

Freezing Medium - TEST Yolk Buffer (TYB) with Glycerol and Gentamicin

Catalog No. 90128

100 mL, 20 x 5 mL Kits

For cryopreservation of semen.

Fuer kryokonservierung des samens.

Per crioconservazione di sperma.

Para crioconservación de semen.

Pour la cryoconservation du sperme.

Para crioconservação de sêmen.

Για κρυοσυντήρηση σπέρματος.

Kryoprezervace lidského spermatu.

Til cryopreserving af sæd.

Siemennestein krysäilöntään.

Spermas kriokonservacijai.

Voor cryopreservatie van semen.

Dia echrony kriogenicznej nasienia.

Pentru crioconservarea spermei.

För kryopreservation av sädesvätska.

Seemnevedeliku külmutatult säilitamiseks.

Ondó krioprezervációjára.

Skirta séklos kriokonservavimui.

Semenin kriyoperzervasyonu için.

Symbols:



Catalog Number



Lot Number



Sterilized using aseptic processing techniques (filtration)



Expiration:
Year - Month - Day



Caution: See instructions for use



Storage Temperature



Manufacturer



CE Mark



MPIE Schutweg 13a
5145 NP Waalwijk,
The Netherlands

ENGLISH

INTENDED USE

Freezing Medium is intended for cryopreservation of semen for use in assisted reproductive procedures.

PRODUCT DESCRIPTION

Component	Specification
Formulation: (see references 3 and 4)	
Major Components:	
TES, Tris, Sodium Citrate and Fructose	
Gentamicin Sulfate.....	10 µg/mL
Glycerol.....	12 % (v/v)
Heat-inactivated egg yolk obtained from specific pathogen free (SPF) laying flocks....	20 % (v/v)

COMPOSITION:

Sodium Citrate	Chicken Egg Yolk
TES Buffer	Fructose
Trizma base	Gentamicin
Glycerol	

QUALITY ASSURANCE

Freezing 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 Freezing Medium Freezing Medium is tested for:

- Endotoxin by Limulus Amebocyte Lysate (LAL) methodology
- Sperm Cryo Survival 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). After 90 minutes, the sample is ready to freeze in straws, vials or pellets using traditional procedures.

Note: Steps 1-5 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. When stored as directed, Freezing Medium is stable until the expiration date shown on the bottle or vial label.

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.

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

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

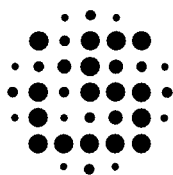
To avoid problems with contamination, handle using aseptic techniques and discard any excess medium that remains in the bottle or vial after the procedure is completed.

Freezing Medium contains:

- Gentamicin Sulfate Antibiotic
- Egg yolk protein

Appropriate precautions should be taken to ensure that the patient is not sensitized to these components.

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



IrvineScientific®