

AQC™ Products POST VASECTOMY QUALITY CONTROL
Catalog #AQC111

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™ Post Vasectomy Quality Controls are intended for use to assess proficiency of laboratory staff in recognizing presence or absence of sperm.

PRODUCT DESCRIPTION

Materials 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 6-8 weeks after opening when handled properly.

MATERIALS NEEDED

1. AQC™ Post Vasectomy Quality Control 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.
4. Glass slides with coverslips.
5. Sterile disposable plastic pipettes or minimum of 5uL pipette with plastic tips.
6. Worksheet supplied with the product.

PROCEDURE

1. Remove the Materials from the refrigerator and foam packing for at least 30 minutes before proceeding.
2. When Materials' temperature is between 18-26° C, vortex one tube of Material for at least 10 - 20 seconds at high (8-10) speed to completely disrupt the cell pellet at bottom of tube. Make sure that pellet is completely in solution!
3. Tap tube lightly on counter before opening to dislodge any sample which may be trapped in the top of the tube.
4. Open top and remove a drop of at least 5uL. Sterile technique is recommended to avoid contaminating the Material. Recap the tube.
5. Place a drop on the glass slide. Coverslip and observe for the presence or absence of sperm.
6. Record result on worksheet. See EXPECTED VALUES below.
7. Repeat procedure using the second tube of Material. Store Materials 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 still are experiencing difficulty.

1. Material not thoroughly mixed or not homogenous.
2. Material temperature not between 18° and 26° C, Materials expired, stored improperly or contaminated.
3. 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 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