AQC™ SPERM VIABILITY QUALITY CONTROL SMEARS
Catalog #AQC107

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INTENDED USE For In Vitro Diagnostic Use

AQC™ Sperm Viability Quality Control Smears are intended for use as a sperm viability quality control or for training, proficiency and competency testing or sperm viability method validation.

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 levels of viability as commonly encountered in clinical practice.

WARNINGS AND PRECAUTIONS

1. Smears are for in vitro use only.
2. Smears are manufactured from human semen and should be handled and disposed of as potential biohazards. Donor may not have been tested for 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^{o} - 28^{o} 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 and calculator.
5. Levey-Jennings Charts

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 X 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.
7. 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.
4. Tallying cells that are mostly white, but slightly pink as live rather than dead. If there is any pink, the cell should be tallied as dead.
5. Smears old and the stain is faded

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, 2010.

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