UnityPoint Health Pïoctor	Page 1 of 22	Section: UPP Hematology	Policy #:
	Approved by: see signature block at end of document		Date: Review by:
HEMATOLOGY LABORATORY	Policy Created: 4/4/2019 Date Reviewed: Oldest first		
	Primary Responsible Parties: Sheanea LaCock Secondary Responsible Parties: Ronald Fitzgerald		
	CAP Standard:		
SUBJECT: SQA VISION SEMEN ANALYSIS			

POLICY CATEGORIES:

I. **POLICY STATEMENT:** Standard operating procedure for SQA-Vision Semen Quality Analyzer

II. PURPOSE: A semen analysis is performed in order to determine the fertility potential of a male. The semen parameters specified by the WHO 5th edition manual are assessed. A semen analysis panel may include other parameters ordered by the physician.

III. PROCEDURE

i. PROCEDURE STATEMENT: The SQA-Vision is an automated sperm analyzer with a powerful visualization system used as an accessory tool. The system performs a highly reliable 70-second semen analysis that follows the WHO 5th Edition guidelines for analyzing Sperm Concentration, Motility, Normal Morphology and many other parameters. The SQA-Vision can run the following sample / test types: FRESH, POSTVASECTOMY, WASHED, SWIM-UP, DENSITY GRADIENT, FROZEN, LONGEVITY and MANUAL, and it runs assayed QwikCheck-beads (latex) for QC purposes and stabilized sperm for proficiency testing. In addition to automated testing, the SQA-Vision visualization system magnifies samples x1188 to x1725. The patient/sample data and additional semen testing results such as WBC's, pH, volume, viscosity, liquefaction status, etc. are entered in the SQA-Vision PC screen. Test results and patient/sample data are saved automatically in the PC archive upon completion of the test and included in one patient report. Semen pictures and video clips can be attached to patient records for documentation purposes. A LIS interface is part of the SQA-Vision software and supports the data transfer to the facility receiving site.

ii. SPECIMEN REQUIREMENTS:

Specimen type: Semen

Specimen volume: Entire ejaculate or entire semen volume of the processed sample

Minimum volume: >0.5 ml (to test a 'neat' sample) or 0.3-0.5 ml to test a diluted 1:2 (1+1) sample

Maximum ejaculation to test time: 1 hour

Provide the patient with the instructions: *Patient Instructions for Semen Collection* and verify that they have followed the instructions summarized below:

- 2-7 days abstinence from ejaculation prior to specimen collection
- Collect sample by masturbation only
- Lubricants, spermicides and other contaminants are not to be used
- The entire specimen must be collected into a clean container (preferably supplied by the physician's office or the laboratory)
- The specimen container should be clearly labeled with the patient name and identifying information
- Transport the specimen to the laboratory right after collection (if collected off-site)
- Keep the sample at room temperature during transportation. Do not heat or cool the sample or the container
- Semen Culture has a special cleansing instruction. See end of this procedure for the directions provided to our patients by the Customer Service Desk.

The semen sample should be tested within one hour of collection. Semen samples must be tested by the laboratory on a priority basis upon delivery - expedite to the testing area.

The entire ejaculate is required for determining sample volume. The collection container should remain at room temperature until liquefaction is complete or 45 minutes, whichever is shorter. Testing must begin within 60 minutes of specimen collection because motility will decline.

Some samples will not liquefy within 45 minutes (most will liquefy within 15 minutes). . If a specimen is not liquefied, the accuracy of the analysis will be compromised. If, after 45 minutes the sample has not liquefied, treat with one vial of powder from the QwikCheck Liquefaction kit, following the package insert instructions. Use 2 vials for samples with volumes >5.0 ml.

SAMPLE REJECTION CRITERIA: Specimens received greater than 2 hours after collection. If testing begins greater than 60 minutes but less than 2 hours after sample collection please note: Results questionable due to age of specimen. It is important to eliminate as many variables as possible when conducting semen analysis testing.

iii. REAGENTS

SQA-Vision Sperm Analyzer (testing device + all-in-one touch screen PC)

SQA-Vision Capillaries (Catalog # 4021) Medical Electronic Systems LLC

SQA-Vision Cleaning Kit (Catalog # 0115) Medical Electronic Systems LLC

Microscope slides, glass, 1" x 3"

Coverslips, 22 x 22 mm

QwikCheck™ Test Strips for semen WBC and pH (Catalog # 0700) Medical Electronic Systems, LLC

QwikCheck™ Liquefaction Kit (Catalog #0900) Medical Electronic Systems, LLC

QwikCheck™ Dilution Kit (Catalog #0800) Medical Electronic Systems, LLC

QwikCheck™ Beads (Catalog # 0200) Medical Electronic Systems, LLC

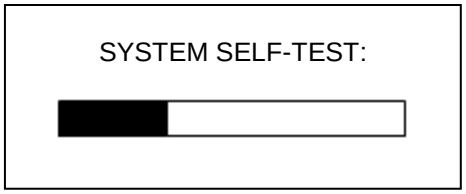
QwikCheck™ Vitality Kit (Catalog # A-CA-01057-00) Medical Electronic Systems, LLC

QwikCheck™ Beads Validation and Training Kit

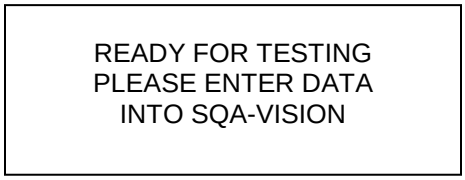
Getting Started:

- Turn on the SQA-Vision device by pressing the main switch located on the left side. The **Power** indicator will illuminate and the following screen will be displayed:

- This start-up/warming up process takes 5-7 minutes.
- When the system stabilization and auto-calibration processes are complete, a series of tests will be run:



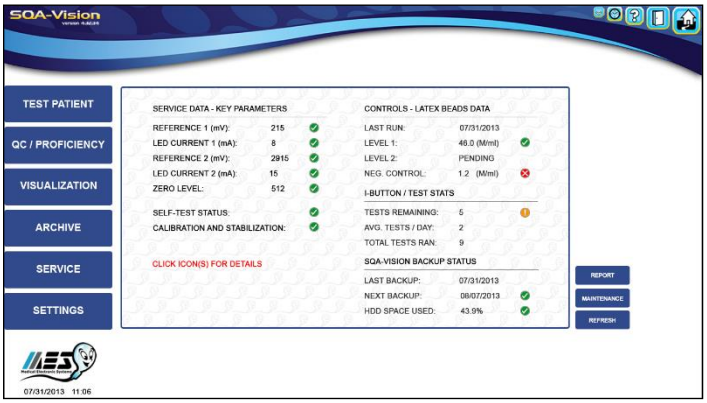
- During stabilization, auto-calibration and self-test do not touch the system or insert a capillary/slide into the device or use the keypad.
- The **device communication** screen will appear when the Self-Test process is complete. The SQA-Vision is now ready:



- If the SQA-Vision requires I-Button tests to be loaded, please see Appendix 2 of this document for instructions.

- The SQA Vision should pass the self-test before turning on the PC. The power button for the PC is located on the bottom right side of the monitor. Double click the SQA-Vision icon on the PC desktop to open the screen below:

- Enter the User Name: **administrator**
- Enter the password: **fertility** and press **ENTER**
- The HOME screen (below) will be displayed.
- Turn the printer on by pressing the power button.



iv. Quality Control

QwikCheck™ Beads are an assayed control for the SQA-Vision (for Concentration). They are for in-vitro use only and are used to assess the accuracy and precision of the SQA-Vision by providing a known target value and +/- range. Three controls are provided: A high and a low control of known concentration and one negative control (for POST VASECTOMY control) are supplied in 5 ml aliquots. Store at room temperature (20-25 °C or 65-77 °F). The expiration date assumes that the beads are stored at room temperature in their original containers and tightly capped to prevent evaporation

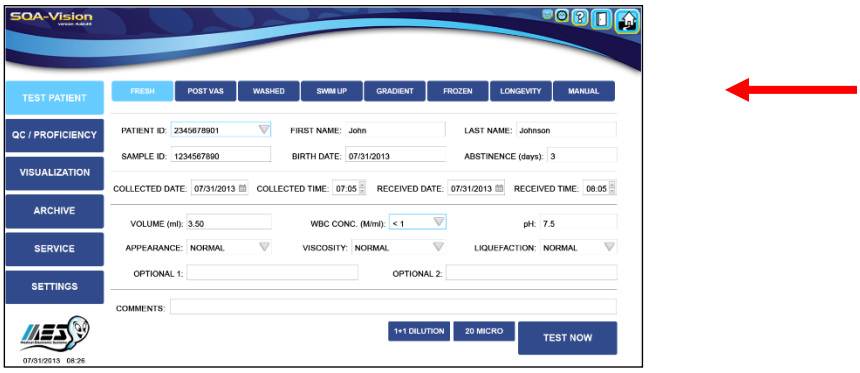
Run controls at the beginning of the shift prior to testing patient samples.

- Follow the SQA-Vision User Guide instructions for setting up the CONTROLS defaults with each new box of QwikCheck™ Beads.
- Mix the beads thoroughly (without introducing bubbles into the media) before opening the bottle each time they are run. It is imperative that the beads are evenly mixed in order to insure accurate results.
- The negative control does not require extensive mixing.
- Open the beads and immediately withdraw a sample of the control material.
- Immediately and tightly close the container after use to avoid evaporation or spillage.

1. Select: **QC/PROFICIENCY>LATEX BEADS** from the **MAIN MENU** of the SQA-Vision.
2. Click: **TEST NOW** on the desired Level of LATEX BEADS to be tested to open the sample preparation instructions screen.
3. Follow the onscreen instructions exactly for filling the testing capillary and refer to the Appendix section of the User Guide: "Filling the SQA-Vision Capillary with a Normal Volume Sample" for details.
4. Mix the beads thoroughly and aspirate them into the SQA-Vision capillary in the same manner you would fill the capillary for a normal volume specimen, making sure the cuvette section of the capillary is completely full of liquid and free of bubbles.
5. Following the on-screen instructions for "Controls" insert the SQA-Vision capillary into the device measurement slot in the same manner you would test a normal sample of semen, being sure to wipe the capillary tip before insertion.
6. Testing will begin automatically.
7. Control test results will be saved automatically when the test is completed.

v. PROCEDURAL NOTES AND PRECAUTIONS

From the MAIN MENU activate **Test Patient** and select Sample / Test Type:



Enter Patient and Sample Data into the SQA-Vision:

- **PATIENT ID** – Unique patient ID/number (Maximum of 20 characters).
- **FIRST NAME** – First name identifying the patient.
- **LAST NAME** – Last name identifying the patient.
- **SAMPLE ID** - Unique sample ID/number (Maximum of 20 characters).
- **BIRTH DATE** – Birth date of the patient.
- **ABSTINENCE** - Number of days since the patient's last ejaculation.
- **DATE/TIME COLLECTED –** Date and time the sample was collected.
- **DATE/TIME RECEIVED –** Date and time the sample was received.
- **VOLUME** – Volume of the **whole** ejaculate (Fresh, Post Vas and Longevity test) or sample (the other types of tests) in milliliters.
- **WBC CONC.** – select < 1 M/ml (normal) OR >= 1 M/ml (abnormal) leukocytes (required entry - QwickCheck™ Test Strips recommended).
- **PH** – pH of the semen sample (QwickCheck™ Test Strips recommended).

QwikCheck™Test Strips for Semen Analysis Leucocytes and pH:

- Place one drop of semen on each of the two test patches
- Wait 60 seconds
- Compare leukocyte and pH results to the color chart provided on the product label
- **WBC's**: If ≥ 1M/ml (dark lavender) select Abnormal (Abnorm) in the Sample Data screen
- **pH**: Enter the number most closely associate with the color of the patch

#)

- **APPEARANCE** – Normal/Abnormal visual assessment of the specimen.
- **VISCOSITY** – Normal/Abnormal (WHO 5th defines NORMAL viscosity as semen leaving the pipette in small discrete drops or forming a thread <2 cm long).
- **LIQUEFACTION** – Normal/Abnormal (WHO 5th defines liquefaction as NORMAL if it occurs within 60 minutes of collection @ room temperature).

QwikCheck™Liqefaction:

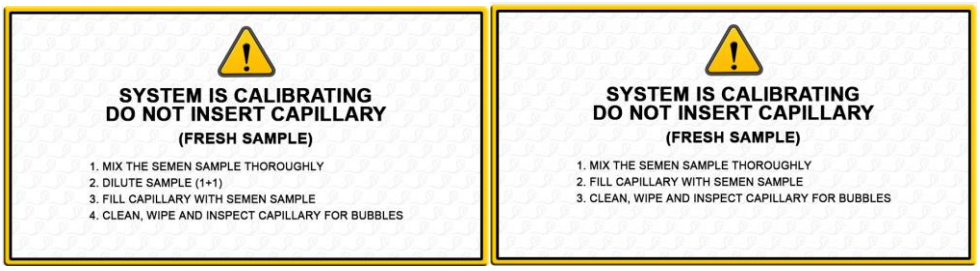
- Select one vial of QwikCheck liquefaction powder
- Tap the vial to move the contents to the bottom of the vial before opening
- Add the entire contents of one vial to a viscous semen sample
- Gently mix the sample to dissolve the powder
- Once the sample has liquefied (5-10 minutes) test in the SQA-Vision

- **COMMENTS** – Enter comments if required.
- **OPTIONAL** – Enter optional fields if necessary.

In the lower right hand corner of the Test Patient screen, there are three options for testing semen:

- **1:2 (1+1) DILUTION** – For testing low volume semen samples of 0.3 to 0.5 ml. Dilute sample 1:2 (1+1) using the QwikCheck™ Dilution kit. **If the LOW VOLUME sample is viscous, first treat it with the QwikCheck™ Liquefaction kit and then dilute the sample.** The SQA-Vision algorithm compensates for the sample dilution as long as the sample has been diluted accurately (For example, if the total sample volume is 0.4 ml then add 0.4 ml of dilution media).
- **20 MICRO** – Recommended if only 20 µl of semen can be used for testing. Only motility-related parameters will be reported (MSC, PMSC, SMI and VELOCITY).
- **TEST NOW** – **Select to begin testing a normal volume (≥ 0.5 ml) sample** if the dilution and 20 Micro buttons are not selected. A complete semen analysis report will be generated. If one of the two options above is selected, **TEST NOW** will initiate the testing process according to a highlighted option.
- Click **TEST NOW** and the system will self calibrate. Do not use the keypad or insert a testing capillary/slide at this time. Prepare a sample for testing per the SQA-VISION on-screen instructions:

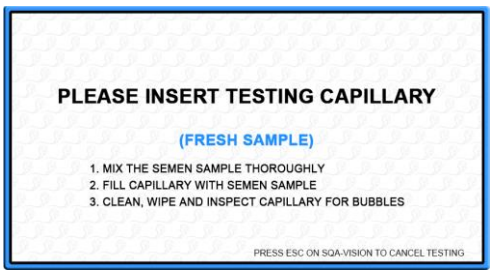
- **Low Volume Sample Instructions**: Aspirate 20 µl of sample into only the thin motility section of the testing capillary. Follow the onscreen instructions (above) and the guidelines in the Appendix section of this User Guide: "Filling the SQA-VISION Capillary with a Low Volume Sample".
- **Non-Diluted and Diluted 1:2 (1+1) Sample Instructions**: Fill the entire testing capillary (not the syringe) following the online instructions (below) and the guidelines in the Appendix section of this User Guide: "Filling the SQA-VISION Capillary with a Normal Volume Sample".



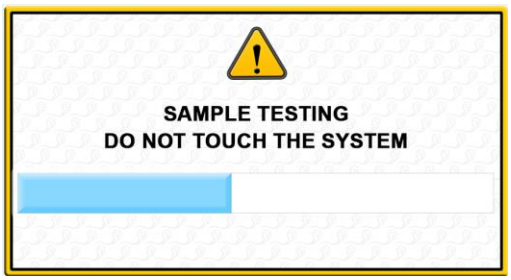
QwikCheck™ Dilution:

- Measure the volume of the neat semen sample.
- Dilute 1:2 (1+1) with QwikCheck-Dilution
- Thoroughly mix the sample in order to evenly distribute the spermatozoa throughout the sample without introducing bubbles (do not us a pipette to mix)
- Fill a testing capillary in the usual manner (Normal Volume) and insert it into the testing compartment of the SQA-Vision with the blue stopper facing down.

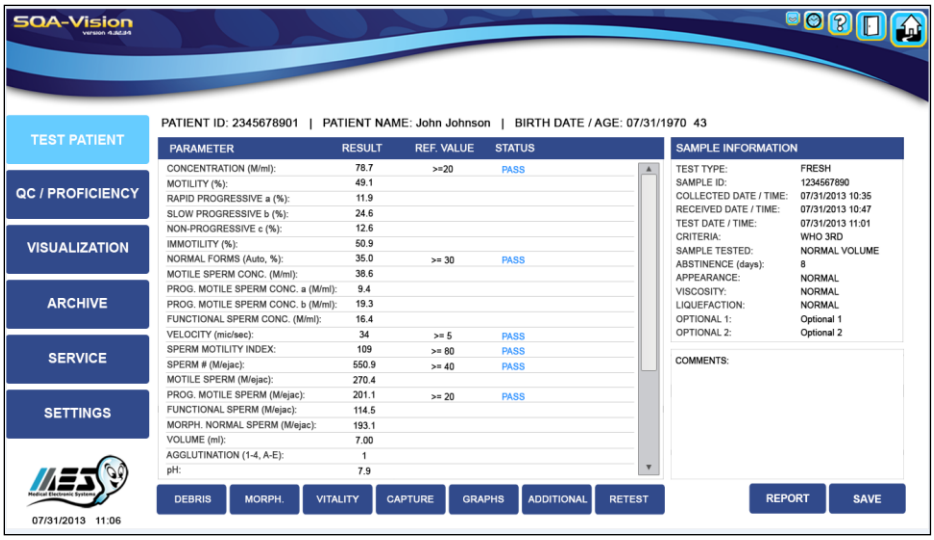
- The **Insert Testing Capillary** screen below will appear when the VISION has completed auto-calibration. Insert the testing capillary as instructed and testing will begin automatically. Make sure the BLUE STOPPER of the capillary is pointing down and the capillary has been completely wiped free of sample before insertion:



- When the testing capillary is inserted, a **Sample Testing** progress bar will be displayed. Do not touch or use the VISION until the progress bar finishes and the screen indicates "**Importing Test Results**" (approximately 75 seconds):



TEST RESULTS: The table below will be displayed after testing **FRESH** and **WASHED** semen samples with normal testing volume or diluted 1:2 (1+1).



- The results are saved automatically (**Save** button will be disabled).
- Click the appropriate buttons to: Open the **Debris Scanner** (if not opened automatically according to the settings), assess **Morphology** or **Vitality** manually, **Capture** video images and/or pictures, generate **Graphs**, enter **Additional Parameters** or to **Retest** the sample.
- The **Semen Analysis Test Report** can be opened by clicking the **REPORT** button. It can be exported, printed, zoomed-in and closed using the taskbar.

DIFFERENT SAMPLE/TEST TYPES – Please refer to SQA-Vision User Guide for details.

vi. REPORTING RESULTS

1. The SQA-Vision will automatically save the patient/sample data and test results. Results will autoverify to the LIS.
2. Patient records can be retrieved from the SQA-Vision PC archive.
3. Print the semen analysis report using the PC printer if required.
4. Attach printed results to worksheet.

IV. MAINTENANCE AND STORAGE:

A. All policies and procedures are reviewed every two years by Laboratory Administration and or the Medical Director of the Laboratory or designee.
B. The Laboratory Administration and Medical Director review policies and procedures when there are changes in practice standards, or requirements.
C. All policies and procedures are reviewed every two years by staff or at the time new or revised ones are put in effect.
D. All policies are retained 8 years after being discontinued or revised.
E. All procedures are retained 2 years after being discontinued or revised.

REPORTING RESULTS

5. The SQA-Vision will automatically save the patient/sample data and test results.
6. Patient records can be retrieved from the SQA-Vision PC archive.
7. Print the semen analysis report using the PC printer if required.
8. Attach printed results to worksheet.

DAILY MAINTENANCE AND BACKUP

- Perform daily cleaning when semen samples are run. Perform weekly cleaning per cleaning kit instructions. **See appendix for cleaning procedure.**
- Backup the archive per the laboratory pre-set schedule.

REPORTABLE RANGE OF THE SQA-VISION

Reportable range of the SQA-Vision automated results						
Sample Type	Sperm Conc. M/ml	Motility %	Morph %	MSC M/ml	PMSC M/ml	Motile / Immotile / Total Sperm M/ml
Fresh	<2 - 400	0 - 100	2 - 30	<0.2 - 400	0 - 400	-
Washed	<2 - 200+	0 - 100	2 - 30	<0.2 - 200+	0 - 200+	-
Swim-up, Density Gradient, Frozen	-	-	-	<0.2 - 200+	0 - 200+	-
Post-Vasectomy	-	-	-	-	-	0 - 400

SEMEN PARAMETERS AND WHO RANGES REPORTED BY THE SQA-VISION		
SEMEN PARAMETER	**REFERENCE VALUE***	**SOURCE**
Concentration (Count)	≥15 M/ml	WHO 5th manual
Total Motile (PR+NP)	≥40 %	WHO 5th manual
Progressive (PR)	≥32 %	WHO 5th manual
Non-progressive (NP)	-	-
Immotile (IM)	-	-
Normal Forms (morphology)	≥4%	WHO 5th manual
Motile Sperm Concentration (MSC)	≥6 M/ml	MES
Progressively Motile Sperm Concentration (PMSC)	≥5 M/ml	MES
Functional Sperm Concentration (FSC)	-	-
Velocity (Average path velocity – VAP)	≥5 mic./sec.	MES
Sperm Motility Index (SMI)	≥80	MES
Sperm #	≥39 M	WHO 5th manual
Motile Sperm	≥16 M	MES
Progressively Motile Sperm	≥12 M	MES
Functional Sperm	-	-
Morphologically Normal Sperm	≥2 M	MES
*** The reference values established above are based on WHO 5th edition manual data or MES (for proprietary semen parameters).**		

LIMITATIONS OF THE PROCEDURE

1. Analysis should begin within 60 minutes of collection, otherwise the critical determination of motility and possibly other parameters may not be reliable.
2. Motility testing is time sensitive and run on the SQA-Vision along with the other parameters. Specimens received more than one hour, but less than two hours after collection should be analyzed. Report OLD2 with motility.
3. If the semen sample is not sufficient for even LOW VOLUME testing (250 µl), append the abbreviation QNS to those tests that were not completed.

REFERENCES

1. World Health Organization, *Laboratory Manual for Examination of Human Semen and Semen-Cervical Mucus Interaction,* 3rd edition, Cambridge University Press, Cambridge, 1992.
2. World Health Organization, *Laboratory Manual for Examination of Human Semen and Semen-Cervical Mucus Interaction,* 4th edition, Cambridge University Press, Cambridge, 1999.
3. World Health Organization, *Laboratory Manual for the Examination and Processing of Human Semen - 5th edition, WHO Press 2010.*
4. Medical Electronic Systems LLC; SQA-Vision User Guide
5. Package insert; Medical Electronic Systems, QwikCheck Beads
6. Package insert; Medical Electronic Systems, QwikCheck Test Strips
7. Package insert; Medical Electronic Systems, QwikCheck Liquefaction Kit
8. Package insert; Medical Electronic Systems, QwikCheck Dilution
9. Package insert; Medical Electronic Systems, QwikCheck Beads Validation and Training Kit
10. Package insert; Medical Electronic Systems, QwikCheck Vitality Kit
11. Dr. Lev Rabinovich, Chief Technology Officer (Medical Electronic Systems)

APPENDIX SECTION

Appendix 1: Setting-up a NEW BOX of QwikCheck Beads CONTROLS

Open **Settings** from the **Service** or **Main Menu** screen to set-up system and testing defaults. Six buttons will be displayed at the top of the screen: **Controls, Proficiency, Test Patient, Visualization, System** and **QwikLink**:

The screen to set-up **Controls** is shown above. Two QC materials, latex beads or stabilized sperm, can be set manually. QwikCheck™beads assayed control information can be set-up manually or by using a barcode reader (scan the barcode shown under "Latex Beads Set-up" and then scan the barcode on the QwikCheck™Beads box).

The information below will automatically be updated:

- **Lot #**
- **Expiry Date**
- **Target**
- **Range**

Set the preferred **Graph Color** for each level of beads by clicking the colored circle. Press: **Clear** to delete the settings or **Save** to keep the settings.

Use the **Report** button to print a copy of the **Settings Report** when the settings are completed.

Set-Up: Non-Assayed Material to Establish the target value and +/- range:

Step 1: Enter the following information from the product labeling:

- **LOT#** - number identifying the control media lot
- **EXP. DATE** – control media expiration date (MM=month, YY=year)

Step 2: Enter the **TARGET VALUE** and **+/- RANGE:**

- Enter 00 for the target value
- Enter 0.0 for the +/- range

Step 3: Save settings

Step 4: Establish the target value and +/- range for each level:

- Fill a testing capillary and run 10 replicates in the **QC/PROFICIENCY** mode following the onscreen instructions
- Calculate the mean target value. Based on laboratory protocols determine the +/- range (Example: 2SD)

- Open Controls Settings again and update the **TARGET VALUE** and **+/- RANGE** for the control

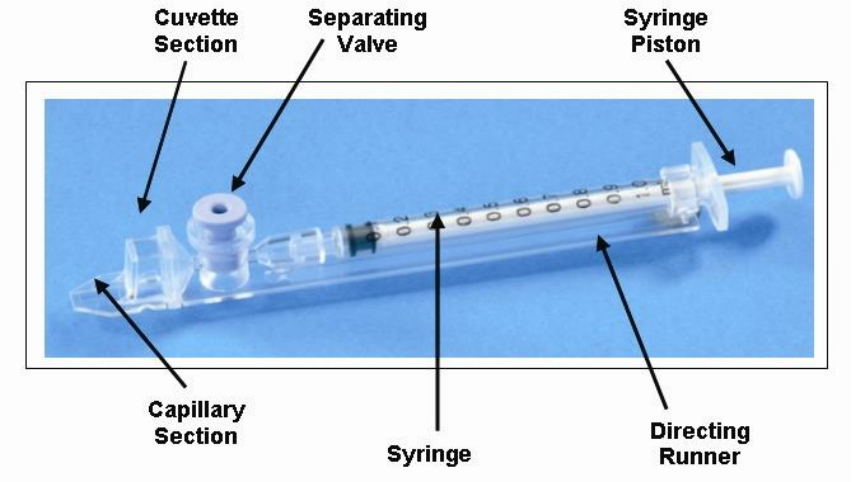
Appendix 2: Adding I-Button Tests

The SQA-Vision requires that I-Button tests are loaded into the system in order to run a test. Please follow the instructions below to add tests:

Select **ADD TESTS TO COUNTER** from the **SERVICE MENU** of the SQA-Vision device or press the **I-Button** key to open the screen below:

Follow the onscreen instructions and the I-Button tests will be loaded to the system.

Appendix 3: Filling the SQA-Vision Testing Capillary with a Normal Volume Sample



Sample size, collection container and preparation:

1. Sample volume should be **at least .5 ml** If sample volume is less than .5 ml see Appendix 2.
2. Sample container should be **wide-necked and deep enough** to facilitate inserting the capillary into the sample at the bottom of the container.
3. The semen sample must be **completely liquefied and well mixed prior to aspiration**. Gently rotate container to fully mix liquefied specimen.

   WARNING: *Do not shake nor use a pipette to aspirate and dispense specimen in order to mix, otherwise air bubbles will form.*

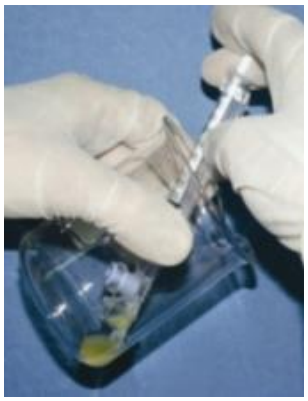


Figure 1

4. **Carefully check that liquefied, fully mixed specimen is free of air bubbles** (or that there is an adequate amount of sample below the air bubbles) before immersing the capillary into the specimen, thus ensuring that no air bubbles will be aspirated into the capillary.

Filling the capillary:

1. **Push the syringe piston in fully**. Place only thin part of the capillary into the bottom of the sample while angling the sample container at about 45 degrees (Figure 1).
2. Placing two fingers below the piston head **pull the piston back slowly while keeping the tip of the capillary well below the sample level and below any surface bubbles** (Figure 1). Continue to aspirate the sample until it appears in the Luer adaptor.

Figure 2

NOTE: *Transferring the sample to a standard "tissue culture dish" (3 cm in diameter/1 cm deep) will allow better visual control when filling the capillary as an intermediate step (see Figure 2).*

3. Holding the capillary in a vertical position (Figure 3), **visually confirm that the sample has completely filled** the thin section (without a meniscus) and the cuvette section and appears in the Luer adaptor. **Tap on the syringe to make sure there are no air bubbles** in the sample. If, after tapping, some air bubbles appear below the Luer adaptor, dip the capillary into the semen sample again and aspirate a small quantity of semen to draw the air bubbles into the syringe.
4. **Quickly (to avoid wicking) and thoroughly wipe the outer surface of the capillary** - both top and bottom (Figure 4) with a delicate wipe (Kimwipes, etc.). It is important to remove all semen from the exterior of the capillary in order to prevent the SQA-VISION optical chamber from becoming clogged. Visually confirm that the capillary chambers are still full following the cleaning process. If some of the sample has been depleted (meniscus formed in the thin part of the capillary) fill the capillary part from the cuvette section by slightly pushing in the piston.

Figure 3 Inspect for bubbles

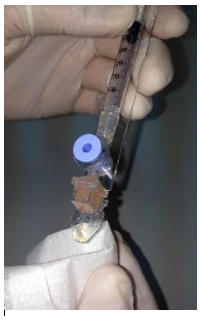


Figure 4 Wipe the tip

5. Slowly and carefully **push-in the separating valve** until it is level with the plastic (Figure 5). The capillary is now ready to be inserted into the SQA-VISION measurement compartment for testing.

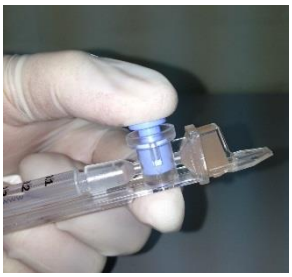


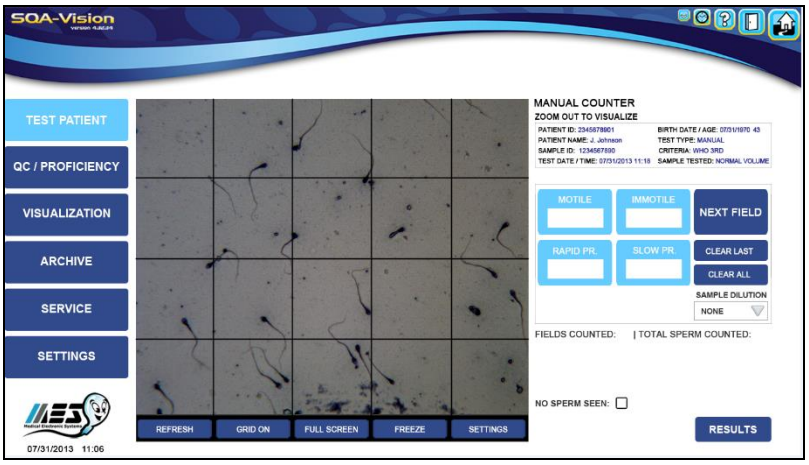
Figure 5 Push-in the piston

Insert the testing capillary into the lower measurement compartment with the blue stopper down. Push it in as far as it will go to ensure that the capillary is properly seated in the compartment.

For filling the capillary with a Low Volume sample, please refer to the SQA-Vision User Guide.

Appendix 4: Using the SQA-Vision Visualization System

1. Follow the instructions in the WHO 5th ed. laboratory manual for the examination and processing of human semen. Thoroughly mix the sample before step #2.
2. Load a fixed coverslip with ~3 µl of semen sample (recommended). Prepare a new slide if air bubbles or liquid spillage occurs.
3. Insert the slide into the Visualization Field of View Stage (Refer to the SQA-VISION User Guide APPENDIX 3: Using Slides in the Visualization System for details).
4. Press the ZOOM-OUT button on the SQA-VISION keypad all the way.
5. Adjust the **FOCUS** knob to bring the image to the best focusing: Turn clockwise all the way. Then turn counterclockwise until a clear image appears on the screen.
6. Click **GRID ON** button at the bottom of the screen. The screen of the SQA-VISION is divided into a grid containing 20-distinct squares (see below):



7. To count a minimum of 200 sperm cells (according to WHO 5th manual), turn the knob of the Field of View Stage and a new field of view will be displayed in the grid.
8. Enter the number of **MOTILE, IMMOTILE** and **PROGRESSIVE** sperm (Rapid and Slow if the SQA-VISION system is set to WHO 3rd or 4th criteria) counted in the entire video screen of each field of view in the **MANUAL COUNTER**.
9. Click **NEXT FIELD** button at the right hand side of the screen and count the sperm cells again.
10. Click **RESULTS** button upon completion of counting and the software will calculate the final semen parameters.
11. Refer to the **Test Patient** and **Visualization** sections of this manual for Morphology, Vitality assessment, capturing images and scanning debris.

Appendix 5: SQA-Vision Cleaning Instructions

When to clean:

Daily or after every 10-15 tests
If the system fails **SELF-TEST**
Weekly

Figure 1

Cleaning kit components:

Fibrous cleaning paddle (fig 1)
Sponge-tipped drying paddle (fig 2)
Cleaning brush - wooden-handled (fig 4)
Cleaning fluid

Figure 2

PLEASE NOTE: Cleaning and drying paddles are for ONE TIME use only!

CLEANING: Weekly

1. Use a fibrous cleaning paddle (fig 1)
   - Moisten with **ONE** drop of cleaning fluid, shaking off excess fluid.
   - Insert into the measurement compartment - fibrous material facing down (paddles are labeled “up” and “down”). Move back and forth three times.
2. Use a sponge-tipped drying paddle to dry the same compartment (fig 3). Insert the sponge tipped paddle and leave it for 10 seconds. Do not move this drying capillary in and out.

Figure 3

Figure 4

CLEANING: Daily

- Insert the brush (bristle-side down) into the lower chamber of the SQA-VISION (fig 5).
- Pull the brush out of the chamber while sweeping or "dusting off" the LED (you will feel a step or shelf at the back and top of the chamber – this is the top of the LED).
- Initiate the Self-Test (press Self-Test button from the Service screen). Review the self-test results. The SQA-VISION should PASS the self-test. If not, repeat cleaning procedure with the brush.

Figure 5

Appendix 6: *Sample Mixing, Semen Liquefaction, and Viscosity*

BACKGROUND:

Incomplete semen liquefaction, high viscosity, decreased viscosity and insufficient mixing can all impact semen test results. The WHO 5th edition laboratory manual for the examination and processing of human semen provides guidelines for handling semen samples to promote accurate testing and reliable results.

THOROUGH MIXING AND REPRESENTATIVE SAMPLING (WHO 5th Edition, section 2.4.1):

It is difficult to obtain a representative sample of semen from a liquefied ejaculate if the sample is not well mixed. In fact, two separate aliquots may show marked differences in sperm motility, vitality, concentration, and morphology. To obtain consistently reproducible results, the sample should be thoroughly mixed before aliquots are taken for assessment (see Box 2.3 below):

Box 2.3 Thorough mixing of semen

Before removing an aliquot of semen for assessment, mix the sample well in the original container, but not so vigorously that air bubbles are created. This can be achieved by aspirating the sample 10 times into a wide-bore (approximately 1.5 mm diameter) disposable plastic pipette (sterile when necessary). Do not mix with a vortex mixer at high speed as this will damage spermatozoa.

LIQUEFACTION & VISCOSITY (WHO 5th Edition, sections 2.3.1 - 2.3.2):

Immediately after ejaculation into the collection vessel, semen is typically a semisolid coagulated mass. Within a few minutes at room temperature, the semen usually begins to liquefy (becomes thinner). The entire sample usually liquefies within approximately 15 minutes at room temperature, although rarely it may take up to 60 minutes or more. *Occasionally samples may not liquefy even after 60 minutes which makes the accurate assessment of the sample difficult. In these cases, additional treatment, mechanical mixing or enzymatic digestion is advised.*

In contrast to a partially liquefied sample, a viscous semen sample exhibits homogeneous stickiness and this consistency will not change over time. *After liquefaction, the viscosity of the sample can be estimated by observing the drops or length of the thread created by gently aspirating the sample into a wide-bore (approximately 1.5 mm diameter) plastic disposable pipette and allowing the semen to drop by gravity. A normal sample leaves the pipette in small discrete drops. If viscosity is abnormal, the drop will form a thread more than 2 cm long.*

Methods to reduce viscosity are the same as those for delayed liquefaction. *Samples observed to have abnormally high viscosity or excessive liquefaction time (greater than 1 hour) should be treated with the MES QwikCheck™ Liquefaction Kit and tested after a 15 minute waiting period to ensure accurate results.*

MANUFACTURER'S RECOMMENDATION FOR RUNNING LOW (DECREASED) VISCOSITY SAMPLES:

In rare cases, samples with decreased viscosity can affect your Sperm Concentration results. A possible indicator of this situation is a test result with lower than observed Sperm Concentration and higher than observed Motility %. Another indicator might be a test result of <2 M/mL for Sperm Concentration but a Motility result of >50%. If the sample is observed to be excessively "watery" (decreased viscosity) or "clear" in opacity and the results match either of the scenarios outlined above, the sample should be re-run on the instruments ***WASHED*** *mode or prepared as a washed sample and run on the instruments* ***WASHED*** *mode as follows:*

- *Measure the sample before washing and place the entire sample into a 15ml centrifuge tube*
- *Add up to 10ml of QwikCheck™Dilution media*
- *Centrifuge at 220g (1200 rpm) for 10 minutes*
- *Remove the supernatant*
- *Re-suspend the pellet with QwikCheck™Dilution media to the original sample volume*
- *Run the sample on the WASHED mode of the SQA-Vision and receive a FULL report*

Appendix 7: *Testing Sperm Samples at Room Temperature*

BACKGROUND:

Room temperature is a general term describing common indoor temperatures. It is usually in the range of 20 °C (68 °F or 293 K) to 25 °C (77 °F or 298 K).

World Health Organization Operations Manual for Delivery of HIV Prevention, Care and Treatment at Primary Health Care Centers…Edition 1, pg. 215; Wikipedia: http://en.wikipedia.org/wiki/Room_temperature

OVERVIEW:

The WHO 5th edition manual recommends assessing sperm motility at either room temperature or at 37 °C (with a heated microscope stage). "These conditions should be standardized for each laboratory" (WHO 5th edition manual, p. 22).

INSTRUCTIONS:

The SQA-Vision is calibrated for room temperature sample testing so there is no heating stage on the device. When performing a validation of the SQA-Vision based on comparing the test results to manual results, the manual results should be performed at room temperature as well.

MANUFACTURER'S RECOMMENDATION:

It is recommended to maintain the room temperature of the lab in the range of 20 °C (68 °F or 293 K) to 25 °C (77 °F or 298 K). In addition semen samples should be at room temperature at the time of testing. Samples should not be pre-heated or incubated prior to testing on the SQA-Vision.

UnityPoint Health Proctor Laboratory is a CAP accredited facility. As of 7/1/11, the responsibility of new and/or substantially revised policies and procedures will be restricted the Laboratory Director whose name appears on the CLIA certificate, whose signature appears below. The biennial review will be completed by the Administrative Director.

POLICY CREATION :		
Author:	***Sheanea LaCock***	***DATE: 4/4/19***
Medical Director:		***DATE:***

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
SECTION MEDICAL DIRECTOR		

REVISION HISTORY (began tracking 2011)			
Rev	**Description of Change**	**Author**	**Effective Date**

REVIEWED BY

Lead	Date	Coordinator/Manager	Date	Medical Director	Date