Reproductive Solutions™

ProteX Collection & NovoSort Sperm Processing Device

Directions For Use

COLLECT SEMEN SAMPLE IN PROTEX COLLECTION CUP (See Andrology Guidelines)

- Patient to collect in-clinic or at-home. As directed by clinician, use 1 ml of standard HEPES buffered sperm wash media.

ONE-STEP DEVICE PREPARATION AND PROCESSING

- **Position Protex:** Choose a stable, undisturbed location to prevent cup movement during NovoSort device insertion and processing.
- **Ready to Add Media to NovoSort:** Determine the correct quantity of media to be added.
  - What is the Total Volume? Total = Either native specimen only, or native with media. Refer to Table 1 for media volume.
  - Example #1: 2.0 ml of total semen volume, use 1.0 ml media
  - Example#2: 3.5 ml of total semen volume, use 1.25 ml media
- **Unpack NovoSort:** Remove from sterile packaging when ready to load.
- **Add Media to NovoSort**: Pipette determined quantity of HEPES buffer media into the center inlet.

Table 1

TOTAL SEMEN VOLUME (ML)	MEDIA ADDED TO NOVOSORT
1.0 - <2.0 mL	0.75mL
2.0 - <3.0mL	1.0mL
3.0 - <4.0mL	1.25mL
4.0mL - <7.0mL	1.5mL

Figure 1

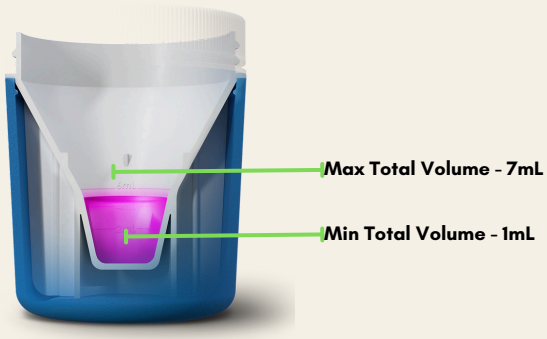
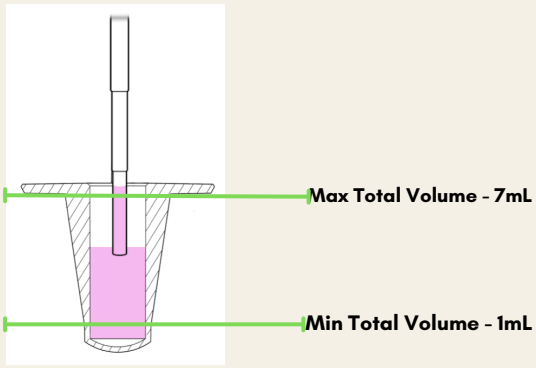


Figure 2



- If volume is greater than Max 7ml, pipette off enough sample to be between 6 and 7 ml
- For low volume samples, min is 0.5ml native sample but must add 1ml media to achieve a total 1.5ml

INSERT FOR PROCESSING

- Gently place the NovoSort device into semen sample within ProteX. And cover ProteX with the cap.
  Note: Avoid jostling the cup which may disturb the fluid interface surface tension
- Processing time differs by procedure and sample quality. Target a TMC that meets your lab standards for each procedure.

(ICSI): 15 Min Conventional IVF: 30 Min (IUI): 30-45 Min

RETRIEVAL OF PROCESSED SPERM

- Withdraw the volume of highly motile sperm for treatment from the middle of the assembly.

Important Notes:

- Insert the pipette no lower than the middle of the height of the device to withdraw the best sperm.
- Do not insert pipette down to the very bottom to pull volume.
- Ensure the retrieval pipette does not contact the mesh. This may break the liquid surface tension and cause mixing of the fluids.

Video DFU

Control No: PTXSB-DFU-NovoS Rev. 03

CLINIC AND ANDROLOGY GUIDELINES

ProteX is designed to protect sperm from thermal fluctuations and biochemical stressors that lower motility, lower counts, and negatively affect sperm quality. This protection occurs both for in-clinic collection or at-home.

COLLECTING IN CLINIC

Prior to patient collection, add room temperature pre-measured 1 mL HEPES buffered sperm wash media to sterile ProteX and then tightly close the ProteX container cap to give to the patient. Instruct the patient to collect as they would in a specimen cup.

COLLECTING AT HOME

Provide the patient a sterile ProteX and a 1 mL vial of media, as described above. Provide the patient a window of time to collect and return to the lab. The practice may decide to tell patients to drop off no more than 24 hours later to optimize clinic and lab efficiencies.

Reproductive Solutions also has an at-home collection system which can be ordered by the patient and shipped directly to their home for their convenience and comfort and transport the sample to the lab according to clinic instructions.

WHEN MEDIA IS ADDED – CALCULATE A CORRECTED NATIVE VOLUME AND CONCENTRATION

It is important to account for the media added to collection when calculating the native volume of ejaculate and concentration of sperm. Review the example and formulas below. An Excel spreadsheet "Semen Parameter Calculator" is available upon request.

Example

1. The patient's sample with medium equals 4 mL and there was 1 mL of medium added to ProteX prior to collection. → **Volume Calculation: 4 mL – 1 mL = 3 mL**

FORMULA

$$\frac{\text{Volume of sample with medium in ProteX} - \text{Volume of medium added prior to collection}}{\text{Volume of semen sample without medium}}$$

2. Identify the concentration / mL of the semen sample with medium as determined during your semen analysis by manual count or computer assisted semen analysis (CASA). → In this example, the concentration / mL of the semen sample with medium = **15,000,000 / mL**

3. Calculate the concentration of the semen sample without medium using the preceding values. → **Concentration Calculation: (4 ÷ 3) = 1.33 x 15,000,000 = 19,950,000 / mL**

FORMULA

$$\frac{(\text{Volume of sample with medium} \div \text{Volume of sample without medium}) \times \text{Concentration / mL of semen sample with medium}}{\text{Concentration / mL of semen sample without medium}}$$