



# Fertility Solutions, Inc

## Product Catalog



# Fertility Solutions Product Catalogue: 2023

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## About Fertility Solutions

Fertility Solutions Inc. manufactures and distributes unique products for male fertility testing laboratories. Founded in 1992 by experts in semen analysis and andrology, the Company fills the substantial need for quality management and teaching tools required for reliable semen analysis, a critical fertility diagnosis test. Often called “the neglected lab test,” semen analysis has often been performed without adequate training or quality control, in spite of government designation as a high-complexity test. Fertility Solutions Inc. creates products that help labs provide accurate results to fertility care providers using cost effective products and methods, and facilitate informed choices for appropriate patient therapy.

### ***Product lines include:***

Semen Analysis Quality Controls - made from human sperm

Competency Challenges

Andrology Laboratory Reagents and Chambers

Sperm Wizard® Academy Training Products

Post Training Examinations

Validation Sets

Fertility Solutions operates in Cleveland, Ohio, and is certified as a women-owned small business. Our products are distributed in North America to general hospital laboratories, pathology laboratories, IVF/ART and andrology laboratories, physician office laboratories, military bases, colleges and universities. Our goal is to help make your laboratory's Andrology Quality Count!

**Clarifying CLIA '88 status of semen analysis**  
reprinted with permission from CAP Today, January, 1996  
William Byrd, Ph.D., Susan Rothmann, Ph.D.

*Editor's note: A number of laboratories have queried the CAP regarding the status of semen analysis. Two CAP expert consultants have agreed to address the most frequent queries for our Surveys participants.*

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.<sup>1</sup>

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.<sup>2</sup>

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.<sup>3,4</sup> 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.*

## Customer Service

Our Laboratory Support Team has many years of 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. Prepaid subscriptions can either be shipped all at once, to be used as needed, or we can schedule regular shipments throughout the year.

Contact us anytime with questions at 216-491-0030 and [techsupport@fertilitysolutions.com](mailto:techsupport@fertilitysolutions.com). We are here to be your one-stop partner in quality.



## Ordering Information

### ***Ordering methods available:***

Email: [sales@fertilitysolutions.com](mailto:sales@fertilitysolutions.com)

Fax: 216-491-0032.

Phone: 216-491-0030 ext. 200

Online: [www.fertilitysolutions.com/sales/index.html](http://www.fertilitysolutions.com/sales/index.html)

order form or submit a pdf of purchase order

### ***Be sure your order contains the following information:***

Ship To and Bill To addresses

Contact name & phone number

PO Number

Item numbers & quantity of each

### ***Payment terms: net 30, US Dollars***

Subscriptions must be prepaid and are not refundable.

Orders are shipped via UPS Ground from our office in Cleveland, OH, although 3 Day, 2 Day, and Overnight service are available on request.



## Sperm Count Quality Control FSI103, FSI203

Fertility Solutions' Sperm Count Quality Control provides laboratories with an easy way to perform routine sperm count QC using an appropriate material. Our Sperm Count Quality Control was introduced in 1995. 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 with human sperm, stabilized in a proprietary diluent and preservative, and mimics actual clinical specimens. Latex beads are poor surrogates for sperm, as reported in several European studies. Similarly, animal sperm has different characteristics and dimensions than human sperm, and is not a reliable control for testing human samples.

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 Levey-Jennings plots with check boxes to make full documentation of usage easy and inspection-ready.

### **Product Volume Usage:**

<b>Standard</b>	<b>FSI103</b>	300 µL
<b>Mini</b>	<b>FSI203</b>	150 µL

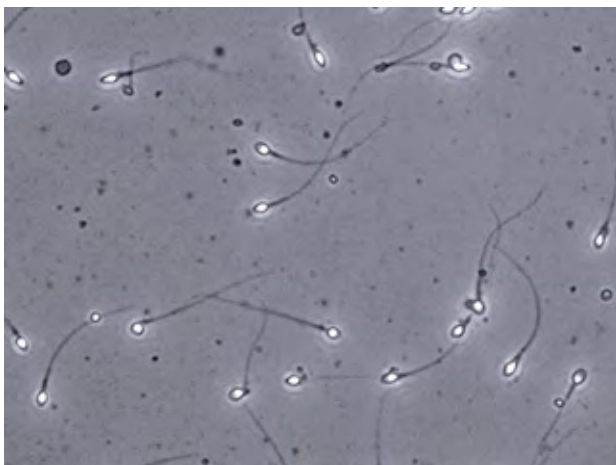
### **Specifications**

2 assayed concentrations between approximately 5 and 60 mil per mL.

Open vial shelf life is 6 weeks, unopened 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





## **Sperm Morphology Quality Control    AQC105, AQC205**

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 over time and among technologists. Sperm Morphology Quality Control contains two modified Papanicolaou-stained and coverslipped semen smears assayed using both Strict classifications (Tygerberg, WHO 4th - 6th Editions) and Traditional schemes (ASCP, WHO 3rd Edition). A differential is also available by request. Levey-Jennings charts provide both easily visible trends or drift and documentation for inspection.

A significant problem with Strict classification is the tendency to become more critical over time, sometimes to the point that no semen analyses have normal sperm. Regular assessment of Sperm Morphology QC smears can detect and help prevent shifts in classification. The smears also can be used to form a training library.

Cytology spray fixed unstained smears are available for labs that use other stains.

### ***Ordering options:***

**AQC105**      Papanicolaou stained, coverslipped

**AQC205**      Unstained, cytology spray fixed

### ***Specifications***

Stained smears are guaranteed 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







## Sperm Virtumorph® Quality Control AQC305

This is our high resolution 8 1/2" x 11" 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. It is paired with one Sperm Morphology QC smear (as used in AQC105). The glass smear comes with a Levey-Jennings chart for percent normal in both Traditional and Strict methods, and a discussion of classification rationale for all 50 numbered sperm is provided for the Virtumorph®. This product is especially suited for sperm morphology beginners and experts who work in labs where multiple technologists analyze morphology.

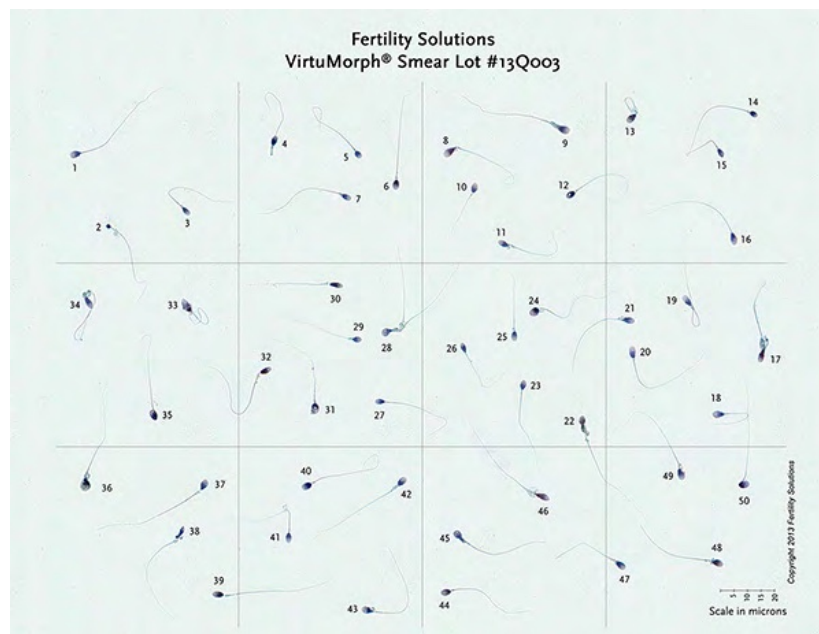
We recommend changing the Virtumorph® every 6 months to prevent "learning" the cells.

### Specifications

Stained smears are guaranteed 6 months from date of receipt. Smears should be stored in a dry location at room temperature (glass smear only).

*Note: Can be packaged with an unstained smear by request.*

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







## Sperm Viability Quality Control AQC107

When sperm aren't moving, the question becomes are they dead or do they have a defect inhibiting their motility? 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. This product contains 2 stained and coverslipped glass smears, 1 high percent viable, 1 low.

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**

Smears are guaranteed for 6 months from date of shipment. Store in a dark, dry environment at room temperature.

**FDA Clearance:** Class I, For In Vitro Diagnosis



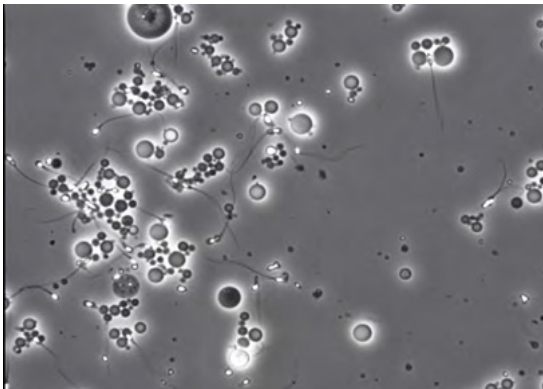
## Antisperm Antibody Quality Control    AQC109

Sperm agglutination or a high percentage of active, non-progressive sperm is an indication that antisperm antibodies (ASA) may be present. Assays for the presence or absence of antibodies are classified as moderate complexity under CLIA'88, thus requiring positive and negative quality controls. Our product provides multiple vials each of both positive and negative sera, and our positive controls detect both IgG and IgA antibodies.

### ***Specifications***

8 vials (4 positive and 4 negative) containing 0.5 mL each.  
Closed vial shelf life is 3 years from date of manufacture.  
Store frozen below -20°C.

***FDA Clearance:*** Class I, For In Vitro Diagnosis



## Post Vasectomy Quality Control FSI111, FSI211

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.

### ***Product Volume Usage:***

<b>Standard</b>	<b>FSI111</b>	300 µL
<b>Mini</b>	<b>FSI211</b>	150 µL

### ***Specifications***

2 assayed vials, positive and negative.

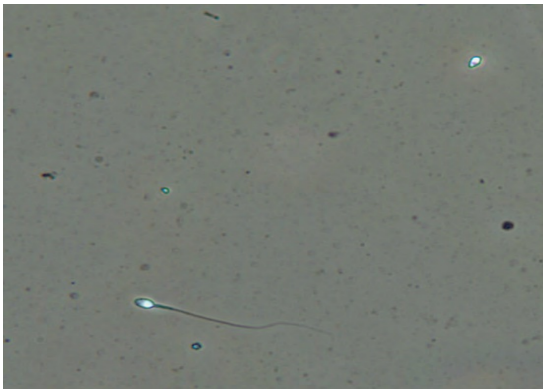
Open vial shelf life is 6 weeks

Unopened vial shelf life is 18 months from date of manufacture.

If concentration is required, unopened vial shelf life is 12 months from date of manufacture.

Store refrigerated at 5-15°C.

***FDA Clearance:*** Class I, For In Vitro Diagnosis





## Sperm Motility Quality Controls AQC119, AQC419

This product tests the accuracy and reliability of the motility semen analysis method using a virtual format. The product re-creates the actual test environment on video of two different semen samples. Each sample has 5 microscopy segments of fresh, untouched semen and 5 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 the total and progressive motility for each lot are presented on pdf 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.

### **Format options:**

**CD-ROM** - compatible with both Mac and Windows  
**AQC119**

**Online** - video streaming via browser from any device  
**AQC419**

### **Specifications**

2 assayed videos of different motility percentages.

Printable Levey-Jennings charts and worksheet

CD-ROM - Store at room temperature.

We recommend the Motility QC be changed quarterly  
to avoid learning the videos.

Online product expires 100 days from first use.



## **PPM (Presence/Absence and Motility) Quality Control AQC113, AQC413**

Provider Performed Microscopy (PPM) semen testing requires the ability to differentiate a low concentration of sperm from the absence of sperm, and to identify any motile sperm present. PPM semen testing is a moderate complexity test under CLIA, requiring quality controls to be analyzed each day of patient testing. Our unique PPM motility quality control is offered as a streaming video quality control for offices that also report the presence of motility. For a liquid quality control, order our Post Vasectomy Quality Control (FSI111), which is made with human sperm, stabilized in a proprietary diluent and preservative to mimic clinical specimens. The PPM video QC is assayed for presence or absence of sperm and motility, while the Post Vasectomy QC is assayed as positive or negative for sperm. We are able to provide assayed values per HPF for either format upon request.

### ***Format options:***

AQC413 - 2 videos streaming online via browser  
Specifications  
2 assayed videos, positive/negative for sperm and motility  
Printable Levey-Jennings lot charts and worksheet  
Product expires 100 days from first use

FSI111 - two 300  $\mu$ L vials  
*See page 11 for details*

## 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 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: 50mL

Shelf Life: 18 months from manufacture date.

Store refrigerated at 2-8°C.

Includes form to record contamination evaluations required for laboratory reagents.



## 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, as well as other disorders.

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: 10ml Eosin stain, 15ml Nigrosin stain in bottles with dropper caps supplied.

Shelf Life: 1 year from manufacture date.

Store at room temperature.

Includes form to record regular contamination evaluations required for laboratory reagents.



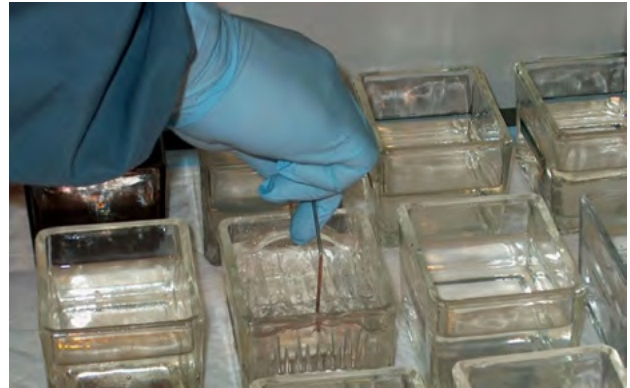


## Sperm Wizard® Papanicolaou Staining Kit SA500

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

### Specifications

- 1 gallon of 100% Alcohol
- 1 gallon of 95% Alcohol
- 2 liters of 80% Alcohol
- 1 gallon of Master\*Clear
- 1 Liter of Modified Mayer's Hematoxylin
- 1 liter of EA-50 Cytology Stain
- 4 oz Cytology Fixative
- Cover\*Safe ¼ oz 2 dropper cap bottles



## Spermocytometer® SA400

For years, the Semen Analysis Experts at Fertility Solutions have relied on the Sperm Wizard® Spermocytometer® for accurate, efficient and cost-effective testing. The single-use design prevents errors that occur with improperly cleaned reusable chambers. No dilution is required for most concentrations. Save laboratory labor on analysis, cleaning, and inspection. Labor is the most expensive laboratory resource: don't waste it!

The Sperm Wizard® Spermocytometer® is engineered specifically for semen analysis. Premium float glass construction prevents the formation of air bubbles and the adhesion of cells to the chamber surface, while the chamber depth keeps all the sperm cells in view. Hemacytometers are too deep (100 µm) to view the moving and non-moving sperm in a single plane of focus, in addition to adding time and extraneous effort to each analysis. Makler chambers wear unevenly over time and are often not loaded correctly.

### Specifications

- 25 slides per box, 2 chambers per slide
- Chamber Depth: ~20 µm
- Chamber Volume: ~6 µl
- Dimensions: 75 x 75 x 1mm
- Premium coated glass



### Requirements

- 10x10 grid eyepiece reticle, appropriate for the diameter of the scope's eyepiece
- Stage Micrometer with 100 10µm divisions

## Competency Testing

CLIA states: “Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by federal regulation.”

Our program addresses this critical inspection focus with the 6 key CLIA components for competency assessment:

1. *“Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing”*

Detailed observation forms are provided for each type of test to make documenting the observation process easy and complete.

2. *“Monitoring the recording and reporting of test results”*

Results are submitted to an online, secure database with a record of submission history.

3. *“Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records”*

Test worksheets are included to allow easy documentation of all steps of the analyses and calculations. Supervisors document their review before submitting results to us.

4. *“Direct observations of performance of instrument maintenance and function checks”*

Our easy competency checklist will guide you through the aspects that need assessed to ensure no aspect of competency evaluation is missed for inspections.

5. *“Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples”*

High quality virtual and physical test materials for evaluation. Result reporting includes the assayed reference ranges for each specimen to allow comparison to established values. Peer ranges are not used for competency. Results are compared to an assayed value.

6. *“Assessment of problem solving skills”*

Multiple competency questions covering general semen analysis knowledge, calculations, problem solving and result evaluation are included with this subscription. No more internal question development and grading required.

It is easy to confuse proficiency testing and competency testing. Simply put, competency tests the 6 parts of analyst ability, while proficiency tests the lab accuracy. In other words, proficiency testing alone is not sufficient to meet the regulatory requirement. Labs that use proficiency testing samples for their competency may appear to have technologists collaborating on proficiency test answers, depending on the timing of each analysis and result submission.

Competency doesn't have to be time consuming and confusing. We make it easy. Our Competency Challenge Program is offered twice a year usually in late spring and fall. Events include all components of competency evaluation, making it easy for your lab to complete this important annual CLIA requirement (required twice the first year of performance, and annually afterward). Participants have a month to perform the analyses, complete observations and submit results online. Once results and observation forms are received and graded, a certificate of participation and an individual result report is issued for each technologist.

Order one unit per technologist for each type of testing performed. Each technologist receives their own physical samples to remove the risk of a sample compromise by another technologist before analysis. Events are ordered individually, because most technologists only need annual competency.

Products include the materials for analysis described for each item number below, plus problem solving and general knowledge questions, observation forms and online result entry. Individual performance reports and certificates sent upon completion.

#### **Available challenges:**

Basic Semen Analysis Competency	CTB
Sperm Count - 1 150uL vial human sperm suspension	
Sperm Motility - 2 online videos showing live and immobilized sperm <i>(Includes progressive motility, and with raw count totals of immobilized sperm)</i>	
Sperm Viability - 2 digital viability smears	
Sperm Morphology Competency	CTM
2 digital sperm morphology smears	
Sperm Viability Competency	CTV
2 digital sperm viability smears	
Post-Vasectomy Competency	CTP
2 150uL vials sperm suspension <i>(Can be reported as positive/negative or with concentrations to match your lab procedure)</i>	
PPM Competency	CTPPM
2 150uL vials sperm suspension	
2 PPM videos showing live sperm <i>(Results reported as Positive/Negative for all samples)</i>	

**The Semen Analysis Trainer    AT100**  
**Addresses the #1 concern of semen analysis technologists:**  
***“How can I confidently perform a test I never really learned?”***

The answer is *The Semen Analysis Trainer* - an exercise-based, self-paced semen analysis training program that uses tested methods from the Fertility Solutions reference laboratory. Serving also as a must-have reference book, *The Semen Analysis Trainer* promotes modern best practices in semen analysis, teaching practical, cost-effective and reliable approaches to this “neglected laboratory test” in laboratory technology.

Promote competence and confidence with training

Curriculum includes:

- Exercises
- Worksheets
- Illustrations
- Semen analysis references

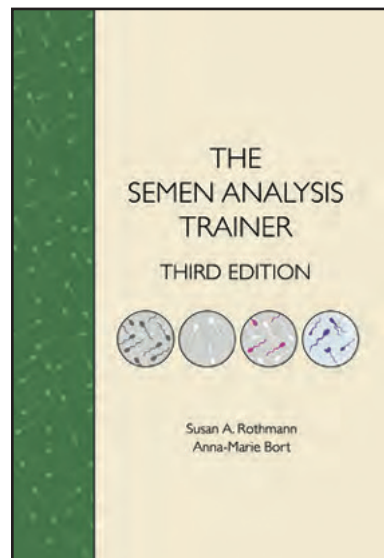
Contents:

- Sperm and Semen Development
- Sperm Count, Motility, and Progressive Motility: Learn reliable and objective methods
- Post-vasectomy Analysis: Special counting considerations
- Sperm Viability: Application and analysis
- Sperm Morphology: Introduction to the *SPERMCONFIRM®* Morphology Algorithm
- Practical Semen Analysis: Skill integration and quality control, semen handling, dilutions, liquefaction, troubleshooting

Optional:

- Training supplies available

*ISBN 978-0-9720181-9-7*



## **The Semen Trainer    AT107** **(Excerpts from The Semen Analysis Trainer)**

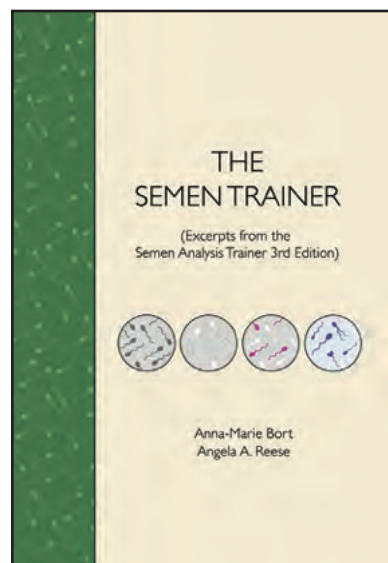
For laboratories wanting semen analysis training that can be adapted to their own in-house procedures, Fertility Solutions now offers *The Semen Trainer*. Excerpted from *The Semen Analysis Trainer 3rd Edition*, *The Semen Trainer* uses the same tested methods from the Fertility Solutions reference laboratory to promote modern best practices in semen analysis, teaching practical, cost-effective and reliable approaches to provide consistent and accurate results. Does not teach specific testing procedures such as count using a specific chamber or a specific motility testing method, for labs who want to keep their own methods.

Promote competence and confidence with training

Curriculum includes:

- Semen and sperm development
- Didactic content
- Illustrations
- Semen analysis references
- Troubleshooting

ISBN 978-0-9660540-9-5



## **PPM Semen Trainer AT105**

Provider Performed Microscopy Presence/Absence  
Motility evaluations, and Post Vasectomy testing

The *PPM Semen Trainer* is the newest self-paced training program from the Sperm Wizard® Academy. Designed for medical professionals wanting to offer Provider Performed Microscopy semen testing, or labs performing only presence/absence post vasectomy analysis, this program provides everything needed to understand, learn, and document training in moderate complexity semen analysis.

Subjects covered include:

- Sperm presence/absence
- Average percent motility
- Average sperm per high power field (HPF)
- Post vasectomy testing

The *PPM Semen Trainer* promotes modern best practices to teach practical, cost-effective, and reliable approaches to these tests.

Promote competence and confidence with training

Curriculum includes:

- Regulatory requirements
- Exercises - virtual & microscopy
- Worksheets
- Illustrations & videos
- Procedures
- Semen analysis references

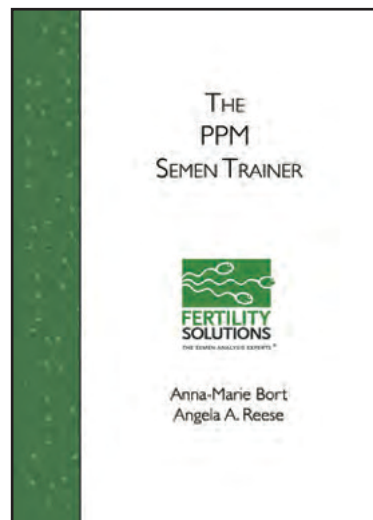
Contents:

- Regulatory Requirements
- Basics of Male Reproduction: Overview of sperm and semen production
- Practical PPM Semen Analysis: Skill integration and quality control
- Sperm and Non-sperm cell Identification
- Qualitative Sperm and Motility (Presence/Absence)
- Quantitative Sperm and Motility (Average sperm per HPF)
- Qualitative & Quantitative Post Vasectomy testing

Optional:

- Individual training supplies available

ISBN 979-8-9854699-1-2





## **SPERMCONFIRM® Morphology Classification Method    SW400** **Teaches Strict and Traditional Morphology Classifications**

This curriculum is based on the Fertility Solutions *SPERMCONFIRM®* Sperm Morphology Algorithm, a rational, repeatable, and defined method for sperm classification. The sequential, exercise-based module builds classification skills tested extensively by Fertility Solutions. This is the original algorithm the WHO 6th edition based theirs on. Our self-paced, comprehensive program comes with a modified Pap stained and coverslipped training smear, and is ideal for both laboratory professionals completely new to sperm morphology as well as experienced morphologists trying to reduce subjectivity, variability between technologists, and overly strict classification. Belongs on the shelf of every sperm morphologist.

Learn an objective method for sperm classification

Curriculum includes:

- Exercises
- Worksheets
- Illustrations
- Virtual and glass morphology smears
- Semen analysis references

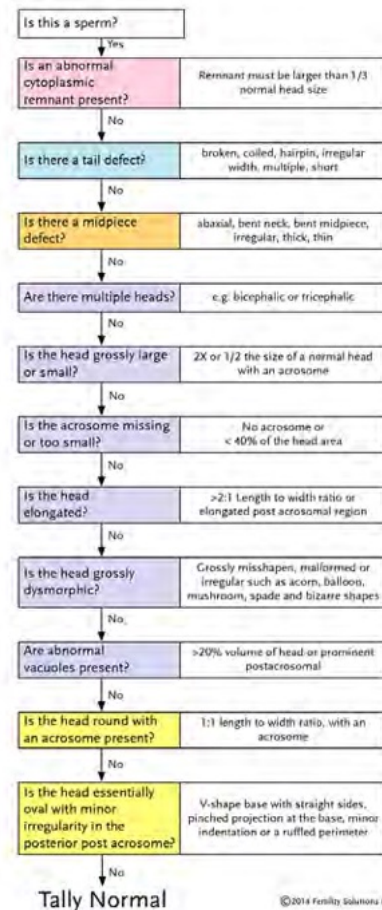
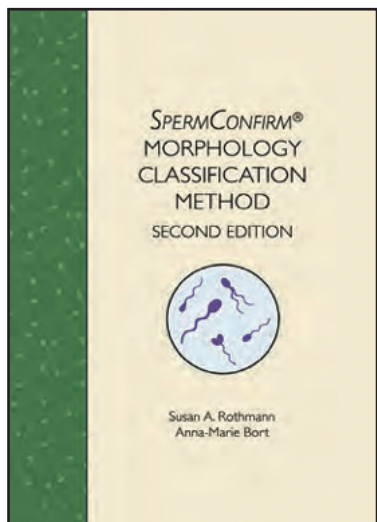
Contents:

- History of algorithm development with detailed explanations of each step
- Extensive photography and full color illustrations
- Worked examples
- Exercises for microscopy, tallying and calculations
- Quality Control strategies
- Glass semen smear

Optional Contents:

- SW903 - Online webinar (~90 minutes) reviewing the algorithm process.
- Includes color photographs and worked examples.

ISBN 978-0-9720181-3-1



**Atlas of Sperm Morphology: A Rational Approach    RA500**  
**Reference Atlas for Objective Classification of Sperm Morphology**  
***A new paradigm in semen analysis***

Images classified using the Fertility Solutions *SPERMCONFIRM*® Sperm Morphology Algorithm, the original sperm morphology algorithm that the WHO 6th edition algorithm is based on.

The *Atlas of Sperm Morphology: A Rational Approach* grew out of the need for a high quality sperm morphology atlas with explanations based on a rational, repeatable and defined method of sperm classification.

For years, traditional approaches to sperm morphology have relied on classification systems that define normal and abnormal forms. Technologists had to memorize these forms in order to recognize 'Normal' and 'Abnormal'. 'Borderline Normal' sperm were typically not mentioned or not given examples. This can result in highly subjective results that over time skew towards over-strictness until a sperm has to be perfect to be classified as normal. Eventually, everything looks abnormal!

With no order, justification or explanation for the classifications provided, diverse presentations and shape variations are difficult to categorize consistently. The previous atlases did not teach the features that typify the different abnormalities and borderline normal forms.

With *A Rational Approach*, we demonstrate a classification method that begins by looking for clear abnormal defects, then narrowing down to normal.

Our goals:

- To raise the consistency in sperm morphology classification skills
- To increase confidence that a classification is correct
- To regain the predictive value of sperm morphology

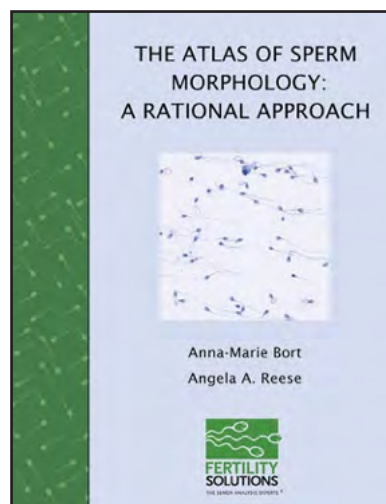
Contents:

- Basics of Male Reproduction: Overview of sperm production
- Sperm and Non-sperm cell Identification
- Detailed explanations of each algorithm step
- Extensive photography and full color illustrations
- Worked examples - Basic, TZI, and Full Differential
- Review of troubleshooting, microscopy best practices, tallying and calculations
- Includes a convenient reference flipbook to keep handy by your microscope!

Online Resources:

- Demonstration videos for microscopy techniques, smear making, and more
- Quiz to test knowledge and classification skills

ISBN 979-8-9854699-0-5



## **Semen Analysis Module for Clinical Laboratory Science SW700, SW701**

### **The turn-key approach for teaching semen analysis**

“How can I teach a test I never learned?”

The answer: *Semen Analysis Module for Clinical Laboratory Science*. Based on practical methods from the Semen Analysis Experts at Fertility Solutions, the module contains a focused, single 2-hour lecture and 2-3 hour lab with exercises promoting contemporary best practices in semen analysis. Most Clinical Lab Science programs do not teach semen analysis methods or have laboratory space available. Let your program stand out by offering an important training topic in the rapidly expanding field of reproductive medicine.

Prepare students for positions in body fluid and fertility testing.

#### **SW700 - Student Workbook**

Contains:

- Fundamentals of Semen Analysis text
- Lecture handouts
- Worksheets for lab case study exercises
- Homework tasks and online lab demonstration videos

#### **SW701 - Instructor Resource**

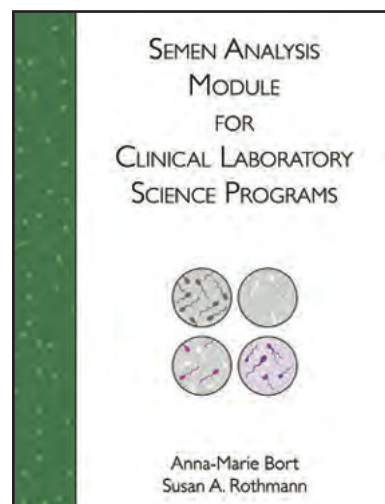
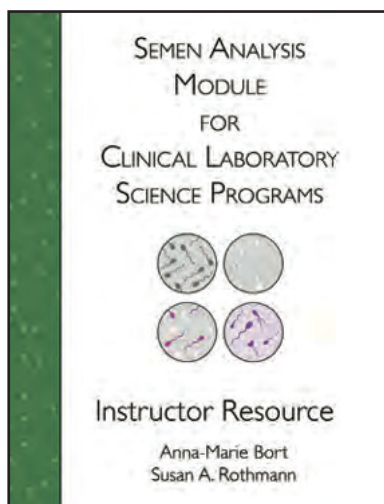
Contains:

- Lecture & lab PowerPoint presentations
- Presenter script on CD
- Grading rubric and answer keys
- Technical support for Instructor

Components available:

- Student Workbook (one per student, order for each group)
- Instructor Resource
- Consumable Laboratory Supplies for 20 students (optional)
- Reusable Microscopy Accessories for 6 stations (optional)

ISBN 978-0-9720181-3-1



## Post Training Examination

CLIA requires that prior to analyzing patient samples, all testing personnel “have demonstrated that they can perform all testing operations reliably to provide and report accurate results.” In order to document skills upon completion of training, Fertility Solutions offers Post Training Examination materials for each laboratory analyst. These assayed materials are shipped upon completion of training, and results are submitted online. Once results are graded by the Semen Analysis Experts at Fertility Solutions, training certification is issued for each analyst.

Order one unit per analyst for each type of testing performed. Each analyst receives their own physical samples, where applicable, to remove the risk of a sample compromise by another analyst before analysis.

### **Available sets:**

#### ***Sperm Count***

EX103: 2 150uL vials

#### ***Sperm Morphology***

EX205: 2 digital smears

#### ***Sperm Viability***

EX107: 2 digital smears

#### ***Post Vasectomy***

EX111: 2 150uL vials

#### ***PPM Sperm Presence/Absence***

EX113: 2 150uL vials, 2 online motility videos

#### ***Sperm Motility***

EX119: 2 online motility videos

## Validation Sets

Method validation is required whenever a procedure is updated or changed. Fertility Solutions offers validation sets to meet all of your regulatory needs, with options for the number of levels needed for your laboratory.

### Available sets:

#### ***Sperm Count***

VAL103 - 1 level	2 300uL vials for multiple replicates of the a single lot
VAL203 - 10 levels	10 150uL vials ranging from 0 through $75 \times 10^6/\text{mL}$
VAL503 - 5 levels	5 150uL vials ranging from 0 through $75 \times 10^6/\text{mL}$

#### ***Sperm Morphology***

VAL105 - 5 levels	2 Pap stained smears, 3 VirtuMorph®
VAL305 - 10 levels	5 Pap stained smears, 5 VirtuMorph®

#### ***Sperm Viability***

VAL107 - 5 levels	5 coverslipped smears ranging up to 90% viable
VAL207 - 10 levels	10 coverslipped smears ranging up to 90% viable

#### ***Post Vasectomy***

VAL111 - 3 levels	3 150uL vials ranging from negative to $\sim 0.5 \times 10^6/\text{mL}$
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#### ***Sperm Motility***

VAL119 - 5 levels	CD-ROM containing 5 motility videos
VAL419 - 5 levels	5 motility videos available online

Item #	Description	Price USD
<b>Quality Controls</b>		
FSI103	Sperm Count QC - 2 300uL vials	\$130
FSI203	Sperm Count mini QC - 2 150uL vials	\$100
FSI111	Post Vasectomy QC - 2 300uL vials	\$110
FSI211	Post Vasectomy mini QC - 2 150uL vials	\$85
AQC105	Morphology QC - 2 Pap stained semen smears	\$242
AQC205	Morphology unstained QC - 2 unstained semen smears	\$237
AQC305	Virtual Morphology QC - 2 Pap stained smear and 1 VirtuMorph®	\$226
AQC107	Viability QC - 2 eosin-nigrosin stained smears	\$216
AQC109	Antisperm Antibody QC - 8 vials of sera (4 positive, 4 negative)	\$289
AQC413	PPM QC - streaming video of 2 qualitative lots	\$104
AQC119	Motility QC - CD-ROM video of 2 lots	\$145
AQC419	Online Motility QC - streaming video of 2 lots	\$130
<b>Laboratory Products</b>		
SA101	Sperm Immobilizing Diluent	\$100
SA200	Sperm Viability Stain	\$113
SA400	Spermocytometer	\$145
SA500	Papanicolaou Stain Kit	\$475
<b>Competency Testing</b>		
CTB	Basic Semen Analysis Competency (Count, Motility, Viability)	\$320
CTM	Sperm Morphology Competency	\$150
CTV	Sperm Viability Competency	\$150
CTP	Post Vasectomy Competency	\$160
CTPPM	PPM Competency	\$185
<b>Training Materials</b>		
AT100	The Semen Analysis Trainer	\$199
AT107	The Semen Trainer	\$85
AT105	The PPM Semen Trainer	\$135
SW400	SPERMCONFIRM® Morphology Classification Method	\$395
RA500	Atlas of Sperm Morphology: A Rational Approach	\$299
SW700	Semen Analysis Module for Clinical Lab Science - Student Book	\$35
SW701	Semen Analysis Module for Clinical Lab Science - Instructor Resource	\$135



Item #	Description	Price USD
<b><i>Post Training Examination</i></b>		
EX103	Sperm Count	\$180
EX205	Morphology	\$180
EX107	Viability	\$180
EX111	Post Vasectomy	\$150
EX113	PPM Presence/Absence and Motility	\$210
EX119	Motility	\$150
<b><i>Validation Sets</i></b>		
VAL103	Sperm Count - 1 level	\$265
VAL203	Sperm Count - 10 levels	\$1600
VAL503	Sperm Count - 5 levels	\$700
VAL105	Morphology - 5 levels	\$1000
VAL305	Morphology - 10 levels	\$1800
VAL107	Viability - 5 levels	\$1000
VAL207	Viability - 10 levels	\$1800
VAL111	Post Vasectomy - 3 levels	\$515
VAL119	Motility CD-ROM - 5 levels	\$300
VAL419	Motility Online - 5 levels	\$300

Subscriptions are available which may include discounts - contact us for details.