

# PureSperm® SpeediKit

## Intended Use: Summary and Explanation

PureSperm®SpeediKit provides all the components required to prepare human sperm for IUI. PureSperm®Unilayer is a sterile (autoclaved SAL-10<sup>-3</sup>) colloidal silica suspension in an isotonic salt solution optimised for the preparation of human sperm, whereby semen is processed by centrifugation through a single layer of colloid. PureSperm® Wash is a sterile isotonic salt solution optimised for washing the sperm pellet after centrifugation with PureSperm®Unilayer and for transferring the sperm to the uterus.

## Components

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

## Performance Characteristics

	pH	Osmolality (mOsm/kg)
PureSperm® Unilayer	7.4-7.8	300-310
PureSperm® Wash	7.3-8.5	290-300

Endotoxin transfer during treatment <1.0 EU/mL

Tubes and stoppers are M.E.A. tested

## Protein Supplementation

PureSperm® Wash contains the component human serum albumin (hSA). The hSA is manufactured from human blood donated in the United States. The blood donors are tested for various viruses before being allowed to donate blood for this purpose. Each plasma donation is individually tested for ALT, HBs antigen, HIV-1/2 antibody and HCV antibody by ELISA. Only those plasma donations found non-reactive for these antibodies have been used for the manufacture of the hSA component. The plasma pool is tested again before manufacture of the hSA product. The final PureSperm® Wash product is filter sterilised.

## Storage and Stability

Store at 2 to 30°C and avoid temperatures above or below these values. Under these conditions the contents of the kit have a shelf-life of 6 months. The expiry date is shown on both tubes and cartons. 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®SpeediKit.

## Precautions and Warnings

- When retrieving the sperm pellet, follow the instructions given in the pack insert to avoid inadvertent contamination
- Use aseptic procedures at all times
- All ejaculates should be considered infected and handling of them should be done accordingly
- If available, use sealed buckets during centrifugation to avoid creation of aerosols
- Clean accidental spills using a dampened cloth or paper. PureSperm®Unilayer causes floors and benches to be extremely slippery
- PureSperm®SpeediKit does not represent any kind of fire or combustion hazard. A material safety data sheet is available from the distributor or manufacturer (see nidacon.com)
- Do not use any solution which shows evidence of bacterial contamination or if stopper accidentally comes in contact with unsterile surfaces
- Do not use contents if tamper-evident seal is broken
- Do not re-use
- All components must be discarded with "biological material"
- 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

## Ordering Information

**Volume**  
5x4mL PureSperm®Unilayer  
5x6mL PureSperm® Wash  
5x Semen collection tubes  
2x Balance tubes

**Article No.**  
PSSK-070



[www.nidacon.com](http://www.nidacon.com)

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

## Manufacturer:

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E-mail: [contact@nidacon.com](mailto:contact@nidacon.com), [www.nidacon.com](http://www.nidacon.com)



### Reagents and Equipment

- Ready to-use tubes of PureSperm® UniLayer and PureSperm® Wash
- Balance tubes
- Bench top centrifuge with swing out rotor
- Sterile pipettes

### Recommendation

Use balance tube when centrifuging single tube

### Procedure for using PureSperm® SpeediKit

Bring all solutions to room temperature.

1. Use a sterile pipette to carefully layer liquefied semen (up to 1.5 mL) on top of the PureSperm® UniLayer
2. Centrifuge at 300 x g for 30 minutes. Do not use the brake. Calculate the correct RPM for your centrifuge.
3. Use a new sterile pipette to aspirate PureSperm® UniLayer supernatant leaving no more than 4-6 mm depth of liquid above the pellet. If no pellet is seen after centrifugation, remove all fluid except the lowest 0.5mL
4. Use a new sterile pipette to aspirate the pellet (or the lowest 0.5mL liquid)
5. Transfer sperm pellet to the tube containing PureSperm® Wash. Resuspend sperm
6. Centrifuge at 500 x g for 10 minutes. Do not use brake
7. Use a new sterile pipette to aspirate PureSperm® Wash supernatant leaving as little liquid as possible above the pellet
8. Resuspend pellet in the remaining PureSperm® Wash. The sperm preparation is now ready for IUI

