QUALITY ASSURANCE

Refrigeration Medium is membrane filtered and aseptically processed according to manufacturin procedures which have been validated to meet a sterility assurance level (SAL) of 10^{-3}.

Each lot of Refrigeration Medium is tested for:

- Endotoxin by Limulus Amebocyte Lysate (LAL) methodology
- Sperm Motility Recovery Assay
- Sterility by the current USP Sterility Test <71>

All results are reported on a lot specific Certificate of Analysis which is available upon request.

DIRECTIONS FOR USE

1. Semen is collected following a two to three day abstinence period.

2. Sample is allowed to liquefy at 37°C for 30 minutes.

3. One vial of medium is thawed and brought to 37°C.

4. The liquefied sample is transferred to a sterile, 15 mL, conical centrifuge tube, the volume determined and medium added dropwise until a 1:1 sample:medium ratio is achieved.

Note: Samples displaying high viscosity may require the additional step of repeated pipetting or passage through an 18 gauge needle to ensure thorough mixing.

5. The sample-medium mixture is placed in a beaker or other suitable container of 37°C water.

6. The container is refrigerated at 2°C to 5°C to allow a slow cooling of the mixture (0.5°C/minute) for a