

0222-08

SupraSperm® 90 SupraSperm® 100 SupraSperm® System

Product No.:

1091
1092
1097

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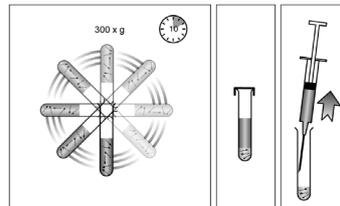
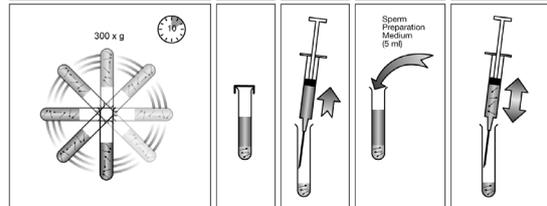
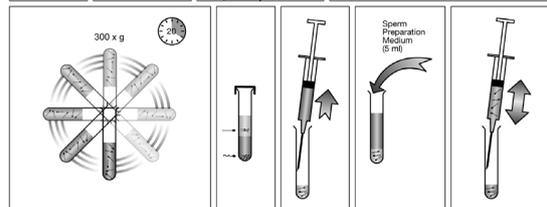
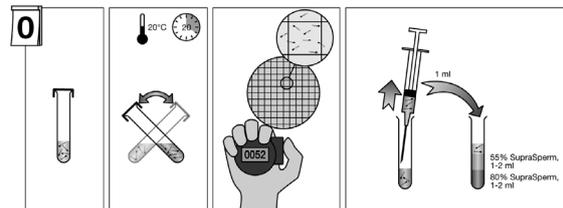
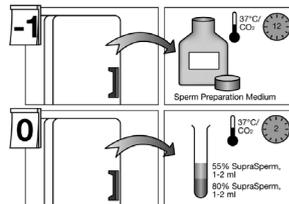
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SupraSperm® 90, SupraSperm® 100, SupraSperm® System

Intended use

SupraSperm® is for the isolation of viable spermatozoa by the density gradient method.

Composition

SupraSperm® 90:

90% Salt solution of colloidal silica particles coated with silane.

10% Sperm Preparation Medium, which consists of Earle's Balanced Salt Solution (EBSS) supplemented with: Synthetic Serum Replacement (SSR®) (USA; ART Supplement)

Human serum albumin (HSA)

Sodium pyruvate

Sodium bicarbonate

HEPES

Gentamicin sulphate 10µg/mL

Phenol red

SupraSperm® 100:

100% Salt solution of colloidal silica particles coated with silane.

Without phenol red.

SupraSperm® System – 55%:

55% Salt solution of colloidal silica particles coated with silane.

45% Sperm Preparation Medium with phenol red.

SupraSperm® System – 80%:

80% Salt solution of colloidal silica particles coated with silane.

20% Sperm Preparation Medium with phenol red.

Quality control testing

Sterility tested (Ph.Eur., USP)

Osmolality tested (Ph.Eur., USP)

pH tested (Ph.Eur., USP)

Endotoxin tested ≤ 0.1 EU/mL (Ph.Eur., USP)

Not Mouse Embryo Assay (MEA) tested

Sperm Survival tested

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com

Storage instructions and stability

Store in original container at 2-8°C, protected from light.

Do not freeze.

Discard excess (unused) media following warming

The product is to be used within 7 days after opening.

When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Precautions and warnings

Do not use the product if:

1. Product packaging appears damaged or if the seal is broken.
2. Expiry date has been exceeded.

Caution: All blood products should be treated as potentially infectious. Source material used to manufacture this product were tested and found non-reactive for HbsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore source material have been tested for parvovirus B19 and found to be non-elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Caution: US federal law restricts this device to sale by or on the order of a physician (Rx only).

Note: Please be aware that a harmless precipitation (colloidal aggregates) may occur. Decanting the medium is recommended when precipitation is present.

Instructions for use

SupraSperm® 90:

Gradients are prepared by using SupraSperm® 90:

- Use Sperm Preparation Medium as diluent for SupraSperm® 90.
- For custom gradient preparation use the formula below to prepare a chosen gradient, using SupraSperm® 90 + Sperm Preparation Medium (Product No.1069/1070).

Calculation formula for preparing of own gradients

X mL SupraSperm® 90 (90% (v/v))

Y mL Sperm Preparation Medium

$$\text{Gradient \%} = \frac{X}{X+Y} \times 0.9 \times 100\%$$

SupraSperm® 100:

Gradients are prepared by using SupraSperm® 100:

- Use Sperm Preparation Medium as diluent for SupraSperm® 100.
- For custom gradient preparation use the formula below to prepare a chosen gradient, using SupraSperm® 100 + Sperm Preparation Medium (Product No.1069/1070).

Calculation formula for preparing of own gradients

X mL SupraSperm® 100 (100% (v/v))

Y mL Sperm Preparation Medium

$$\text{Gradient \%} = \frac{X}{X+Y} \times 1.0 \times 100\%$$

SupraSperm® System:

2 x 1 mL of semen sample should be used to run two gradients for each semen sample.

Dispense 2 mL 55% SupraSperm® to a centrifuge tube.

Use pipette to dispense 2 mL 80% SupraSperm® underneath the first solution.

Carefully dispense 1 mL semen sample on top of the prepared gradient.

Spin the gradients in a centrifuge at 300 x G for 20 minutes.

Remove the supernatant from pellet and place the pellet in a clean centrifuge tube.

Re-suspend the pellet in 2-3 mL of Sperm Preparation Medium (Product No.1069/1070) and centrifuge again at 200 x G for 10 minutes.

Remove the supernatant from pellet and place the pellet in a clean centrifuge tube.

Repeat the wash process.

Re-suspend the pellet in the desired concentration with Sperm Preparation Medium.

Instructions for use (Density gradient)

1. From each semen sample prepare a separate gradient for each 1 mL volume. Each gradient is

prepared using 1-2 mL of 55% SupraSperm® underlaid with 1-2 mL of 80% SupraSperm®, and pre-equilibrated in a CO₂ environment at 37°C. *NOTE! Gradients should be prepared immediately before use for optimal results.*

2. The semen sample is thoroughly mixed (i.e. repeated tilting for 20 minutes at room temperature). If the sample does not liquefy, you may need to pass it through a narrow pipette and/or mix it with a small amount of pre-equilibrated Sperm Preparation Medium.
3. After the mixing process is completed, sperm concentration and motility should be assessed.
4. Carefully dispense 1 mL of liquefied semen sample on top of the prepared gradient. *NOTE! Adding too much sperm will result in overloading and poor separation.*
5. The gradient is centrifuged at 300 x g for 20 minutes.
6. Remove the supernatant from the pellet and take care not to leave any residues on the tube wall. Transfer the sperm pellet with as little of the 80% solution as possible into a clean centrifuge tube.
7. Re-suspend the pellet in 5 mL of pre-equilibrated Sperm Preparation Medium and centrifuge again at 300 x g for 10 minutes. Aspirate the supernatant. Repeat this washing procedure.
8. Add a small amount of pre-equilibrated Sperm Preparation Medium and determine motility and concentration of spermatozoa in the washed sample.
9. Finally, re-suspend the washed sperm in a suitable volume of pre-equilibrated Sperm Preparation Medium. In normal circumstances, fertilization will occur if IVF insemination is performed in a final concentration of 100.000 motile spermatozoa/mL.

NOTE! Centrifuge times can be changed to 15 minutes in all steps if you have several sperm samples in one day and no possibility of running them all in parallel.

When the caps of the tubes are tightened the prepared semen can be kept at room temperature (20-25°C) for up to one hour prior to insemination. It is recommended that the sperm samples be wrapped in aluminium foil.

Alternatively the unwrapped sperm sample can be stored in a CO₂ environment at 37°C.