

Clinic and Lab Staff Guidelines

ProteX™ fully replaces the traditional specimen cup in your clinic process. 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 no matter if a patient collects in the clinic or at home. The ProteX collection method requires **adding 1 mL of room temperature sperm wash medium (with HEPES/MOPS) to ProteX prior to the patient collection.**

Collecting in Clinic

Prior to patient collection appointment, bring pre-measured 1 mL sperm wash medium (with HEPES/MOPS) to room temperature. Just prior to collection, clinic staff member must add the room temperature sperm wash medium to sterile ProteX and then re-seal the ProteX container for the patient. Instruct the patient to collect as they would in a specimen cup.

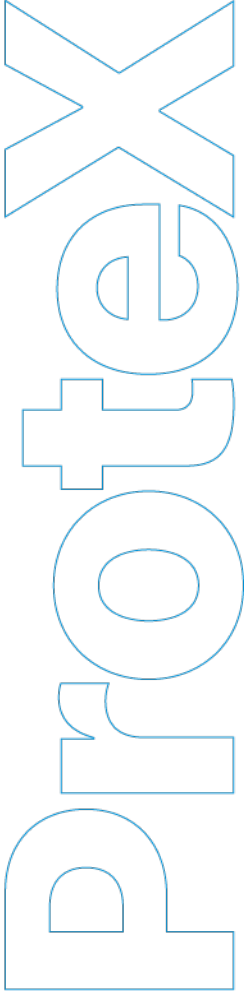
Collecting at Home

At the end of the initial patient consultation appointment, assemble the patient's take-home bag. Provide the patient a window of time to collect and agree to timing for sample drop-off. Though data indicates sample viability after collection may be up to 48 hours, the practice may decide to tell patients to drop off no more than 24 hours later to optimize clinic and lab efficiencies. Upon drop-off, staff must ensure proper labelling is secure and chain of custody documentation is filled out before patient leaves.

How to Assemble Patient Take-home Bags

Patient take-home bags are not provided by Reproductive Solutions at this time. Please create your own with the following contents:

- ProteX** in sterile sealed packaging.
- 1 mL of sperm wash medium** in a small vial provided by your practice.
- Patient instructions:** How to collect semen in the ProteX container.
- Patient labels** consistent with your clinic and lab standard operating procedures. It is recommended that the label include a place to record time of collection.
- Return instructions** provided by your practice. It is recommended to include location, date, and time to return the sample.



Andrology Staff Guidelines

ProteX™ is designed to protect sperm from thermal fluctuations and biochemical stressors that lower motility, lower counts, and negatively affect sperm physiology. Stress in sperm is indicated by hypermotility at analysis as well as premature capacitation and other biochemical processes. Every case of ProteX comes with a certificate of biocompatibility to confirm ProteX has been tested via HSSA (Human Sperm Survivability Assay).

The ProteX collection method includes **adding 1 mL of room temperature sperm wash medium (with HEPES/MOPS) to ProteX prior to the patient collection.**

Samples collected in ProteX may initially have a slower forward progression than traditional methods. This is because sperm in ProteX are not shocked and better maintain their pre-ejaculatory quiescence. Forward progression naturally increases with time and processing as biochemical pathways activate, without activating shock proteins that lead to faster apoptosis.

How to Calculate Volume and Concentration When Sperm Wash Medium is Added Prior to Collection

It is important to account for the medium added prior to collection when calculating the volume of ejaculate and concentration of sperm. Review the example and formulas below.

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:
 $4 \text{ mL} - 1 \text{ mL} = 3 \text{ mL}$

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:
 $(4 \div 3) = 1.33 \times 15,000,000 = 19,950,000 / \text{mL}$

FORMULA

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



ProteX

Semen Parameter Calculator

Volume of Media addition to ProteX mL

Total Volume Observed
(media + sample) mL

Observed Concentration million/mL

Observed Motility %

Original Volume	2 mL
Original Concentration	150 million/mL
Total Cells	300 million
Total Motile Cell	60 milliom

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