

## AQC™ ANTISPERM ANTIBODY QUALITY CONTROL Catalog #AQC109

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 Control is intended for use as antisperm antibody quality control or for training, proficiency and competency testing or method validation.

### PRODUCT DESCRIPTION

AQC™ Antisperm Antibody Quality Control is supplied as two lots of sera that are positive or negative for antisperm antibodies.

### WARNINGS AND PRECAUTIONS

1. Product is for in vitro use only.
2. Antisperm Antibody Quality Control is 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. Product as been incubated at 56°C for 30 minutes.

### STORAGE AND STABILITY

1. Product routinely shipped 2 Day Air and may arrive defrosted. This does not influence the performance of the reagents. The product should be stored in the freezer at a temperature below -10°C upon arrival.
2. When stored unopened below -10°C, the product is stable until the expiration date stated on the label.
3. When stored below -10°C, the product 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 and calculator.
5. Levey-Jennings Charts.

### PROCEDURE

1. Thaw one vial of each lot and bring to temperature needed for testing.
2. Note product lot number on worksheet.
3. Perform testing using both lots with the laboratory method for antisperm antibody testing.
4. Record answer on worksheet, then record the results on the supplied Data Documentation Table. See EXPECTED VALUES Section below.
5. Store product 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 product used.
2. Error in test procedure or test reagents.
3. Product 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, 2010.