

AQC™ Products SPERM VIABILITY QUALITY CONTROL SMEARS
Catalog #AQC107

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™ Sperm Viability Quality Control Smears are intended for use to increase proficiency of laboratory staff sperm viability assessment skills, to investigate sperm viability methods or to train technical staff in sperm viability measurement.

PRODUCT DESCRIPTION

AQC™ Sperm Viability Quality Control Smears are supplied as eosin-nigrosin stained semen smears on glass microscope slides. The Smears contain sperm with different viability as commonly encountered in clinical practice.

WARNINGS AND PRECAUTIONS

1. Smears are for in vitro use only.
2. Sperm Viability Smears are made 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.
3. Wear appropriate laboratory safety equipment.

STORAGE AND STABILITY

1. Smears should be stored when not in use in a light-resistant dry container at room temperature (20° - 28° C). Keep light exposure to a minimum to prevent fading. Do not store in a humid environment or in an air tight container that could allow condensation near the slides. When stored properly, the Smears are stable for a minimum of 6 months from receipt.

MATERIALS NEEDED

1. Personal protective devices such as lab coat and gloves suitable for potential biological hazards.
2. Bright-field microscope with high power (40X) objective.
3. Two-key or multi-key tally device.
4. Worksheet.
5. Process Control Chart.

PROCEDURES

1. The microscope should have a centered light source and clean, oil-free objectives.
2. Clear tally of previous numbers.
3. Evaluate 200 cells using the 40X lens. Categorize sperm according to live (white, unstained) or dead (pink, stained).
4. Compute percent viable sperm as follows: $\#live/200 \times 100$.
5. Record tally numbers on worksheet, then record the results on the supplied Process Control Chart. See EXPECTED VALUES Section below.
6. Repeat procedure using the second Smears. Store Smears in light-resistant container in a dry environment after use.

EXPECTED VALUES

Expected values were established in the Fertility Solutions Inc. clinical reference laboratory. Based on analysis of at least 20 replicates, 2 SD were computed (95% confidence). Laboratories should verify their own ranges. 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, systematically check all causes for error. Call technical support at 216-491-0030 X204 if you still are experiencing difficulty.

1. Wrong Smears used for Table, error in computations, values incorrectly transcribed from the worksheet to graph.
2. Microscope improperly calibrated.
3. Smears stored improperly.

REFERENCES

1. Kinzer DK and Rothmann SA. The Andrology Trainer. Fertility Solutions Inc., 1998. (Product #AT100)
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.
4. WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, Cambridge University Press, 1992, 1999.