



FERTILITY SOLUTIONS

THE SEMEN ANALYSIS EXPERTS™

ANDROLOGY QUALITY COUNTS™

PROFICIENCY CHALLENGES

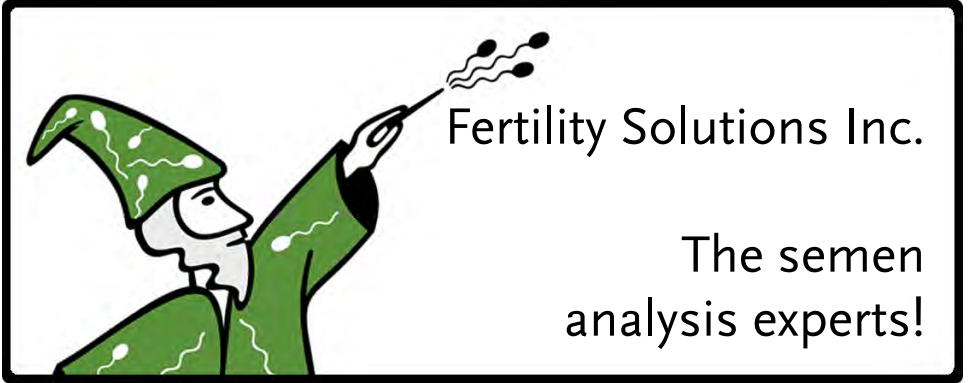
SPERM WIZARD™ EDUCATIONAL PRODUCTS

ANDROLOGY LABORATORY PRODUCTS

Product Catalogue

2011

Contents and Welcome



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Clarifying CLIA '88 status of semen analysis

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William Byrd, Ph.D.

Susan Rothmann, Ph.D.

Q. I am confused about the status of semen analysis under the Clinical Laboratory Improvement Amendments of 1988. Can you clarify its complexity level and performance requirements?

A. It is not surprising that you are confused about semen analysis and CLIA '88. Semen analysis was listed as a waived test in the original CLIA '88 proposed rules. But in the final rules, semen analysis was defined in two categories: as moderate complexity for qualitative semen analysis, which tests only for the presence or absence of sperm; and high complexity for quantitative semen analysis, where various components of the semen are enumerated - for example, sperm count, percent motile sperm, and percent normal forms.¹

To add to the confusion, the definition was amended after the 1992 Final Rules were published. Recognizing that some physicians wanted to perform qualitative semen analyses in their offices, especially after vasectomy, CLIA '88 authors included this test in a post-Final Rule category, physician-performed microscopy.

The term recently was changed to include various nonphysicians. The test category provider-performed microscopy now replaces physician-performed microscopy, which allows physicians, nurse practitioners, and physician assistants to perform provider-performed microscopy tests, including qualitative semen analysis.²

Once laboratorians understand the procedures' complexity level, the performance requirements are clear:

Control procedures are performed on a routine basis to monitor the stability of the method or test system; control and calibration materials provide a means to indirectly assess the accuracy and precision of the patient test results...For qualitative tests, the laboratory must include a positive and negative control with each run of patient specimens...For quantitative tests, the laboratory must include at least two samples of different concentrations of either calibration materials, control materials, or a combination thereof...not less frequently than once each run of patient specimens...A run is an interval within which the accuracy and precision of a testing system is expected to be stable, but cannot be greater than 24 hours. --Subpart 493.1218, p.7,166.

Quantitative semen analysis usually contains at least three distinct components: sperm count, sperm motility, and sperm morphology. Control materials for all components are available from several vendors. It is important to understand the different requirements for unassayed and assayed controls. Laboratorians must determine the mean and standard deviation for each lot of unassayed material by repetitive testing. Target values of assayed control materials are acceptable performance standards as long as they are verified by the laboratory. Records must be kept for at least two years.

PPM and high-complexity tests also require periodic proficiency testing. A U.S. Health and Human Services-approved proficiency test for analyzing semen components does not currently exist. Prior to its dissolution in the fall of 1995, the College's Reproductive Biology Resource Committee designed several semen analysis Surveys for 1997. They may be transferred to the CAP Hematology/Clinical Microscopy Resource Committee if sufficient interest exists. Until a Survey is available, laboratories performing semen analysis must comply with the following section of CLIA '88:

If a laboratory performs tests that are not included under Subpart I Proficiency Testing Programs, the laboratory must have a system for verifying the accuracy and reliability of its test results at least twice a year. --Subpart 493.1709, p. 7,184.

As with other high-complexity tests, educational requirements for supervising and performing quantitative semen analysis must be followed.

Laboratorians and clinicians have often voiced concerns that semen analysis results were highly subjective and variable.^{3,4} CLIA '88 places semen analysis in categories requiring rigorous quality assessment, creating the opportunity for more meaningful and reproducible results.

References:

1. ***Clinical Laboratory Improvement Amendments of 1988, Final Rule. Federal Register Part II. February 28, 1992; 57(40):42.***
2. ***Clinical Laboratory Improvement Amendments of 1988. Federal Register. April 24, 1988; 60(78):2044.***
3. ***Baker DJ, Paterson MA, Klaassen JM, Wyrick-Glatzel. Semen evaluations in the clinical laboratory: How well are they being performed? Lab Med. 1994; 25:509-514.***
4. ***Chong AP, Walters CA, Weinrieb SA. The neglected laboratory test: the semen analysis. J Androl. 1983; 4:280-282.***

Dr. Byrd is commissioner, Reproductive Laboratory Accreditation Program, University of Texas Southwestern Medical Center, Dallas, and was a member of the CAP/ASRM Reproductive Biology Resource Committee. Dr. Rothmann was a consultant to the committee.

QUALITY CONTROLS

The Industry Standard in Quality Control

AQC™ Sperm Count Quality Control

AQC103



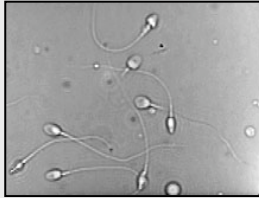
Fertility Solutions Inc.'s AQC™ Sperm Count Quality Control provides laboratories with an easy way to perform routine sperm count QC using an appropriate material. AQC™ Sperm Count Quality Control was introduced in 1995 and formed the basis for sperm count proficiency testing in the USA. It remains the most widely accepted QC for sperm counting. Since sperm have oval or other shaped heads and a tail which may be coiled, straight or overlapped with other sperm, counting QC should look like clinical samples. **Our unique quality control is made from human sperm, stabilized in a proprietary diluent and preservative, that mimics actual semen specimens.** Latex beads are poor surrogates for sperm, as reported in several European studies.

The product is packaged with two levels, as required by CLIA '88 for high complexity testing. The assay results for each lot are included as Levy-Jennings plots with check boxes to make full documentation of usage easy and inspection-ready.

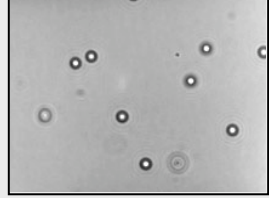
QUALITY CONTROLS



Human Sperm



Sperm Count QC



Latex Beads

Sperm have oval heads and tails that curl, coil and overlap which increases counting difficulty. An appropriate quality control is one that appears similar to human sperm. Latex beads are uniform spheres that are easy to count but do not resemble human sperm.

We offer multiple configurations of our AQC™ Sperm Count Quality Control:

Product	Volume	Usage
Standard	300 μ L	sufficient for 30-45 determinations using sperm counting chambers, 10-20 using hemacytometers
Mini	150 μ L	sufficient for 15--25 determinations using sperm counting chambers, 5-10 using hemacytometers
Large	4.0 mL	sufficient for 4-5 determinations using analyzers that require large sample volume

Specifications

Volume: 2 assayed concentrations between 5 and 60 mil per mL. With most sperm counting chambers, the standard volume is sufficient for 30 determinations.

Shelf Life: Open vial shelf life is 6 weeks, closed vial shelf life is 12 months from date of manufacture. Store refrigerated at 5-15°C.

FDA Clearance: Class II, for semen analysis quality control

QUALITY CONTROLS

AQC™ Sperm Morphology Quality Control

AQC105



Sperm morphology is an important predictor of fertility and is often the most influential parameter in selecting fertility treatment and ART options. Maintaining classification precision requires longitudinal quality control to ensure consistent and uniform classification of normal and various abnormal forms over time and among technologists. AQC™ Sperm Morphology Quality Control contains two modified Papanicolaou-

stained semen smears assayed using both WHO 3rd Edition and Strict/WHO 4th Edition (synonymous with Kruger and Tygerberg) classifications. A differential of common forms is also provided with the WHO 3rd classification. Levy-Jennings charts provide both immediate feedback and documentation for inspection.

A significant problem with Strict/WHO 4th classification is the tendency to become more strict over time, sometimes to the point that no semen analyses have normal sperm. Regular assessment of AQC™ Sperm Morphology Quality Control smears can detect and help prevent shifts in classification. The smears also can be used to form a smear library for training.

Unstained smears are available for labs that use other stains.

Specifications

Shelf Life: 6 months from date of receipt. Smears should be stored in a dry location at room temperature.

FDA Clearance: Class I, For In Vitro Diagnosis

QUALITY CONTROLS

AQC™ Sperm VirtuMorph™ Quality Control AQC305

This is our high resolution 11"x17" color print of a Pap-stained semen smear. Like a semen smear, the VirtuMorph™ is analyzed to determine the percent of sperm with normal forms, but the paper format permits numbering of sperm for specific standardization of classification. Our approach has revolutionized sperm morphology proficiency testing and training and forms the basis of our revised Sperm Wizard Morphology Training Program. It is paired with one Sperm Morphology QC smear (as in AQC105). Both smears have Levy-Jennings charts for percent normal with both WHO 3rd and WHO4th/Strict methods and a discussion of classification rationale for ten numbered sperm. This product is especially suited for sperm morphology beginners and experts who work in labs where multiple technologists analyze morphology.



Specifications

Shelf Life: 6 months from date of receipt. Smears should be stored in a dry location at room temperature (glass smear only).

FDA Clearance: Class I, For In Vitro Diagnosis (glass smear only)



Q: Why should I use a disposable counting chamber instead of a Makler or Hemacytometer?

A: Using chambers designed for other tests, or using a plain slide with coverslip without a controlled volume, can lead to inaccurate results in analyzing sperm concentration and motility.

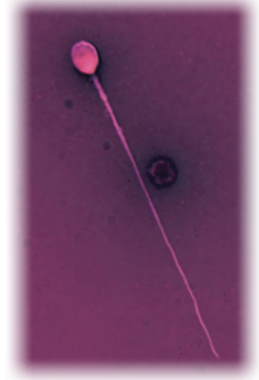
Sperm Wizard Spermocytometers™ contain two chambers with depths of 20 µM, which keep all the cells in view and allows for their free movement.

QUALITY CONTROLS

AQC™ Sperm Viability Quality Control

AQC107

When sperm aren't moving, the question becomes are they dead or do they have a motility defect? The easiest method to differentiate between the two is a viability stain based on cell membrane exclusion. Live cells exclude the stain and appear white against the dark black-purple of the nigrosin. Dead sperm are stained pink. Since this is a quantitative assay, it is high complexity and needs appropriate quality control. Document the QC quickly with Levey-Jennings plots included with the product.



Specifications

Shelf Life: Smears are stable for 6 months from date of shipment. Store in a dark dry environment at room temperature.

FDA Clearance: Class I, For In Vitro Diagnosis

AQC™ Antisperm Antibodies

AQC109



Sperm agglutination or a high percentage of active, non-progressive sperm is an indication that antisperm antibodies (ASA) may be present. Assays for ASA using describe presence or absence of antibodies thus require quality control, since this testing is moderate complexity under CLIA'88. Our product provides both IgG & IgA positive and

negative sera.

Specifications

Volume: 8 vials (4 positive and 4 negative) contains 0.5 mL.

Shelf Life: Closed vial shelf life is 3 years from date of manufacture. Store frozen below at -20°C.

FDA Clearance: Class I, For In Vitro Diagnosis

QUALITY CONTROLS

AQC™ Post-Vasectomy Quality Control

AQC111

Post-vasectomy semen testing requires the ability to distinguish a low concentration of sperm from the absence of sperm. Results are usually expressed qualitatively, making this a moderate complexity test under CLIA, requiring a positive and negative control each day of testing. Our QC contains a negative vial with no sperm and a positive vial with less than 2 million sperm per ml.

Specifications

Volume: Each vial contains 0.3 mL. With most sperm counting chambers, the volume is sufficient for 30 determinations.

Shelf Life: Open vial shelf life is 6 weeks, closed vial shelf life is 12 months from date of manufacture. Store refrigerated at 5-15°C.

FDA Clearance: Class I, For In Vitro Diagnosis

AQC™ Sperm Motility Quality Control

AQC119

This product tests the accuracy and reliability of the motility semen analysis using a virtual format. The product re-creates the actual test environment on video of two different semen samples. Each sample has multiple microscopy segments of motile and immobilized fields to simulate microscopic analysis using both objective (recommended) and subjective methods. The video comes with all the paperwork needed to document the quality testing. Reference ranges for each lot are presented on Levey-Jennings charts, and a printable worksheet containing all of the calculation formulas is included. The control is quick and easy to use with a duration of approximately 5 minutes per sample.



Specifications

Shelf Life: Product expires 100 days from first use. Store at room temperature.

LABORATORY SUPPLIES

Everything you need for Modern Andrology

Sperm Immobilizing Diluent

SA101



If you use a hemacytometer to count sperm, you need a reliable semen diluent. Our ready to use reagent for diluting and immobilizing sperm was especially formulated by Fertility Solutions Inc. to reduce sperm clumping that interferes with counting. Note: This diluent cannot be used to maintain motility. It will immobilize sperm immediately after contact.

Specifications

Volume: 100 mL

Shelf Life: 1 year from manufacture date. Store refrigerated at 2-8°C.

Sperm Viability Stain

SA200

Sperm motility is an important predictor of actual sperm function as it relates to fertility. However, there are some instances when immotile sperm are actually viable. This phenomenon is seen in Kartagener syndrome where an ultrastructural defect of the axoneme renders the sperm immotile but alive.

Sperm viability staining measures the integrity of the cell membrane. Viable sperm exclude the stain Eosin-Y thus making the sperm appear white. Dead sperm cannot exclude the stain. Using a dark counterstain such as nigrosin makes the sperm appear dark pink or bright white and are easier to differentiate.

Specifications

Volume: 20ml Eosin stain, 30ml Nigrosin stain in dropper bottles

Shelf Life: 1 year from manufacture date. Store at room temperature.

LABORATORY SUPPLIES

Sperm Viability Combo Pack

SA300

For easier ordering, we have put together this discounted Sperm Viability Combo Pack with all you need for testing. The Combo Pack includes Eosin and Nigrosin in convenient dropper bottles (SA200) and 2 human semen smears stained with Eosin-Nigrosin for excellent high-contrast discrimination of viable and non-viable sperm, with accompanying Levey-Jennings graphs for easy documentation (AQC107).



Specifications

Volume: 20ml Eosin stain, 30ml Nigrosin stain in dropper bottles

Shelf Life: Stains are 1 year from manufacture date. Store in a dark dry environment at room temperature.

FDA Clearance: Class I, For In Vitro Diagnosis (AQC107 only)

Sperm Wizard™ Papanicolaou Staining Kit

SA500

This is a complete set of reagents to stain semen smears for sperm morphology. This unique product includes the stains, alcohols, acid, bluing agent, clearing agent and mounting media for performing modified Papanicolaou stain, the recommended stain for sperm morphology analysis.

Contains

- 1 gallon of 100% Alcohol
- 2 gallons of 95% Alcohol
- 2 liters of 80% Alcohol
- 1 gallon of Master*Clear
- 1 pint of Harris Hematoxylin
- 1 liter of 0.5% HCL Solution
- 1 liter of Ammonia Water
- 1 liter of EA-65 Cytology Stain
- 1 liter of OG-6 Cytology Stain
- Cover*Safe ¼ oz 2 dropper cap bottles

LABORATORY SUPPLIES

Sperm Wizard™ Procedure Manuals

Our written, step by step procedures are available for training laboratory personnel in specific areas of semen analysis. All procedures are in NCCLS format, meet all CLIA and CAP requirements and guidelines. Procedures are available for the following subjects:

MAN103	Sperm Concentration and Motility
MAN105	Sperm Morphology
MAN107	Sperm Viability
MAN109	Antisperm Antibody Assay (Direct)
MAN 110	Antisperm Antibody Assay (Indirect)
MAN111	Post-Vasectomy Screening



Q: How do I know which classification system I'm using so I can check my results?

A: It depends on the reference atlas you use. For example, Adelman & Cahill's *Atlas of Sperm Morphology* uses the ASCP classification while Menkveld et al's *Atlas of Human Sperm Morphology* uses WHO 4th Ed. (Strict). Of course, my **Sperm Confirm Atlas** contains all five major classifications: ASCP, MacLeod, WHO 2nd, WHO 3rd and WHO 4th!

Sperm Confirm™ Atlas

SC102



Sperm Confirm™ Human Sperm Morphology and Semen Cytology Atlas is the only atlas which identifies sperm using the five major classification systems: MacLeod, ACSP, WHO 2nd Edition, WHO 3rd Edition, and WHO 4th/Strict. The Atlas contains 88 examples of cells commonly observed in semen cytology preparations, including various sperm morphologies, leukocytes, and immature sperm precursors. A discussion of classification rationale for the five systems accompanies each cell. Introductory text chapters compare and contrast the classification schemes and provide technical information. Photographs are laminated to protect them at the bench. Sperm Confirm makes an excellent training tool for the novice as well as a discussion focus for experienced cytologists.

Specifications

- 88 Full Color Images of sperm and cells commonly found in semen
- Sperm are classified using 5 major classification schemes
- Each cell accompanied by description and classification
- Revised 2008

The Sperm Wizard™ Troubleshooting Tool

SW100

Technical calls from our customers have identified the need for a tool that can help identify sources of sperm counting errors. In response, Fertility Solutions has developed the Sperm Wizard™ Semen Analysis Troubleshooting Tool which can rapidly and effectively identify various sources of sperm counting errors. The Sperm Wizard™ will guide you through three important exercises like Basic Hemacytometer Count, Sperm Count with Undiluted Reagent and Sperm Count with Diluted Reagent. One of our Technical Support Personnel will go over your answers and contact you to evaluate your results.

Specifications

Shelf Life: Open vial shelf life is 6 weeks, closed vial shelf life is 12 months from date of manufacture. Store refrigerated at 5-15°C.

TRAINING MATERIALS

AQC™ Andrology Trainer™ Third Edition

AT100



The Andrology Trainer™ Third Edition is designed to provide and document a training standard for semen analysis and related sperm testing procedures. Specific exercises with worksheets are provided to guide the learner through a logical sequence of training and testing procedures. Quality control techniques, quality assurance procedures, laboratory safety and maintenance, as well as patient test management are discussed with specific reference to semen testing.

It is paired with The Semen Analysis Video Trainer, an interactive video that presents the theory and practice of semen analysis in an exciting format. The Program can be used alone, but a complete package of all materials needed for the exercises (except patient samples) is available separately (The Andrology Trainer™ Tech Pak), or the two can be purchased together with a discounted price as The Andrology Trainer™ Training Pack.

Written by Susan A. Rothmann, Ph.D & Angela A. Reese, B.S
Developed & Published by Fertility Solutions Inc.

Specifications

- Training methods for basic sperm testing procedures including quality control and assurance
- Appropriate safety and maintenance information included
- Diagrams of workspace layouts improve work efficiency
- Extensively updated and expanded to provide standard training procedures for sperm concentration, motility, morphology, viability and post-vasectomy
- Many new exercises and examples as well as new in-depth training for motility determination and sperm counting chambers
- P.A.C.E accredited for 117 hours

TRAINING MATERIALS

AQC™ Andrology Trainer™ Tech Pack

AT300

Fertility Solutions Inc combines quality controls and laboratory products together to create the Andrology Trainer™ Tech Pak. The Tech Pak provides the disposable reagents and products (except patient semen samples) required to complete the exercises in the Andrology Trainer™. Create more time for working on the Program by having everything you need in the correct amount.

Contains

- Sperm Count Quality Control (AQC103) - Two units of each level
- Sperm Motility QC Video (AQC119)
- Sperm Morphology QC (AQC105) - 1 smear
- Sperm Viability QC (AQC107) - 1 smear
- Sperm Immobilizing Diluent (SA101)
- Sperm Viability Stain (SA200)

AQC™ Andrology Trainer™ Training Pack

AT500



A convenient package of our Andrology Trainer™ products at a discounted price.

Contains

- AQC™ Andrology Trainer™ Third Edition
- AQC™ Andrology Trainer™ Tech Pack

TRAINING MATERIALS

Sperm Wizard™ Morphology Training Program SW300

The Sperm Wizard™ Sperm Morphology Training Program is a comprehensive curriculum for sperm morphology analysis. Results of most proficiency testing encompass the entire testing range of 1 to 100%, indicating an urgent need for training and standardization. Our program has been widely accepted as an innovative and creative training method for sperm morphology. The self-paced program can be completed without leaving the laboratory, greatly reducing training cost.

At the core of the program are our unique VirtuMorph™ Virtual Semen Morphology Smears, high resolution 11"x17" color prints of a Pap-stained semen smear. Like a semen smear, the VirtuMorph™ is analyzed to determine the percent of sperm with normal forms. Ten sperm are numbered and have complete morphology descriptions and classifications using WHO3rd Edition and WHO4th/Strict methods. The format makes it easier to understand classification rationale and competency than a glass slide because it allows trainees to discuss specific cells where everyone can see it.

Our Training Program also contains the Sperm Confirm Atlas, assayed and unassayed semen smears, an instructional video for preparing and staining smears and logical, self-paced exercises. A chart for documenting completion of each exercise maps progress through the program. A certificate of program completion will be sent after the documentation chart is reviewed.

Contains

- Master Curriculum
- Supervisor Manual with answers to quizzes and smear results
- Trainee Workbooks purchased separately (SW400)
- Sperm Wizard™ Morphology Training Program Oversight (SW600) is required for every 5 trainees in the program.
- A Sperm Wizard™ candle & Happy Sperm Keychains for each trainee.
- P.A.C.E accredited for 85 hours

Sperm Wizard™ Semen Analysis Starter Pack SW200

With the Sperm Wizard™ Semen Analysis Starter Pack, we've put all the bench references, procedures, QC and reagents needed for semen analysis in one package. Each kit comes with our Sperm Wizard™ candle and Happy Sperm key chains to decorate your semen analysis area!

Contains

- The Andrology Trainer™
- The Sperm Confirm™ Atlas
- AQC™ Quality Controls for count, morphology, motility and viability
- Viability stain (SA200)
- Semen Immobilizing Diluent (SA101)
- Laminated procedure wall charts
- Sample sperm counting chambers

Sperm Morphology Smear Wizard SW500

The Sperm Morphology Smear Wizard™ teaches how to make excellent semen smears and stain them properly. Suggested by customers whose semen smear quality made classification of morphology difficult, the product includes complete procedures for smear preparation and staining with a modified Papanicolaou method originated by sperm morphology pioneer John MacLeod, videos of semen smearing and staining techniques, and photomicrographs of good and poorly-stained smears. The product also contains stained and unstained smears from the same morphology lot along with photos of microscopic fields from the stained smear so you can compare your technique against a standard. The smears come with Levy-Jennings plots of percent normal forms for WHO 3rd and Strict/WHO4th, allowing them to be used for quality control too. Supplemental smears and photos are available, singly or as a "Sperm of the Month" package.

Customization Available: supplemental smears and photos (SW501)

COMPETENCY TESTING

Demonstrate your competency with confidence

If you wonder how your laboratory's semen analysis compares to your peers, or are concerned about meeting government laboratory requirements for semen analysis proficiency testing, Fertility Solutions Inc. has THE solution — Proficiency Challenges. The experts in semen analysis quality control and improvement, Fertility Solutions Inc. offers a set of proficiency challenges for external quality control to help you meet regulations like this:

"...the laboratory must have a system for verifying the accuracy and reliability of its test results at least twice a year..." Federal Register Part II. 1992; (Friday February 28) 57: No. 40 [42 CFA 405 et al.]

Unlike other proficiency testing services, Fertility Solutions manufactures its own products. It is the only proficiency test manufactured and analyzed by semen analysis experts. Our unique proficiency challenges have been tested by many laboratories that perform different types of sperm analysis.

- Challenges are offered twice a year, in March and September
- Both challenge events include two levels of proficiency materials
- Results of up to 5 participants for each challenge
- Each participating laboratory receives a peer group analysis report and certificate documenting performance and peer ranges.
- Laboratories with out-of-range answers receive extensive corrective action assistance from our Sperm Wizard!

Sperm Count	2 0.15 mL levels of sperm suspension
Sperm Morphology	1 unstained human semen smear and 1 virtual smear. Stained smears are available by request.
Sperm Viability	2 Eosin-Nigrosin stained human semen smears.
Antisperm Antibody Screen	2 levels of human serum, each containing 0.15 ml.
Post-Vasectomy Screening	2 levels of sperm suspension, each containing 0.15 ml.
Sperm Motility	CD with videos containing multiple microscopic fields showing live and immobilized sperm.

Customer Service



Our Laboratory Technical Support Team is board-certified & board-eligible, with many years experience in andrology testing. We provide personalized attention to your specific situation. Our Customer Service Team will work with you to find or create the product mix appropriate for your lab's setting. All products are shipped promptly, within 10 days of placing the order. Prepaid subscriptions can either be shipped all at once, to be used as needed, or we can schedule regular shipments throughout the year. Educational wall charts are available on a variety of andrology topics, and can be provided on request.

Contact us anytime with questions at **1-800-959-7656** and **techsupport@fertilitysolutions.com**. If we don't know the answer to your question, we'll find it!

How to Order

PHONE

Call our toll-free number at 1-800-959-7656 to speak to Customer Sales. Please be sure to have your PO# ready!

FAX

Send the order form to 1-216-491-0032. Be sure your faxed order form contains the following information:

- Ship To and Bill To addresses
- Contact name & phone number
- PO Number
- Item numbers & quantity of each

Our standard payment terms are net 30 days from date of invoice. Subscriptions and Proficiency Challenges, however, must be prepaid and are not refundable. Orders are shipped via UPS Ground from our office in Cleveland, OH, although 2nd Day and Overnight service is available on request. There is an additional charge for this service.