

PROTEX COLLECTS, NOW SELECTS:

SINGLE STEP SPERM SEPARATION FOR USE IN IUI, IVF, ICSI

Simple and Fast One-Cup Processing

- 1 Insert device into ProteX
- 2 Load media
- 3 Wait 30-45 min
- 4 Ready for ART procedure

Yields Motile, High-Quality Sperm

- Sample never leaves ProteX
- No additional processing steps
- No damage from traditional procedures

Reduce Risk, Save Cost and Laboratory Time

- Reduce chain of custody risk
- Reduce risk of sample mix-ups
- Eliminate multiple step processing
- Save labware and media costs



ProteX Swim Up Basket Testing Protocol (Revised 5/04/2023)

Sample ID		Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Sample 7	Sample 8	Sample 9	Sample 10
Volume	3.0 Min (2mL + 1mL media)										
Concentration	Min 10 Million										
Motility	Min 30%										
Initial (Control)	Concentration										
	Motility										
0 Minutes	Concentration										
	Motility										
30 Minutes	Concentration										
	Motility										
1 Hour	Concentration										
	Motility										
2 Hours	Concentration										
	Motility										
3 Hours	Concentration										
	Motility										
24 Hours	Concentration										
	Motility										

Instructions For Use For testing of ProteX Optimo-IVF (Proposed)

Thank you for choosing ProteX Optimo-IVF to collect, protect and prepare your semen sample for an Assisted Reproductive Technology procedure.

Simply follow your established clinical protocol for the collection of the semen sample, with the exception that the ProteX will be used in place of the standard specimen cup (SSC). Follow all standard good practice laboratory procedures when handling semen samples and sterile lab ware.

Remove the single use ProteX from the sterile packaging. It is recommended that 1 mL of media be added to the ProteX before the semen sample is collected. The media should be added to the ProteX by a laboratory technician, if the collection is in the clinic, or by the patient, if the semen sample is collected off site.

When the semen sample collected in the ProteX arrives to the lab, simply set the ProteX, with the lid and tamper proof seal in place on the bench until it is ready to be prepared for processing. There is no rush, the sample will be stable for hours.

When you are ready to process the sample for ART, break the tamper proof seal on the ProteX. The chain of custody does not change, the collection and preparation will all be accomplished in a single, identified and verified container.

Remove the single use Optimo-IVF accessory from the sterile packaging.

The Optimo-IVF assembly has a removable semen separation tube in the center of the assembly. Turn the tube 360 degrees to assure the tube moves freely in the assembly.

Using a pipette, draw 0.75 mL of media and deposit the media into the center well of the Optimo-IVF assembly.

Gently lower the Optimo-IVF assembly into the ProteX; it will seat into the ProteX. It is important that all actions are gentle so as not to create currents in the fluids.

Using forceps or your fingers, slowly remove the separation tube from the Optimo-IVF assembly. Discard the tube.

The removal of the tube will establish the surface tension of the mesh in the Optimo-IVF assembly. The movements of the fluids will be restricted; however, the movement of viable sperm will not be restricted.

At the 5 minute time point, check the motility of the sample in the interior well of the Optimo-IVF to access if the sample is sufficient for the processing for your planned ART procedure. It is recommended that the sample be harvested between the time points of 5 minutes to 15 minutes for ICSI, not to exceed 45 minutes for other ART procedures.

Record your results on the ProteX Optimo-IVF tracking sheet and report them as agreed to Reproductive Solutions, having redacted all HIPPA information, in exchange for the testing of ProteX Optimo-IVF.