

**AQC™ Products SPERM COUNT QUALITY CONTROL**  
**Catalog #AQC103**

Products of Fertility Solutions Inc. 11811 Shaker Blvd. #330 Cleveland OH USA 44120 (Tele 216-491-0030) (Fax 216-491-0032)

**INTENDED USE For In Vitro Diagnostic Use**

AQC™ Sperm Count Quality Controls are intended for use to assess proficiency of laboratory staff sperm counting skills, to investigate routine sperm counting methods or to train technical staff in sperm counting.

**PRODUCT DESCRIPTION**

AQC™ Sperm Count Quality Controls contain suspensions of stabilized human sperm at concentrations commonly observed in clinical practice.

**WARNINGS AND PRECAUTIONS**

1. Materials are for in vitro use only.
2. Materials are derived from human material and should be handled and disposed of as potential biohazards. Donor's blood was negative when tested for Human Immunodeficiency Virus (HIV), nonreactive for hepatitis B surface antigen by FDA required tests and nonreactive when tested for syphilis by a serologic test for syphilis (STS). Warning. The risk of transmitting infectious agents is present. Careful donor selection and available laboratory tests do not eliminate the risk of transmitting infectious agents. Materials contain dilute buffered formalin. Wear appropriate laboratory protective safety equipment while handling.
3. Users should keep the Material Safety Data Sheet on file.
4. Due to the nature of semen collection, bacteria may be present in some Materials.

**STORAGE AND STABILITY**

1. Materials should be stored at 2°- 8° C. DO NOT FREEZE.
2. When stored unopened at 2°- 8° C, the Materials are stable until the expiration date stated on the label.
3. When stored at 2°- 8° C, the Materials should be stable for 6 weeks after opening when handled properly.

**MATERIALS NEEDED**

1. AQC™ Sperm Count Materials at room temperature (between 18° and 26° C)(to save time, remove the Materials from refrigerator first).
2. Personal protective devices such as lab coat and gloves suitable for potential biological hazards.
3. Vortex mixer, phase contrast microscope and tally device OR Computer Assisted Sperm Analyzer (CASA).
4. Sperm counting chamber(s), micropipettor and tips for loading semen onto the counting chamber.
5. Micropipettors, tips, and diluent for making dilutions if necessary.
6. Process Control Chart supplied with the product.

**PROCEDURE**

1. Remove the Materials from the refrigerator and foam packing for at least 30 minutes before proceeding.
2. To dislodge the pellet on the bottom of the tube, wait until the Materials' temperature is 18-26° C, gently mix by vortexing at low speed for 5 - 10 sec. until the clear liquid turns turbid. Lightly tap the vial on a countertop before opening to remove any liquid from the top of the cap. Open top and mix several times with a pipette.
3. Use a calibrated micropipettor to precisely remove an amount appropriate for the counting chamber used (most sperm counting chambers need 5 uL to load). If using a hemacytometer chamber, make a dilution using a calibrated micropipettor to obtain precisely the required amounts of materials and diluent. Phosphate Buffered Saline is recommended. Sterile technique is recommended to avoid contaminating the Material. DO NOT WARM THE CHAMBER OR MICROSCOPE STAGE ABOVE ROOM TEMPERATURE (between 18° and 26° C) OR CLUMPING MAY OCCUR.
4. Recap the tube tightly and store upright. Perform the count as usual and make appropriate calculations to determine the concentration (# sperm per ml).
5. Record result on worksheet, then graph result on corresponding Process Control Chart. See EXPECTED VALUES below. Repeat procedure using the second Material.
6. Store Materials in refrigerator after use.

**EXPECTED VALUES**

Expected values were established in the Fertility Solutions Inc. clinical reference laboratory. Based on analysis of at least 20 replicates, 2 SD were computed (95% confidence). Laboratories should verify their own ranges. Some of the common reasons that cause results to differ from expected values are listed below. Before repeating the procedure, determine the most likely cause of error. If the results of repeat testing remain out of control, you will need to check all causes for error. Call technical support at 216-491-0030 X204 if you still are experiencing difficulty.

1. Over vortexing or imprecise dilution. Materials or dilution not thoroughly mixed or not homogenous.
2. Material temperature not between 18° and 26° C, Materials expired, stored improperly or contaminated.
3. Counting chamber not loaded correctly or not cleaned adequately. Too few squares counted on the chamber.
4. Microscope light source not centered, phase rings not aligned, CASA threshold or calibration settings improper.
5. Error in computations or numbers incorrectly transcribed from the worksheet to graph.

**REFERENCES**

1. Kinzer DK and Rothmann SA. The Andrology Trainer. Fertility Solutions Inc., 1998. (Product #AT100)
2. Laboratory Quality Management (GS Cembrowski and RN Carey, eds.), ASCP Press, 1989.
3. WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, Cambridge University Press, 1992, 1999.

## **FOR BEST RESULTS**

LET THE REAGENTS WARM TO ROOM TEMPERATURE

GENTLY VORTEX THE REAGENTS ON LOW SPEED  
FOR 5-10 SECONDS TO DISLODGE THE PELLETT

DO NOT OVER-VORTEX. VORTEX ONLY UNTIL  
THE CLEAR LIQUID TURNS TURBID

TAP THE VIAL ON A COUNTERTOP BEFORE OPENING  
TO REMOVE ANY RESIDUAL LIQUID IN THE CAP

USE ONLY A CALIBRATED MICROPIPETTE TO  
REMOVE THE REQUIRED VOLUME OF REAGENT AND TO  
MAKE ALL DILUTIONS

FOR ASSISTANCE, CALL 1-216-491-0030 x204