

**AQC Products POST VASECTOMY QUALITY CONTROL**  
**Catalog #AQCIII**

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**

AQCTM Post Vasectomy Quality Control is intended for use as post-vasectomy sperm count quality control or for training, proficiency and competency testing or method validation.

**PRODUCT DESCRIPTION**

Product 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 material and should be handled and disposed of as potential biohazard. 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 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. Product should be 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. AQCTM Post Vasectomy Quality Control **at room temperature** (between 18° and 26° C. Remove the product from refrigerator and packaging. Allow 30 minutes to warm).
1. Personal protective devices such as lab coat and gloves suitable for potential biological hazards.
2. **Vortex** mixer, phase contrast microscope.
3. Counting chambers or glass slides with coverslips.
4. Micropipettors and tips.
5. Worksheet.
6. Levey-Jennings Charts.

**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 until a vortex in the vial is observed.
3. Observe for the presence or absence of sperm using the laboratory testing procedure for post-vasectomy sperm analysis. Scan the entire chamber or slide to confirm a negative value.
4. Record result on worksheet. See EXPECTED VALUES below.
5. Repeat procedure using the second vial of product. Store product in refrigerator after use.

**EXPECTED VALUES**

Presence or absence of sperm was established in the Fertility Solutions Inc. clinical reference laboratory. 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 continue to have difficulty.

1. Material not thoroughly mixed or not homogenous.
2. Material temperature not between 18° and 26° C,
3. Materials expired, stored improperly or contaminated.
4. Not enough sample placed on slide.

**REFERENCES**

1. WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, Cambridge University Press, 1992, 1999.
2. Laboratory Quality Management (GS Cembrowski and RN Carey, eds.), ASCP Press, 1989.
3. Rothmann SA and Morgan BW (1989). Laboratory diagnosis in andrology. Cleve. Clinic J. Med. 56:805-810.

## **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