

AQC™ ANTISPERM ANTIBODY QUALITY CONTROL
Catalog #AQC109

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™ Antisperm Antibody Quality Controls are intended for use to increase proficiency of laboratory staff, to investigate antisperm antibody methods or to train technical staff in antisperm antibody assessment.

PRODUCT DESCRIPTION

AQC™ Antisperm Antibody Quality Controls are supplied as serum samples which are positive or negative for antisperm antibodies.

WARNINGS AND PRECAUTIONS

1. Materials are for in vitro use only.
2. Antisperm Antibody Quality Controls are made from human serum 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. Wear appropriate laboratory safety equipment.
3. Users should keep the Material Safety Data Sheet on file.
4. Materials have been heat-treated at 56°C for 30 minutes.

STORAGE AND STABILITY

1. Materials are routinely shipped 2 Day Air and may arrive defrosted. This does not influence the performance of the reagents. The materials should be stored in the freezer at a temperature below -10°C upon arrival.
2. When stored unopened below -10°C, the Materials are stable until the expiration date stated on the label.
3. When stored below -10°C, the Materials should be stable for 6 weeks after opening when handled properly.

MATERIALS NEEDED

1. Personal protective devices such as lab coat and gloves suitable for potential biological hazards.
2. Reagents, equipment and supplies for the antisperm antibody testing procedure used.
3. Tally device.
4. Worksheet.
5. Data Documentation Table.

PROCEDURE

1. Thaw material and bring to temperature needed for testing.
2. Note Material lot number on worksheet.
3. Perform testing.
4. Record answer on worksheet, then record the results on the supplied Data Documentation Table. See EXPECTED VALUES Section below.
5. Repeat procedure using the second Material. Store Materials in freezer after use.

EXPECTED VALUES

The expected values have been established in the Fertility Solutions Inc. clinical reference laboratory. Some of the usual reasons that cause results to differ from the expected values are listed below. Before repeating the procedure, review the following items to determine the most likely cause of error. Repeat the test. If the results are still out of control, you will need to systematically check all causes for error. Call technical support at 216-491-0030 X204 if you still are experiencing difficulty.

1. Wrong Material used.
2. Error in test procedure or test reagents.
3. Materials used after expiration date or stored improperly.

REFERENCES

1. Laboratory Quality Management (GS Cembrowski and RN Carey, eds.), ASCP Press, 1989.
2. Rothmann SA and Morgan BW (1989). Laboratory diagnosis in andrology. Cleve. Clinic J. Med. 56:805-810.
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