

AQC Products SPERM COUNT QUALITY CONTROL

Catalog #AQC103, AQC203

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 Control is intended for use as a sperm count quality control or as a reagent for training, proficiency and competency testing or sperm count method validation.

PRODUCT DESCRIPTION

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

WARNINGS AND PRECAUTIONS

1. Product is for in vitro use only.
2. Product is derived from human semen 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. Product contains dilute 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 products.

STORAGE AND STABILITY

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

MATERIALS NEEDED

1. AQC™ Sperm Count Quality Control **at room temperature** (between 18° and 26° C. Remove the product from refrigerator and packaging. Allow 30 minutes to warm).
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. Levey-Jennings Charts supplied with the product, calculator and worksheet.

PROCEDURE

1. Remove the product from the refrigerator and foam packing. Wait for at least 30 minutes until the product temperature is 18-26° C, before proceeding.
2. Pipette any liquid from the cap and add to the contents of the vial before mixing. Vortex on medium speed for 2 to 3 pulses of 2 to 3 seconds each to dislodge the pellet on the bottom of the vial until the clear liquid turns turbid and a vortex in the vial is observed.
3. Use a calibrated micropipettor to precisely remove an amount appropriate for the counting chamber used (use 6 uL to load the Spermocytometer®). If using a hemocytometer chamber, make a dilution using a calibrated micropipettor to obtain precisely the required amounts of product and diluent. Phosphate Buffered Saline is recommended. Sterile technique is recommended to avoid contaminating the product. **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 using your laboratory's methods for the chamber. Count only complete sperm, those with a head, midpiece and tail. If you are using a disposable chamber, we recommend counting the number of sperm in 5 complete grids. Make the appropriate calculations to determine the concentration (# million sperm per ml).
5. Record result on worksheet, then graph result on corresponding Levey-Jennings Chart. See EXPECTED VALUES below. Repeat procedure using the second vial.
6. Store product 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. Overly aggressive vortex mixing or imprecise dilution. Product or dilution not thoroughly mixed or not homogenous.
2. Product temperature not between 18° and 26° C, product 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. Rothmann SA and Reese AA. The Andrology Trainer: Third Edition. Fertility Solutions Inc., 2009. (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.
4. Rothmann SA and Reese AA. "Semen Analysis: The test techs love to hate". Medical Laboratory Observer, April 2007.

FOR BEST RESULTS

LET THE REAGENTS WARM TO ROOM TEMPERATURE

GENTLY VORTEX THE REAGENTS ON MEDIUM SPEED
FOR 5-10 SECONDS TO DISLODGE THE PELLET

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