AQC Products POST VASECTOMY QUALITY CONTROL
Catalog #AQC111, AQC211

Fertility Solutions
11811 Shaker Blvd. Suite 330
Cleveland OH USA 44120
Telephone 216-491-0030 x200  Fax 216-491-0032

INTENDED USE
For In Vitro Diagnostic Use
AQC Post Vasectomy QC is intended for use to as post-vasectomy sperm count QC or for training, proficiency and competency testing or method validation.

PRODUCT DESCRIPTION
AQC Post Vasectomy QC 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 a potential biohazard. Donor’s blood was negative when tested for Human Immuno deficiency 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, which is available at fertilitysolutions.com/downloads.
4. Due to the nature of semen collection, bacteria may be present in some products.

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. AQC Post Vasectomy QC at room temperature (between 18° and 26° C).
2. Personal protective devices such as lab coat and gloves suitable for potential biological hazards.
3. Microscope (recommend phase contrast with 20X objective).
4. Vortex mixer, sperm counting chamber(s), micropipettor and tips for loading semen into the counting chamber.
5. Value Charts supplied with the product.

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. 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, make a dilution using a calibrated micropipettor to obtain precisely the required amounts of product and diluent (recommend SA101 Sperm Immobilizing Diluent). Sterile technique is recommended to avoid contamination.
4. Recap the vial tightly and store upright. Observe for the presence or absence of sperm using the laboratory testing procedure for post-vasectomy sperm analysis. Scan the entire chamber to confirm a negative value.
5. Record result. See EXPECTED VALUES below.
6. 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 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 ext207 if you continue to have difficulty.
1. Material not thoroughly mixed and not re-suspended.
2. Material temperature not between 18° and 26° C,
3. Materials expired, stored incorrectly or contaminated.

REFERENCES

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FOR BEST RESULTS

LET THE REAGENTS WARM TO ROOM TEMPERATURE

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.

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

FOR ASSISTANCE, CALL 1-216-491-0030 ext207