

PRODUCT INFORMATION

SpermTec G-100

Catalogue no.

Without Phenol red and Gentamicin

ST-100-10	10 ml
ST-100-50	50 ml
ST-100-100	100 ml
ST-100-250	250 ml
ST-100-500	500 ml

Catalogue no.

With Phenol red and Gentamicin

ST-100-10RG	10 ml
ST-100-50RG	50 ml
ST-100-100RG	100 ml
ST-100-250RG	250 ml
ST-100-500RG	500 ml

SpermTec G-80

Catalogue no.

With Gentamicin without Phenol red

ST-80-10	10 ml
ST-80-50	50 ml
ST-80-100	100 ml
ST-80-250	250 ml
ST-80-500	500 ml

Catalogue no.

With Phenol red and Gentamicin

ST-80-10RG	10 ml
ST-80-50RG	50 ml
ST-80-100RG	100 ml
ST-80-250RG	250 ml
ST-80-500RG	500 ml

SpermTec G-45

Catalogue no.

With Gentamicin without Phenol red

ST-45-10	10 ml
ST-45-50	50 ml
ST-45-100	100 ml
ST-45-250	250 ml
ST-45-500	500 ml

Catalogue no.

With Phenol red and Gentamicin

ST-45-10RG	10 ml
ST-45-50RG	50 ml
ST-45-100RG	100 ml
ST-45-250RG	250 ml
ST-45-500RG	500 ml

Application

SpermTec® is a silane coated silica particles colloidal suspension medium for semen preparation in IUI, IVF, ICSI.

Composition

SpermTec® is composed of silica particles covalently coated with silane suspended in HEPES buffered EBSS (Earle's balanced salt solution).

SpermTec® is an isotonic gradient with a density of +/- 1.12g/ml.

Material not included

- 3cc syringes with 1½" 21g needle
- SpermTec® Wash medium
- Centrifuge (must be able to operate for up to 30 minutes at 100g)
- Optional: incubator or water bath at 37°C
- LAF Bench (ISO Class 5)

Quality Control

- pH: 7,20 – 7,90
- (Release criteria: 7,20 – 7,60)
- Osmolality: 300 - 330 mOsm/kg (100% stock solution)
310 - 340 mOsm/kg (45% gradient)
310 - 330 mOsm/kg (80% gradient)
- Endotoxin: < 0,5 EU/ml
- Sterility: SAL 10⁻³
- Density: 1,1150 – 1,1250 g/ml (100% stock solution)
1,0970 – 1,1070 g/ml (80% gradient)
- Viscosity: < 1.75 cP (100% stock solution)
< 1.65 cP (80% gradient)
- Sperm Survival Test ≥ 80% (after 45 minutes exposure of density selected spermatozoa to the test medium)
- Not MEA tested
- Certificate of Analysis and MSDS are available upon request.

Sterility

SpermTec® is sterilized by using aseptic processing techniques. **STERILE A**

Calculation of G-Forces

Use the following formula in order to calculate the g-force for your centrifuge:

$$g = 1.118 \times r \times \text{rpm}^2$$

OR

$$\text{rpm} = \text{Square root } \{g / (1.118 \times r)\}$$

r = radius of centrifuge in mm

rpm = rotations per minute / 1000

Example 1

r = 100 mm

rpm = 1800 rotations per minute

$$g = 1.118 \times 100 \times 3.24 = \mathbf{362g}$$

spermtec[®] 100-80-45

Example 2

r = 100 mm

g = 350g

rpm = $\text{SQR} \{350 / (1.118 \times 100)\} = 1.77$

rpm = **1770 rotations per minute**

Precautions and Warnings

Always work under hygienic conditions (LAF-bench ISO Class 5) to avoid possible contamination.

Always wear protective clothing when working with specimens.

Handle specimens as if capable of transmitting HIV or hepatitis.

All human organic material should be considered potentially infectious.

In case the product contains gentamicin, appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

Pre-use checks

Do not use if the seal on the bottle is broken or open when the product is delivered.

Do not use if the product shows any signs of microbial contamination or has changed colour.

Mix the density gradient bottle by 5 bottle inversions before use.

Storage & Conservation

Store products without gentamicin: between 2°-25°C before first use. After opening store between 2°-8°C.

Store products with gentamicin: between 2°-8°C.

Use aseptic working procedures during opening and closing of the bottles ((LAF-bench, ISO Class 5). Avoid freezing.

Do not use after expiry date.

Do not freeze.

After opening the container, do not use the product longer than 7 days. Sterile conditions must be maintained and product must be stored at 2° - 8° C.

Cannot be re-sterilized after opening.

Stable after transport (up to 5 days) at elevated temperatures ($\leq 37^\circ\text{C}$).

Technical Support



Gynotec B.V.
Jonckherenhof 7 – 6581 GC Malden – The Netherlands
Phone (+31) 24 3586582 – Fax (+31) 24 3581355
info@gynotec.nl – www.gynotec.com


0344

Distributor:

Instructions for use

Instructions preparation of gradients

Dilution of SpermTec® G-100

We recommend to prepare a two-layer gradient system (e.g. 45%-90% or 40%-80%) starting from SpermTec® Stock Solution 100%. If preferred a multi-layer gradient system can also be used (e.g. 45%-70%-90%).

Preparing a 90% gradient:

Mix 1 part SpermTec® Wash with 9 parts SpermTec® Stock Solution 100%.

Preparing a 45% gradient:

Mix 5.5 parts SpermTec® Wash with 4.5 parts SpermTec® Stock Solution 100%.

Alternatively, any HEPES-buffered EBSS-based medium can be used for the preparation of the gradients.

Note: Prepare and repack the gradients under sterile conditions (e.g. LAF bench, ISO Class 5). Prepare the gradients max 24 hours prior to use. Mix well after diluting the SpermTec® Stock Solution 100%.








Instructions fresh semen samples

1. Bring all components of the system and samples to room temperature or 37°C.
2. Place 2.5ml SpermTec® upper layer (40% - 45%) into a sterile disposable centrifuge tube.
3. Place 2.5ml SpermTec® lower layer (80% - 90%) beneath the upper layer by using a 3cc syringe with a 1½" 21g needle. The two layers must be distinctly separated. Do this by placing the tip of the needle on the bottom of the test tube and slowly dispense the SpermTec® lower layer. The two layer gradient remains stable for up to two hours.
4. Carefully place up to 2.5ml of liquefied semen onto the upper layer by using a transfer pipette or syringe.
5. Centrifuge at 350g to 400g for 15 to 18 minutes. In case you do not see a visible pellet afterwards continue the procedure with a second centrifugation for 3 to 5 minutes.
6. Aspirate the supernatant down to the pellet.
7. Add with a syringe 2-3ml SpermTec® Wash medium and re-suspend the pellet.
8. Centrifuge at 300g for 8 to 10 minutes. A higher sperm concentration will require the maximum 10 minutes centrifugation to ensure a complete and thorough sperm wash.
9. Aspirate the supernatant down to the pellet and repeat steps 7 and 8.
10. Aspirate the supernatant and resuspend with a suitable volume of appropriate medium.

Instructions frozen semen samples

1. Bring all components of the system and samples to room temperature or 37°C.
2. Place 1.0ml SpermTec® upper layer (e.g. 45%) into a sterile disposable centrifuge tube.
3. Place 1.0ml SpermTec® lower layer (e.g. 80%) beneath the upper layer by using a 3cc syringe with a 1½" 21g needle. The two layers must be distinctly separated. Do this by placing the tip of the needle on the bottom of the test tube and slowly dispense the SpermTec® lower layer. The two layer gradient remains stable for up to two hours.
4. Carefully place up thawed semen sample onto the upper layer by using a transfer pipette or syringe (max. 0.5ml)
5. Centrifuge at 350g for 15 to 20 minutes.
6. Aspirate the supernatant down to no less than the 0.5ml mark above the pellet.
7. Add with a syringe 2-3ml SpermTec® Wash medium and re-suspend the pellet.
8. Centrifuge at 300g for 8 to 10 minutes.
9. Aspirate the supernatant down to the pellet and repeat steps 7 and 8.
10. Aspirate the supernatant and resuspend with a suitable volume of appropriate medium.

In case samples do not liquefy, causing no passage through the layers, increase the centrifugal force up to, but no more than, 500g in order to separate the sperm.

SYMBOL	MEANING
	Catalogue number
	Batch code
	Use by (expiry date)
	Temperature limitations
	Sterile medical device processed using aseptic technique (filtration)
	Consult instructions for use
	CE mark

Used Abbreviations

ICSI	Intracytoplasmatic Sperm Injection
IVF	In Vitro Fertilization
IUI	Intra Uterine Insemination