

## FERTILITY SOLUTIONS PROFICIENCY TEST PRODUCTS SPERM COUNT PRODUCTS

### Catalog #PT103, #PT111

Products of Fertility Solutions Inc. 13000 Shaker Blvd. Cleveland OH USA 44120 (Tele 216-491-0030) (Fax 216-491-0032)

#### INTENDED USE For In Vitro Diagnostic Use

Proficiency Test Sperm Count Products are intended for use to assess proficiency of laboratory staff sperm counting skills, to investigate routine sperm counting methods or to train technical staff in sperm counting.

#### PRODUCT DESCRIPTION

Products contain suspensions of stabilized human sperm at concentrations commonly observed in clinical practice.

#### WARNINGS AND PRECAUTIONS

1. Products are for in vitro use only.
2. Products are derived from human material and should be handled and disposed of as potential biohazards. Products contain dilute buffered formalin.
3. Wear appropriate laboratory protective safety equipment while handling.
4. Users should keep the Product Material Safety Data Sheet on file.
5. Due to the nature of semen collection, bacteria may be present in some Products.

#### STORAGE AND STABILITY

1. Products should be stored at 2°- 8° C. DO NOT FREEZE. DO NOT USE ABOVE ROOM TEMPERATURE.
2. When stored unopened at 2°- 8° C, the Products are stable until the expiration date stated on the label.
3. When stored at 2°- 8° C, the Products should be stable for 6 weeks after opening when handled properly.

#### MATERIALS NEEDED

1. AQC™ Sperm Count Products **at room temperature** (to save time, remove the Products from refrigerator first).
2. Personal protective devices such as lab coat and gloves suitable for potential biological hazards.
3. Vortex mixer, microscope (phase contrast recommended) and tally device OR Computer Assisted Sperm Analyzer (CASA).
4. Sperm counting chamber(s), micropipettor and tips for loading semen onto the counting chamber.
5. Micropipettors, tips, and diluent for making dilutions if necessary.
6. Worksheet (Supplied with Product)

#### PROCEDURE

1. Remove the Products from the refrigerator and foam packing for at least 30 minutes before proceeding.
2. To dislodge the pellet on the bottom of the tube, wait until the Reagents' temperature is 20-25° C, gently mix by vortexing at low speed for 5 - 10 sec. until the clear liquid turns turbid. Lightly tap the vial on a countertop before opening to remove any liquid from the top of the cap. Open top and mix several times with a pipette.
3. Use a calibrated micropipettor to precisely remove an amount appropriate for the counting chamber used (most sperm counting chambers need 5 uL to load). If using a hemacytometer chamber, make a dilution using a calibrated micropipettor to obtain precisely the required amounts of reagent and diluent. Do not use a blood cell diluting pipette. Fertility Solutions Inc. diluent is recommended. Sterile technique is recommended to avoid contaminating the Product. DO NOT WARM THE CHAMBER OR MICROSCOPE STAGE ABOVE ROOM TEMPERATURE OR CLUMPING MAY OCCUR.
4. Recap the tube tightly and store upright. Perform the count as usual and make appropriate calculations to determine the concentration (# sperm per ml).
5. Record result on worksheet, following worksheet instructions. Repeat procedure using the second Product.

#### COMMON SOURCES OF ERROR

Some of the common causes of counting errors are listed below. Review this list before performing the procedure to avoid obvious errors. A Quality Control program should be used regularly to check the accuracy of daily tests. If the results of repeat testing remain out of control, determine cause for error. Call technical support at 216-491-0030 X204 if needed..

1. Improper dilution.
2. Product or dilution not thoroughly mixed or not homogenous.
3. Product temperature not between 22° and 25° C, Products expired, stored improperly or contaminated.
4. Counting chamber not loaded correctly, not cleaned adequately, or worn. Too few squares counted on the chamber.
5. Microscope light source not centered, phase rings not aligned, CASA threshold or calibration settings improper.
6. Error in computations or numbers incorrectly transcribed from the worksheet.

#### 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. WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction,
4. Cambridge University Press, 1992, 1999.

## FERTILITY SOLUTIONS PROFICIENCY TEST PRODUCTS SPERM MORPHOLOGY SMEARS

### Catalog #PT105

Products of Fertility Solutions Inc. 13000 Shaker Blvd. Cleveland OH USA 44120 (Tele 216-491-0030) (Fax 216-491-0032)

#### INTENDED USE For In Vitro Diagnostic Use

AQC™ Sperm Morphology 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 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. Sperm Morphology Smears are made from human semen and should be handled and disposed of as potential biohazards.
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. 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. Brightfield microscope with high power (40X) and oil immersion (100X) objectives, and immersion oil.
3. Multi-key tally device.
4. Worksheet (Supplied with Products)

#### PROCEDURES

1. Smears were air-dried and were NOT fixed.
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 (see Sperm Confirm™ reference for more information - product #SC100).
4. Record tally numbers on worksheet, following worksheet instructions.
5. Repeat procedure using the second smear.

#### COMMON SOURCES OF ERROR

Some of the common causes of counting errors are listed below. Review this list before performing the procedure, to avoid obvious errors. A Quality Control program should be used regularly to check the accuracy of daily tests. If the results of repeat testing remain out of control, determine cause for error. Call technical support at 216-491-0030 X204 if you still are experiencing difficulty.

1. Wrong smear used for Result table, error in computations, values incorrectly transcribed from the worksheet.
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. Rothmann SA. Sperm Confirm™: A Photo-Slide Atlas of Human Semen Cytology and Sperm Morphology, Fertility Solutions Inc., 1997. (Product #SC100)
3. 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.
4. Laboratory Quality Management (GS Cembrowski and RN Carey, eds.), ASCP Press, 1989.
5. WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, Cambridge University Press, 1992, 1999.

## FERTILITY SOLUTIONS PROFICIENCY TEST PRODUCTS SPERM VIABILITY SMEARS

### Catalog #PT107

Products of Fertility Solutions Inc. 13000 Shaker Blvd. Cleveland OH USA 44120 (Tele 216-491-0030) (Fax 216-491-0032)

#### INTENDED USE For In Vitro Diagnostic Use

AQC™ Sperm Viability 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

Sperm Viability 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 semen and should be handled and disposed of as potential biohazards.
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 (Supplied with Products).

#### 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, following works heet instructions.
6. Repeat procedure using the second smear.

#### COMMON SOURCES OF ERROR

Some of the common causes of counting errors are listed below. Review this list before performing the procedure, to avoid obvious errors. A Quality Control program should be used regularly to check the accuracy of daily tests. If the results of repeat testing remain out of control, determine cause for error. Call technical support at 216-491-0030 X204 if you still are experiencing difficulty.

1. Error in computations, values incorrectly transcribed to the worksheet.
2. Microscope improperly calibrated or dirty.
3. Slides 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.

## **FERTILITY SOLUTIONS PROFICIENCY TEST PRODUCTS ANTISPERM ANTIBODY PRODUCTS**

### **Catalog #PT109**

Products of Fertility Solutions Inc. 13000 Shaker Blvd. Cleveland OH USA 44120 (Tele 216-491-0030) (Fax 216-491-0032)

#### **INTENDED USE For In Vitro Diagnostic Use**

AQC™ Antisperm Antibody Products are intended for use to increase proficiency of laboratory staff, to investigate antisperm antibody methods or to train technical staff in antisperm antibody assessment.

#### **PRODUCT DESCRIPTION**

Antisperm Antibody Products are supplied as serum samples which are positive or negative for antisperm antibodies.

#### **WARNINGS AND PRECAUTIONS**

1. Products are for in vitro use only.
2. Antisperm Antibody Products are made from human serum and should be handled and disposed of as potential biohazards.
3. Wear appropriate laboratory safety equipment.
4. Users should keep the Product Material Safety Data Sheet on file.
5. Products have been heat-treated at 56°C for 30 minutes.

#### **STORAGE AND STABILITY**

1. Products are routinely shipped 2 Day Air and may arrive defrosted. This does not influence the performance of the products. The products should be stored in the freezer at a temperature below -10°C upon arrival.
2. When stored unopened below -10°C, the Products are stable until the expiration date stated on the label.

#### **MATERIALS NEEDED**

1. Personal protective devices such as lab coat and gloves suitable for potential biological hazards.
2. Products, equipment and supplies for the antisperm antibody testing procedure used.
3. Tally device.
4. Worksheet (Supplied with Products).
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#### **PROCEDURE**

1. Thaw Product and bring to temperature needed for testing.
2. Note Product lot number on worksheet.
3. Perform testing.
4. Record answer on worksheet, following worksheet instructions.
5. Repeat procedure using the second Product.

#### **COMMON SOURCES OF ERROR**

Some of the common causes of counting errors are listed below. Review this list before performing the procedure, to avoid obvious errors. A Quality Control program should be used regularly to check the accuracy of daily tests. If the results of repeat testing remain out of control, determine cause for error. Call technical support at 216-491-0030 X204 if you still are experiencing difficulty.

1. Wrong Product used.
2. Error in computations or data transcription error.
3. Error in test procedure or test products.
4. Products used after expiration date or stored improperly.

#### **REFERENCES**

1. Laboratory Quality Management (GS Cembrowski and RN Carey, eds.), ASCP Press, 1989.
2. Rothmann SA and Morgan BW (1989). Laboratory diagnosis in andrology. Cleve. Clinic J. Med. 56:805-810.
3. WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, Cambridge University Press, 1992, 1999.