



## AQC SPERM VIABILITY QUALITY CONTROL SMEARS Catalog #AQC107

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### INTENDED USE For In Vitro Diagnostic Use

AQC Sperm Viability QC Smears are intended for use as a sperm viability QC or for training, proficiency and competency testing or sperm viability method validation.

### PRODUCT DESCRIPTION

AQC Sperm Viability QC Smears are supplied as eosin-nigrosin stained and coverslipped 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° - 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. AQC Sperm Viability QC smears.
3. Bright-field microscope with high power (40X) objective.
4. Two-key or multi-key tally device.
5. Calculator.
6. Levey-Jennings Charts supplied with the product.

### PROCEDURE

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 objective. Tally sperm that have excluded the stain and are all white or faintly pink as **viable**; tally sperm that are stained partially or totally dark pink as **non-viable**.
4. Count only complete sperm; those with a head, midpiece and tail.
5. Analyze multiple areas of smear, not just one small section.
6. Record tally numbers, calculate % viable sperm as follows:  $\# \text{ live}/200 \times 100$  and then record the results on the supplied Levey-Jennings Chart. See EXPECTED VALUES Section below.
7. Repeat procedure using the second smear.
8. Store smears in light-resistant container in a dry environment after use.

### EXPECTED VALUES

Expected values were established in the Fertility Solutions clinical reference laboratory. Based on analysis of at least 20 replicates, the 3 SD limits were computed (99% confidence interval). 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 ext207 if you are still experiencing difficulty.

1. Wrong smear analyzed, error in computations, values incorrectly transcribed to graph.
2. Microscope optics not centered and aligned.
3. Smears stored incorrectly and stain transferred to all cells.
4. Tallying cells that are mostly white, but faintly pink as dead rather than live.
5. Tallying cells partially dark pink as alive rather than dead.
6. Smears old and the stain is faded

### REFERENCES

1. Rothmann SA and Reese AA. The Andrology Trainer: Fourth Edition. Fertility Solutions Inc., Cleveland, 2010.
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.