SPERM MORPHOLOGY QUALITY CONTROL SMEARS
Catalog #AQC105, AQC205 and AQC305 Glass Slides

Fertility Solutions
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Cleveland OH USA 44120
Telephone 216-491-0030 x200 Fax 216-491-0032

INTENDED USE For In Vitro Diagnostic Use

Sperm Morphology Quality Control (QC) Smears are intended for use as sperm morphology QC, training, proficiency and competency testing or sperm morphology method validation. At least one smear should be analyzed once per week and within 7 days of patient testing.

PRODUCT DESCRIPTION

Sperm Morphology QC Smears are supplied as semen smears on glass microscope slides (either modified Papanicolaou-stained or unstained) and contain sperm with different types of morphology commonly seen 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 must be stored in a dry light-resistant container at room temperature (18° - 26°C).
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 potential biological hazards).
2. Sperm Morphology Quality Control Smear(s).
3. Bright field microscope with oil immersion (100X) objective, and immersion oil.
4. Multi-key tally device.
5. Levey-Jennings Charts supplied with the product and calculator.

PROCEDURES

1. The microscope should have a centered light source and clean, oil-free objectives.
2. Clear tally of previous numbers. Perform a differential analysis (200 cells recommended) using the oil immersion objective. Categorize sperm according to the classification system used by the laboratory. (Minimum of Normal, Borderline and Abnormal recommended)
3. Record tally numbers, calculate % normal and record the result on the supplied Levey-Jennings Chart. See EXPECTED VALUES Section below.
4. Store smears in light-resistant container 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, you will need to check all causes for error. Call Technical Support at 216-491-0030 ext 200 if you are still experiencing difficulty.

1. Wrong smear analyzed, error in computations, values incorrectly transcribed 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. Rothmann SA and Bort AM. Semen Analysis Trainer. Fertility Solutions Inc., Cleveland, 2015.
2. Rothmann SA and Bort AM. Sperm Confirm Morphology Classification Method. Fertility Solutions Inc., Cleveland, 2015.
3. Bort AM, Rothmann SA, Quigley JR, Pillow RL. Sperm morphology using a novel dichotomous key algorithm improves analysis stability, reproducibility and teachability. Androl 2014; 2(Suppl),103.
4. Rothmann SA, Bort A-M, Quigley JR, Pillow R. Sperm morphology classification: a rational method for schemes adopted by the world health organization. Methods Mol Biol 2013; 927,27-37
5. WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, Cambridge University Press, 2010.

10/08/2015 v004

SPERM MORPHOLOGY QUALITY CONTROL SMEARS

Catalog # AQC305 *VIRTUMORPH®* Smear

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INTENDED USE For In Vitro Diagnostic Use

Sperm Morphology *VIRTUMORPH®* Smears are intended for use as sperm morphology quality assurance, training, proficiency and competency testing or sperm morphology method validation. When used appropriately, the product can help the lab meet inspection requirements for demonstrating consistency among technologists. The *VIRTUMORPH®* smear should be analyzed a minimum of once per month.

PRODUCT DESCRIPTION

VIRTUMORPH® smears are photographs containing 50 sperm with different types of morphology commonly seen in clinical practice.

WARNINGS AND PRECAUTIONS

1. Smears are for in vitro use only.

STORAGE AND STABILITY

1. Smears must be stored in a dry light-resistant container at room temperature (18° - 26°C).
2. Keep light exposure to a minimum. When stored properly, the *VIRTUMORPH®* smears do not expire.

MATERIALS NEEDED

1. *VIRTUMORPH®* smear.
2. Well illuminated workspace
3. *VIRTUMORPH®* Worksheet.
4. *VIRTUMORPH®* smears answer key supplied with the product.

PROCEDURES

1. Using the *SPERMCONFIRM®* Morphology Classification Algorithm, perform a differential analysis for each of the 50 cells. Categorize sperm according to the classification system used by the laboratory.
2. Record individual results on the worksheet and compare results to answer key provided. See EXPECTED VALUES Section below.
3. Store *VIRTUMORPH®* smear appropriately after use.

EXPECTED VALUES

Expected values were established in the Fertility Solutions clinical reference laboratory by expert sperm morphologists. While it is not possible to remove all subjectivity, worked classifications are provided based on a consensus evaluation of each sperm using *SPERMCONFIRM®* Morphology Classification Algorithm. Print and other minor variation among smears can change the appearance of some sperm. Laboratories should verify the results for their specific smear. 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 ext 206 if you are still experiencing difficulty.

1. Wrong smear analyzed, error in tallying
2. Different classification scheme used; establish ranges for the scheme being used.
3. Minor variation in printed appearance of sperm.

REFERENCES

1. Rothmann SA and Bort AM. Semen Analysis Trainer. Fertility Solutions Inc., Cleveland, 2015.
2. Rothmann SA and Bort AM. Sperm Confirm Morphology Classification Method. Fertility Solutions Inc., Cleveland, 2015.
3. Bort AM, Rothmann SA, Quigley JR, Pillow RL. Sperm morphology using a novel dichotomous key algorithm improves analysis stability, reproducibility and teachability. Androl 2014; 2(Suppl),103.
4. Rothmann SA, Bort A-M, Quigley JR, Pillow R. Sperm morphology classification: a rational method for schemes adopted by the world health organization. Methods Mol Biol 2013; 927,27-37
5. WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, Cambridge University Press, 2010.