PureSperm® Wash

Intended Use

For washing the sperm pellet recovered from a PureSperm density gradient, for use in the swim-up method and for extending semen, or sperm pellet for use in IUI.

Components

Sodium chloride	Purified water
Potassium chloride	Glucose
Magnesium sulphate	Calcium lactate
Potassium dihydrogen phosphate	Sodium pyruvate
Sodium bicarbonate	EDTA
Human serum albumin (hSA)	HEPES

Performance Characteristics

pH	7.3-8.5
Osmolality (mOsm/kg H_2O)	290-300
Endotoxin levels	<1.0 EU/mL
Sperm survival 18 hours after density gradient separation	>70%

Bottles and stoppers are M.E.A. tested

Storage and Stability

Store unopened bottles at 2 to 30ºC and avoid temperatures above or below these values. Under these conditions Pure Sperm® Wash has a shelf-life of 12 months. The expiry date is shown on both bottles and cartons.

Open and close bottles under aseptic conditions. After opening, store at 2 to 8ºC when not in use. Shelf-life on the product label applies when the product is stored according to manufacturer's recommendations.
No antibiotics, unstable additives or preservatives have been added by the manufacturer to PureSperm® Wash.

Precautions and Warnings

- Use aseptic procedures at all times
- If available, use sealed buckets during centrifugation to avoid creation of aerosols
- PureSperm® Wash does not represent any fire or combustion hazard. A material safety data sheet is available from the distributor or manufacturer (see nidacon.com)
- Do not use any PureSperm® Wash which shows evidence of bacterial contamination
- Do not use contents if tamper-evident seal is broken or if stopper accidently comes in contact with unsterile surfaces
- Do not re-use PureSperm® Wash from any procedure due to risk for cross contamination
- Federal Law (USA) restricts this device to sale by or on the order of a physician
- Please check for regulatory compliance governing the use of ART products in your country

Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.
There are no reports of proven virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes.
It is strongly recommended that every time PureSperm®Wash is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

CE 2460

Manufacturer:
Nidacon, Flöjelbergsgatan 16 B, SE-431 37 Mölndal, Sweden
Tel: +46-31-703 06 30, Fax: +46-31-40 54 15
E-mail: contact@nidacon.com, www.nidacon.com

Nidacon

INS-PSW-XH/19

Gradient procedure

Recommendations

Prepare two PureSperm® gradients for each semen sample. This reduces the risk of overloading a single gradient, provides security when handling tubes or recovering sperm pellets and provides two tubes to balance the centrifuge rotor.

Reagents and Equipment

- PureSperm®Wash, PureSperm®40/80 or PureSperm®100 with PureSperm®Buffer
- Bench top centrifuge with swing out rotor
- Disposable sterile conical centrifuge tubes
- Sterile pipettes

Density gradient procedure

Bring all solutions to room temperature

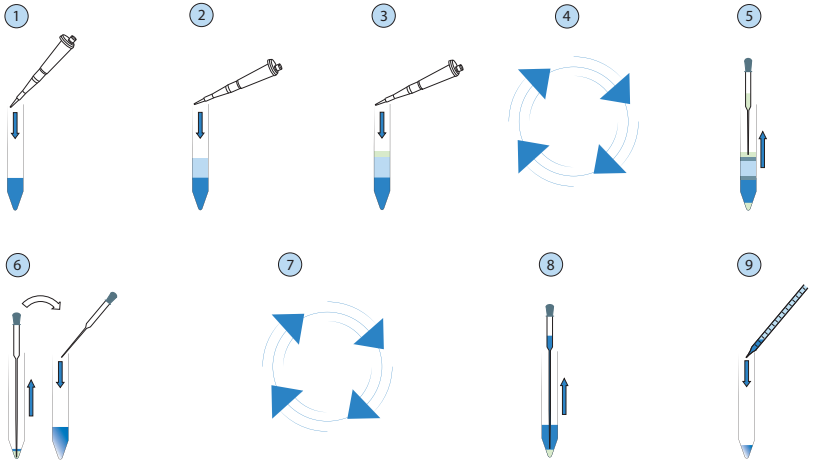
1. Use a pipette with a sterile tip to add 2mL of PureSperm®80 to a conical centrifuge tube
2. Use a new sterile pipette tip to carefully layer 2mL PureSperm®40 on top of the PureSperm®80
3. Carefully layer liquefied semen (up to 1.5mL) onto the PureSperm® gradient
4. Centrifuge at 300 x g for 20 minutes. Do not use the brake. Calculate the correct RPM for your centrifuge
5. Use a sterile Pasteur pipette to aspirate, in a circular movement from the surface, everything except the pellet and 4-6mm of PureSperm®80. If no pellet is seen after centrifugation, remove all fluid except the lowest 0.5mL
6. Use a new sterile Pasteur pipette to aspirate the pellet (or the lowest 0.5mL liquid). Transfer sperm pellet to new tube and resuspend pellet in 5mL PureSperm®Wash
7. Centrifuge at 500 x g for 10 minutes. Do not use the brake
8. Carefully aspirate PureSperm®Wash supernatant leaving as little liquid as possible above pellet. If no pellet is seen, leave the bottom 0.25mL fluid
9. Resuspend the sperm pellet in a suitable volume of culture medium to obtain the desired sperm concentration. The sperm sample is now ready for analysis or use

Calibrate the centrifuge; to achieve the correct g force:

$Rpm = \sqrt{[\ (g/(1.118 \times r)]} \times 10^3$

For example; to achieve 300 x g when radius = 165 mm the centrifuge speed must be:

$Rpm = \sqrt{[\ (300/(1.118 \times 165)]} \times 10^3 = 1275$



Swim-up procedure

Recomendations

Since PureSperm®Wash does not contain any antibiotics, it is recommended to add antibiotics when used in preparations for ART (e.g., Penicillin, 100 U/mL).

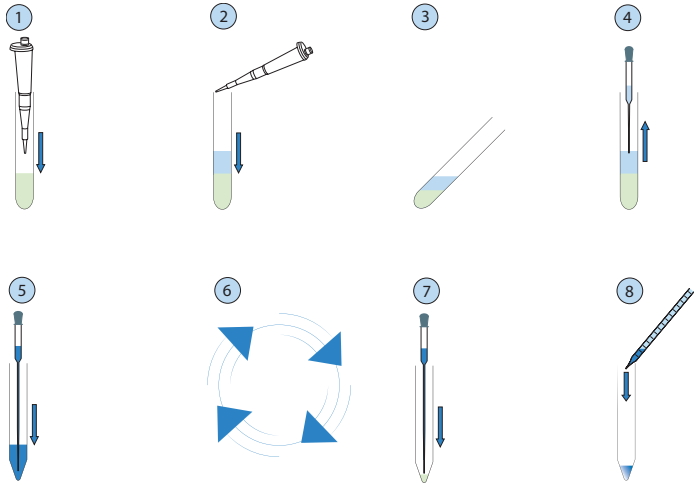
Equilibrate PureSperm®Wash at room temperature prior to use

Reagents and Equipment

- PureSperm®Wash
- Disposable sterile round bottomed centrifuge tubes
- Disposable sterile conical centrifuge tubes
- Sterile pipettes
- CO_2 incubator
- Bench top centrifuge with swing out rotor

Swim-up procedure

1. Use a pipette with a sterile tip to transfer 1mL of liquefied semen into a sterile round-bottomed centrifuge tube. Avoid touching the inside walls of the tube. If too viscous, dilute with PureSperm®Wash before transfer
2. Use a new sterile pipette tip to carefully layer 1.5mL PureSperm®Wash over the semen
3. Without disturbing the layers, place the centrifuge tube and contents, at a 45º angle, into a 5-6% CO_2 incubator at 37ºC for 60 minutes. Motile sperm will migrate into the medium
4. Carefully remove the uppermost 0.5 - 1.0mL of medium containing motile sperm with a sterile pipette
5. Place the removed fluid in a sterile conical centrifuge tube
6. Centrifuge at 500 x g for 10 minutes. Do not use the brake. Calculate the correct RPM for your centrifuge
7. Aspirate PureSperm®Wash supernatant carefully, leaving no more than 2 mm depth of liquid above pellet
8. Resuspend the sperm pellet in a suitable volume of PureSperm®Wash to obtain the desired sperm concentration. The sperm sample is now ready for analysis or use



Ordering Information

Volume	**Article No.**
100mL	PSW-100

For further technical information or assistance, please contact your distributor or the manufacturer.

www.nidacon.com

Flöjelbergsgatan 16 B
SE-431 37 Mölndal
Sweden
Tel: +46-31-703 06 30
Fax: +46-31-40 54 15
E-mail: contact@nidacon.com
www.nidacon.com

Nidacon