

SpermRinse™



US

EN: Indication for use

Medium for sperm preparation.

Product Description

SpermRinse™ is a bicarbonate and HEPES buffered medium containing human serum albumin and gentamicin as an antibacterial agent.

For use after equilibration at +37°C and 5% CO₂ or ambient atmosphere.

Storage instructions and stability

Store dark at +2 to +8°C.

SpermRinse™ is stable until the expiry date shown on the container labels and the LOT-specific Certificate of Analysis.

Media bottles should not be stored after opening. Discard excess media after completion of the procedure.

Directions for use

Swim up preparation

Using a sterile, non-toxic pipette, add 1.0 mL of semen to a test tube labelled with patient ID. Overlay 2.0 mL of SpermRinse™. Place the tube in incubator at +37°C and 5% CO₂ for 30–60 minutes or heat the tube to +37°C for 30–60 minutes. Aspirate the top medium and transfer to a clean tube. Add 5.0 mL of SpermRinse™, mix and centrifuge for 10 minutes at 150–1000 g.

Aspirate the supernatant and re-suspend the pellet in 5.0 mL of equilibrated IVF™ to remove the gentamicin and repeat the centrifugation.

Discard the supernatant and suspend the sperm in 1.0 mL of equilibrated IVF™.

Gradient separation

Mix SpermRinse™ with SpermGrad™ to obtain 90% and 45% gradient concentrations, respectively.

Using a sterile, non-toxic pipette, add 1.5 mL of 90% solution into a conical centrifuge tube first and then slowly add 1.5 mL of 45% solution on top. Finally, the semen is gently layered on top of the gradient.

Centrifuge for 10 minutes at 150–1000 g. Remove the supernatant in two top layers, taking care not to leave residue on the tube walls. Transfer the sperm pellet with as little of the 90% solution as possible to a sterile conical tube, containing 5 mL of SpermRinse™. Centrifuge for 10 minutes at 150–1000 g. Discard the supernatant and wash one more time with SpermRinse™. After the second wash, re-suspend the pellet in 1.0 mL of equilibrated IVF™.

Specifications

Sterile filtered SAL 10³

Mouse Embryo Assay (1-cell) [% expanded blastocyst within 96 hours] ≥ 80

Bacterial endotoxins (LAL assay) [EU/mL] < 0.25

LOT specific test results are available on the Certificate of Analysis provided with each delivery.

Precautions

Discard product if bottle integrity is compromised. Do not use SpermRinse™ if it appears cloudy.

SpermRinse™ contains human serum albumin and gentamicin.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBC, HCV and HTLV II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

Re-use may result in microbiological contamination and/or property changes in the product.

To avoid contamination Vitrolife strongly recommends that media should be opened and used only with aseptic technique.

The risks of reproductive toxicity and developmental toxicity for IVF media, including Vitrolife's IVF media, have not been determined and are uncertain.

Not for injection.

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

Description of ISO Symbols

Sterilized using aseptic processing techniques

Temperature limit

Do not re-use, discard after procedure

Date of manufacture

Use by - see label

Caution: Consult accompanying documents.

Catalog number

Batch code

CE Mark (Conformité Européenne)

CHINA

CN:

产品名称:洗精液

适用范围

用于精子制备。

产品型号及技术要求编号

型号:见标签

规格:见标签

产品注册证及技术要求编号

产品注册证编号:见标签

产品技术要求编号:见标签

产品描述

洗精液(SpermRinse™)是一种含有血清白蛋白和抗凝剂乙酸盐的碳酸氢盐和HEPES(羟乙基哌嗪乙酰胺)缓冲的培养液。

在+37°C和二氧化氮浓度为5%的环境下平衡后使用。

产品生产日期、失效日期、储存条件及运输条件

生产日期:见标签。

失效日期:见标签。

储存条件:避光,+2°C~+8°C。

运输条件:在运输过程中储存温度可以超过8°C,但不超过12°C,且最长时间不超过7天。

SpermRinse™在包装标签和该产品批号的质检报告上标注的储存有效期是固定的。

产品包装打开后不得再继续储藏。使用后丢弃剩余产品。产品为一次性使用。

使用方法

上游法准备

用一支无菌的移液管,加入1mL精液到一支标记了患者身份的试管中。

在上层加入2.0 mL SpermRinse™,将管置于+37°C和5%二氧化氮的培养箱中-60分钟,然后加热至+37°C-30分钟。取上层液体并转移到一支干净试管中,加入5.0 mL SpermRinse™,混匀并在150-1000 g条件下离心10分钟。

弃去上清液,将沉淀5.0 mL平衡的IVF™重悬以去除大液滴,重新离心。

丢弃上清液,用1.0 mL平衡好的IVF™重悬制剂精子。

梯度分离制备

SpermRinse™与SpermGrad™稀释分别获得90%和45%的梯度液。用无菌的吸管移取1.5 mL 90%的梯度液到圆形的恒温管中,然后移入1.5 mL 45%的梯度液浸没于其上层,最后,将精液悬浮于梯度的底层。

+50-1000 g,30分钟。弃去残余精液和两层上清液,小心地将上清液和恒温管一起倒置,转移精液至尽可能少的90%梯度分层液的恒温管中,最后,将精液悬浮于梯度的底层。

150-1000 g,30分钟。弃去残余精液和两层上清液

