

SpermWash[®] kit

PRODUCT INFORMATION

SpermWash[®] kit

Product no.
SWKIT

one unit

Content

One ampoule containing 2 ml SpermWash[®] medium, two syringes (2 ml), one short and two long hypodermic needles, one ampoule holder, and instructions for use.

Application

SpermWash[®] kit is a simple, easy, and safe “swim up” system developed for isolation of motile spermatozoa from the seminal plasma in the most natural and gentle way; self-migration. Only recommended for normal quality semen samples and slightly oligo- or asthenozoospermia.

Composition

SpermWash[®] medium is composed of Earle's balanced salt solution (EBSS) including HSA, pyruvate, Hepes, Phenol red, sodium-bicarbonate and Gentamicin (10µg/ml).

Quality Control

- pH: 7.4 ± 0.2 (37° C, 5% CO₂)
- Endotoxin: < 0.1 EU/ml
- Osmolality: 285 ± 10 mOsm/kg

Shelf Life

One year from production date. Store refrigerated (2°- 8° C). Avoid freezing and exposure to light.

Sterility

The medium is manufactured under sterile conditions and sterility is ensured by testing each batch. Sterility tests verify the absence of viable microorganisms (bacteria, yeast and fungi).

Packages

The medium is supplied sterile filtered in pharmaceutical grade borosilicate glass bottles with Teflon-coated rubber stoppers and tamper proof seals.

Worldwide distribution:



Vesterport 3 • 8000 Aarhus C • Denmark
Phone (+45) 86 76 06 99 • Fax (+45) 86 76 06 85
e-mail: info@cryosinternational.com
www.cryosinternational.com

ProVitro • Vesterport 3 • 8000 Aarhus C • Denmark

Local distribution:

(Instructions for use on back page)

SpermWash® kit

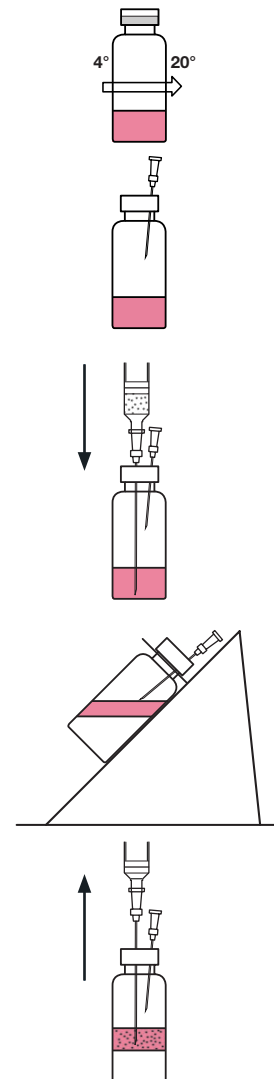
Instructions for use

Preparation time: hands-on: 2-5 minutes. Heat incubation: minimum 1 hour.

1. Preheat the SpermWash® ampoule to room temperature. Set the incubator at 37° C.
2. Remove the cap from the ampoule and wipe the rubber membrane with 70% ethanol.
3. Insert the short hypodermic needle into the rubber membrane using it as a valve for pressure equalization.
4. When the ejaculate has liquefied for 15-30 minutes and following analysis, aspirate the semen into one of the syringes. Attach one of the long hypodermic needles and expel any air bubbles. Hold the ampoule vertically and insert the needle all the way to the bottom of the ampoule. The syringe containing the semen is carefully emptied so that the ejaculate is layered under the medium at the bottom of the ampoule.

AVOID MIXING THE LAYERS!

5. Gently remove the needle and syringe along the inner side of the ampoule in order to avoid semen in the medium. Discard the needle and syringe.
6. Carefully place the ampoule in the ampoule holder at a 45° angle in order to maximize the surface between the semen and the medium. Place the ampoule in the incubator at 37° C. The ampoule must remain in the incubator for minimum one hour (maximum 3 hours).
7. After “swim-up”-incubation, carefully remove the ampoule from the incubator and place it in an upright position. Attach a new long hypodermic needle to a new syringe. Carefully aspirate 0.5-1.0 ml of the top layer (the red medium) and withdraw the needle. The syringe now contains the SpermWash® medium with the selected motile spermatozoa ready to inseminate. Keep the syringe in the incubator until insemination.



NB: If the ejaculate does not liquefy properly, the sperm from the bottom may “jump” up through the medium into the needle when aspirating the top layer. If this happens aspirate and discard the sperm from the bottom so that the SpermWash® medium is left. Use another needle/syringe (not supplied in the “kit”) to aspirate the medium with the selected spermatozoa.

It is recommended to make another semen analysis prior to insemination. For IUI at least 2×10^6 spermatozoa with good/excellent motility are required. Treatment with $<0.5 \times 10^6$ motile spermatozoa cannot be recommended. There should be no (or only very few) immotile spermatozoa in the purified sperm preparation.

Graphical symbols used on the labels are in accordance with the European Standard for labelling of medical devices (EN 980:2003).

| SYMBOL | MEANING |
|--|---|
| REF | Catalogue number |
| LOT | Batch code |
| Hourglass icon | Use by (expire date) |
| Thermometer icon with 2°C and 8°C markings | Temperature limitations (store at 2°- 8° C) |
| STERILE A icon | Sterile medical device processed using aseptic technique (sterile filtration) |
| Open book icon | Consult instructions for use |
| Factory icon | Manufacturer |