific pathogen free (SPF) laying flocks.....	20 % (v/v)

COMPOSITION

<u>Copolymer Surfactant</u>	<u>Antibiotics</u>
TES Buffer	Gentamicin Sulfate
<u>Buffers</u>	<u>Energy Substrates</u>
Trizma Base	Dextrose
<u>Protein</u>	<u>Water</u>
Chicken Egg Yolk	WFI Quality

QUALITY ASSURANCE

Refrigeration Medium 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 Refrigeration Medium is tested for:

- Endotoxin by Limulus Amebocyte Lysate (LAL) methodology
- Sperm Motility Recovery Assay
- 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

1. Semen is collected following a two to three day abstinence period.
2. Sample is allowed to liquefy at 37°C for 30 minutes.
3. One vial of medium is thawed and brought to 37°C.
4. The liquefied sample is transferred to a sterile, 15 mL, conical centrifuge tube, the volume determined and medium added dropwise until a 1:1 sample:medium ratio is achieved.

Note: Samples displaying high viscosity may require the additional step of repeated pipetting or passage

through an 18 gauge needle to ensure thorough mixing.

5. The sample-medium mixture is placed in a beaker or other suitable container of 37°C water.

6. The container is refrigerated at 2°C to 5°C to allow a slow cooling of the mixture (0.5°C/minute) for a maximum of 96 hours.

7. See references 2, 3 and 5 for exact methodological details.

Note: Steps 1-4 can be performed at room temperature.

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 at -10° C or colder.

Do not expose medium to repeated freeze-thaw cycles. If smaller aliquots are desired, thaw the product, aliquot into sterile labeled containers and freeze until time of use.

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

Discard after use.

PRECAUTIONS AND WARNINGS

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

The user facility of this device is responsible for maintaining traceability of the product and must comply with national regulations regarding traceability, where applicable.

Refrigeration Medium will appear opaque. Do not use any bottle of medium which shows evidence of particulate matter or is not yellow in color.

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.

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

Information on known characteristics and technical factors that could pose a risk if the product were to be re-used have not been identified therefore the product is not to be used following the initial use of the container.

CONTRAINDICATION

Product contains Gentamicin Sulfate and egg yolk protein. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic or egg yolk protein.

Glossary of Symbols*:

REF

Catalog Number

LOT

Lot Number

STERILE A

Sterilized using aseptic processing techniques
(filtration)



Expiration:
Year - Month - Day



Caution, consult accompanying
documents



Consult instructions for use or
consult electronic instruction for use



Storage Temperature
below -10°C



Do not re-use



Do not re-sterilize



Do not use if package is damaged and
consult instruction for use



Date of manufacture



Manufacturer

Rx Only

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.



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