

AQC™ Products SPERM MORPHOLOGY QUALITY CONTROL SMEARS
Catalog #AQC105

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 Morphology Quality Control Smears are intended for use to assess proficiency of laboratory staff sperm morphology skills, to investigate routine sperm morphology methods, or to train technical staff in sperm morphology.

PRODUCT DESCRIPTION

AQC™ Sperm Morphology Quality Control Smears are supplied as semen smears on glass microscope slides (either Papanicolaou-stained or unstained) and contain sperm with different types of morphology commonly encountered in clinical practice.

WARNINGS AND PRECAUTIONS

1. Smears are for in vitro use only.
2. Smears contain human material and should be handled and disposed of as potential biohazards. Donor has not been tested for infectious agents.
3. Wear appropriate laboratory safety equipment.

STORAGE AND STABILITY

1. Smears must be stored in a dry light-resistant container at room temperature (20° - 28° C). Do not store in a humid environment or in an airtight container that could allow condensation to form on the slides.
2. Keep light exposure to a minimum. When stored properly, the smears are stable for 6 months from receipt.

MATERIALS NEEDED

1. Personal protective clothing such as lab coat and gloves (the Smears contain human semen and should be treated as potentially biological hazards).
2. Microscope with high power (40X) and oil immersion (100X) objectives, and immersion oil.
3. Multi-key tally device.
4. Worksheet
5. Data Documentation Table

PROCEDURES

1. **If** unstained slides are included, they may be stained immediately with PAP or Wright-Giemsa stain. (If coverslip is attached, slide has been prestained.)
2. The microscope should have a centered light source and clean, oil-free objectives.
3. Clear tally of previous numbers. Perform a differential analysis (200 cells recommended) using the oil immersion objective. Categorize sperm according to the criteria you routinely use (answers are supplied for the 1992 3rd Edition WHO Criteria and for Strict Criteria (see Sperm Confirm reference for more information - product #SC102).
4. Record tally numbers on worksheet, then record the result on the supplied Process Control Chart. See EXPECTED VALUES Section below.
5. Repeat procedure using the second Smears. Store Smears in light-resistant container 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, you will need to check all causes for error. Call technical support at 216-491-0030 X204 if you still are experiencing difficulty.

1. Wrong Smear used for Table, error in computations, values incorrectly transcribed from the worksheet to graph.
2. Different classification scheme used; establish ranges for the scheme being used.
3. If CASA system used, check threshold or calibration settings.

REFERENCES

1. Kinzer DK and Rothmann SA. The Andrology Trainer. Fertility Solutions Inc., 1998. (Product #AT100)
2. Kruger TK, Acosta AA, Simmons KF, Swanson RJ, Matta JF, Veeck L, Morshedi R, and Brugo S. New method of evaluating sperm morphology with predictive value for IVF. Urology 30:248, 1987.
3. Laboratory Quality Management (GS Cembrowski and RN Carey, eds.), ASCP Press, 1989.
4. Rothmann SA. Sperm Confirm: A Photo-Slide Atlas of Human Semen Cytology and Sperm Morphology, Fertility Solutions Inc., 1997. (Product #SC102).
5. WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, Cambridge University Press, 1992.