User Manual

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SECTION 1: System Specifications and Requirements

The SQA-iO is a high-performance PC-based semen analyzer. The device works with a computer app that interfaces with the device to guide the user through sample testing and results archiving on the cloud. The SQA-iO device is intended for prescription use only.

Device Hardware: Houses a measurement compartment for testing and USB connection for connectivity.

Specifications

- Dimensions: 8 X 9.5 X 10.5 cm / Weight: 0.350 Kg
- Analysis Time: 75 seconds
- Power supply: 5V DC (USB)
- Noise level: 0 [dBA]
- Device power consumption: 1.7 [BTU/hour] = 0.5 [Watts]
- Sources of radiant energy: Two LEDs (motility and concentration channels)
- Detector system: Two photo detectors (Motility and Optical Density)
- Software: Resides on flash memory and on a secure server on the Cloud
- Motility channel input signal: Analog, up to 5V
- Recommended browsers for optimal performance: Chrome, Microsoft Edge

SQA-iO Minimum Requirements

- PC: Intel Core i5 M520 2.4GHz or equivalent
- RAM: 4GB
- Monitor Screen: Color, Wide screen – minimum resolution 1024 x 768
- Operating system compatibility: Windows 7 Professional or above
- Communication Ports: one USB port
- Internet Access: 5mb/second

Operating/Sample Temperature, Humidity and Altitude

- Operates in ambient temperature (15-38ºC). Calibrated at room temperature: 20-25ºC (68-77ºF).
- Maximum operational humidity up to 80% for temperatures up to 31ºC. Linearity decreased 50% at 38ºC.
- Intended for indoor use at a maximum altitude of 2000m, mains supply fluctuations ±10%, Overvoltage Category II, Pollution Degree II.

Quality Control/Calibration

- Internal: Electronic Self-Test/Auto-Calibration runs @ start-up. Reference values verified prior to each test.

Sample Testing

- Calibrated to test samples at room temperature 20-25ºC (68-77ºF) within one hour of sample collection.
- Test only liquefied human semen samples. QwikCheck Liquefaction vials (available from MES and sold separately) can be used to liquify semen sample prior to aspirating the sample into the testing capillary, when needed.

Accessory (optional) devices:

- SQA-VU Visualization system works only with the SQA-iO to visualize sperm samples and capture Motility videos and Morphology images. Additional information can be found in Appendix 7.
- SQA-iO Docking station enables both the SQA-iO and SQA-VU to connect to one power source and maintain a small laboratory footprint.

SECTION 2: Semen Parameters and Reportable Range

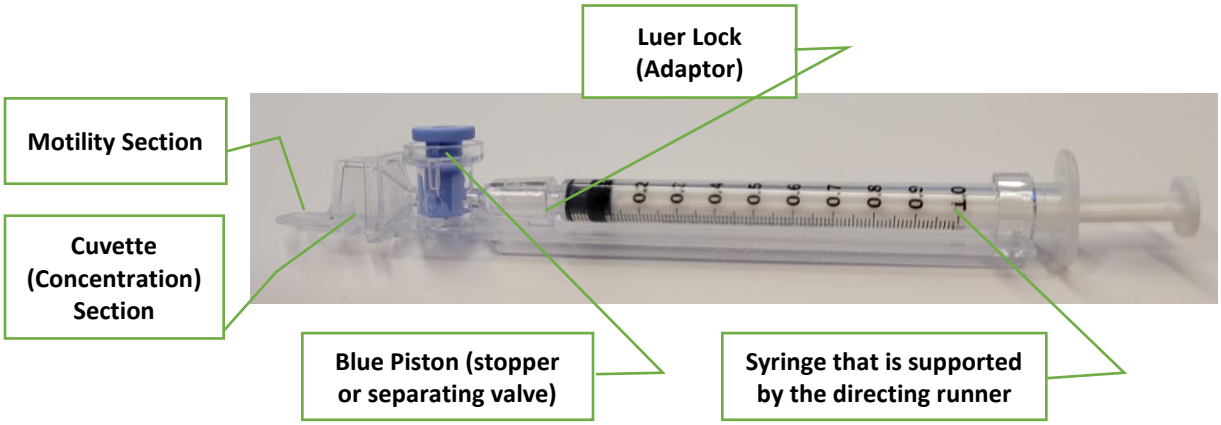
The SQA-iO is a high-performance PC-based analytical medical device that tests semen samples. The device works with a computer application that contains the device, patient, sample, test results and facility information.

After collection and preparation, a semen sample is withdrawn into an SQA testing capillary and inserted into the SQA-iO where the sample testing is performed. Test results are available in 75 seconds.

SQA-iO Reportable Range			
WHO 5th	**Range**	**WHO 6th**	**Range**
CONCENTRATION (M/ml)	<2-400	CONCENTRATION (M/ml)	<2-400
TOTAL MOTILITY (PROG + NON PROG) (%)	0-100	TOTAL MOTILITY (PROG + NON PROG) (%)	0-100
PROGRESSIVE (%)	0-100	PROGRESSIVE (RAPID + SLOW) (%)	0-100
		RAPIDLY PROGRESSIVE (%)	0-100
		SLOWLY PROGRESSIVE (%)	0-100
NON-PROGRESSIVE (%)	0-100	NON-PROGRESSIVE (%)	0-100
IMMOTILE (%)	0-100	IMMOTILE (%)	0-100
NORMAL FORMS (%)	2-30	NORMAL FORMS (%)	2-30
MOTILE SPERM CONC.* (M/ml)	<0.2-400	MOTILE SPERM CONC.* (M/ml)	<0.2-400
PROG. MOTILE SPERM CONC.* (M/ml)	0-400	PROG. MOTILE SPERM CONC.* (M/ml)	0-400
		RAPID PR. MOTILE SPERM CONC.* (M/ml)	0-100
		SLOW PR. MOTILE SPERM CONC.* (M/ml)	0-100
FUNCTIONAL SPERM CONC.* (M/ml)	0-120	FUNCTIONAL SPERM CONC.* (M/ml)	0-120
VELOCITY (VCL)* (mic/sec)	0-100	VELOCITY (VCL)* (mic/sec)	0-100
SPERM MOTILITY INDEX**	0-500	SPERM MOTILITY INDEX**	0-500
SPERM # (M/ejac)	0-900	SPERM # (M/ejac)	0-900
MOTILE SPERM* (M/ejac)	0-800	MOTILE SPERM* (M/ejac)	0-800
PROG. MOTILE SPERM* (M/ejac)	0-700	PROG. MOTILE SPERM* (M/ejac)	0-700
FUNCTIONAL SPERM* (M/ejac)	0-150	FUNCTIONAL SPERM* (M/ejac)	0-150
MORPH NORMAL SPERM* (M/ejac)	0-260	MORPH NORMAL SPERM* (M/ejac)	0-260

*MES parameters are indicated by an asterisk. ** This parameter is not reported in the US market

SECTION 3: Technology



Testing Capillary

- Disposable, plastic, testing capillary. Requires 500µl of sample for normal volume testing, 10 µl for low volume testing.
- Designed to collect and test samples in a biologically safe manner. Use only manufacturers' certified testing capillaries.

Cuvette Section (Concentration assessment)

- Millions of sperm cells are analyzed in the 'tall' cuvette section of the testing capillary based on spectrophotometry analysis of the semen sample and application of proprietary algorithms.

Motility Section (Motility parameter assessment)

- Tens of thousands of sperm cells are analyzed in the 'thin' motility section of the testing capillary as they move through a light beam in the device.
- Light disturbances are then converted into analog signals and analyzed by proprietary algorithms.

Inserting the Testing Capillary into the SQA-iO

- After filling the testing capillary (see Appendix Section for guidelines), insert the SQA testing capillary all the way into the SQA-iO measurement chamber with the BLUE PISTON facing down.

SECTION 4: Getting Started

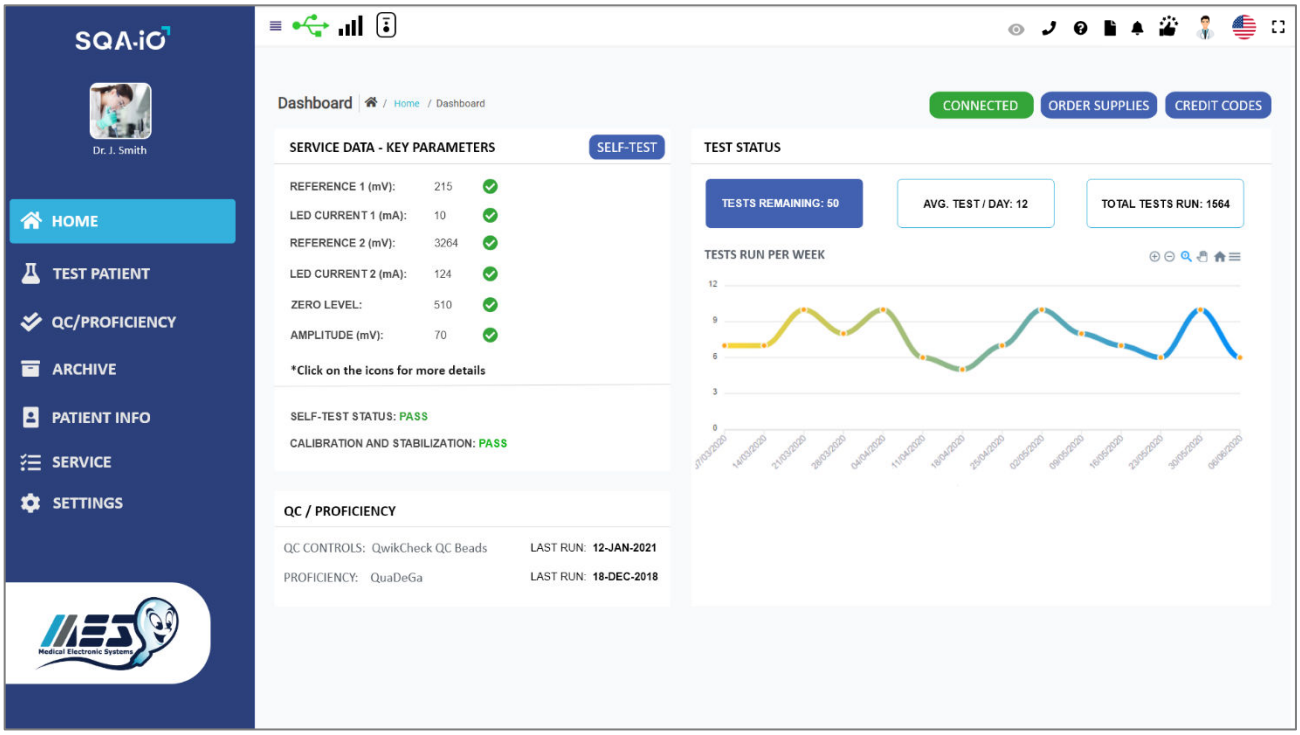
First time connecting: Follow the **SQA-iO Quick Start Guide** instructions or directly download the software from www.sqa-io.com and register your account following the on-screen instructions. This is the time to set all preferred testing and your facility defaults and to load test credits.

Connecting to the SQA-iO for testing:

- Connect the SQA-iO to the computer using the supplied USB cable.
- Go to: www.sqa-io.com or click on the desktop icon to activate the SQA-iO interface.
- Enter the unique 8-digit registration number located inside your device kit
- If you are asked to authorize the download of a driver required to run the SQA-iO app, please accept.
- Log into the SQA-iO using your username and password.
- The SQA-iO will now go through a calibration check, wait until it finishes.
- The device is now ready for sperm testing

SECTION 5: SQA-iO Navigation and Testing

- **Navigation:** The SQA-iO navigation bar is always available. Click on one of the options on the SQA-iO navigation bar to select where you want to go.
- **Security:** The security time-out default is set to one hour of SQA-iO inactivity, but it can be changed to the laboratory security preference. A timeout warning will be displayed. If the device/app is not used for another 5 minutes, the SQA-iO will shut down. Log back in when ready to start testing.



The Home Screen provides the following information:

- This icon is **GREEN** when the device is connected and **RED** when disconnected.
- This icon is **BLACK** when the internet connection is stable, **RED!** when the internet is slow, and will display **GREY** bars when there is no internet connection.
- **Service Data – Key Parameters:** Displays the SQA-iO calibration and self-test parameters. A **GREEN** checkmark icon indicates everything is within normal limits, **YELLOW** indicates borderline limits and **RED** indicates out of range. Click on the checkmark for details and the **REPORT** button to run a calibration report for your records.
- **Test Status:** Provides the current status of the # of remaining test as well as a graph of tests run per week.

Test Patient

Select the TEST TYPE based on the following sample definitions/options:

- **FRESH** – Sample is not enriched, diluted or treated and is within 1 hour of collection. Required testing volume is ≥0.6 ml (the entire testing capillary needs to be filled) or, if less sample is available, the sample can be diluted 1:2 [1+1] for a full report of all semen parameters. A 10-microliter sample can be loaded into just the thin capillary section for a limited report of just motility parameters.

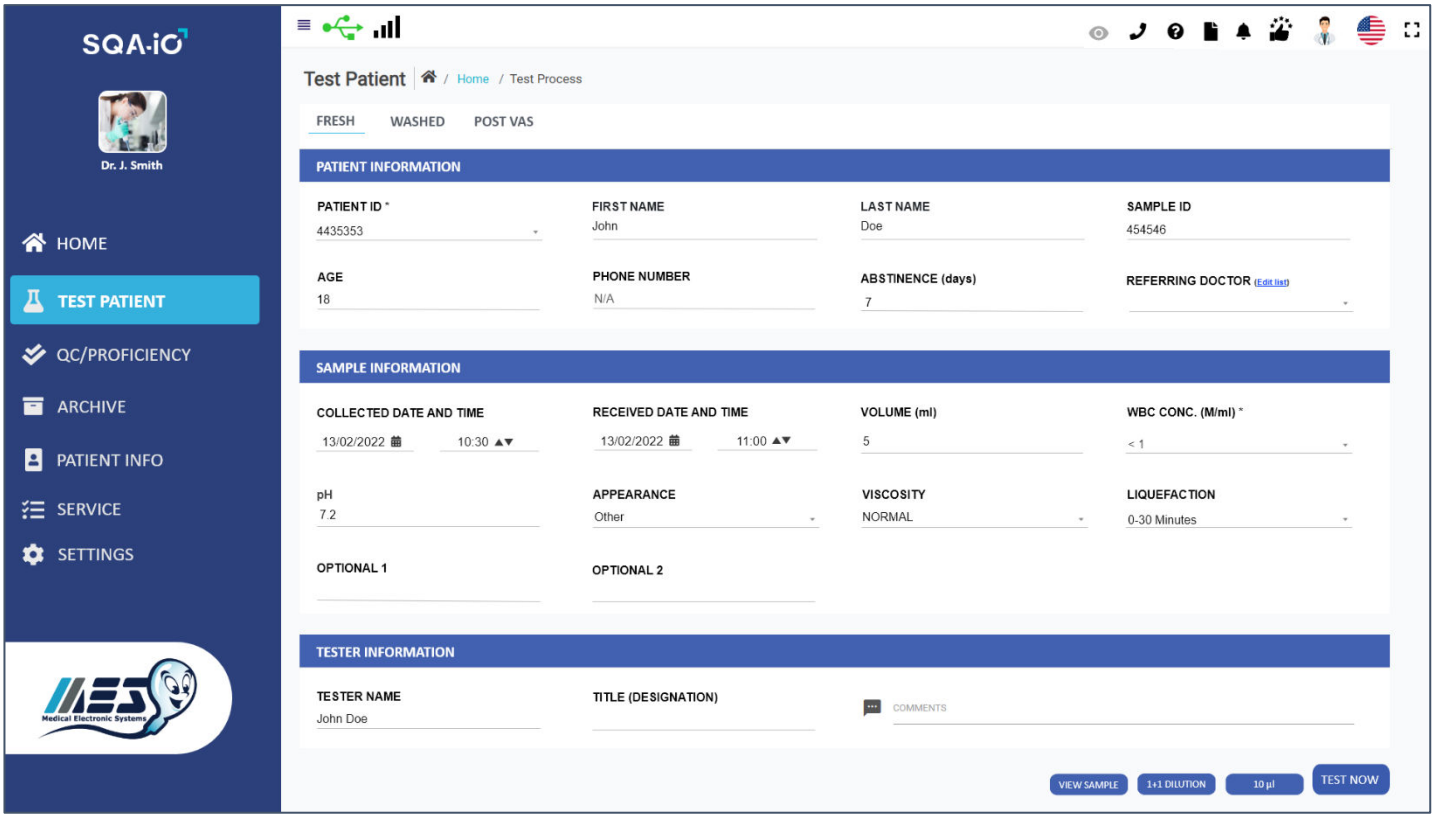
- **WASHED** – Sample is enriched or prepared for artificial insemination by centrifugation using a washing media to replace the seminal plasma. The testing volume required is ≥ 0.6 ml (the entire testing capillary needs to be filled) or, if less sample is available, the sample can be diluted 1:2 [1+1] for a full report of all semen parameters. A 10-microliter sample can be loaded into just the thin capillary section for a limited report of just motility parameters. This test is not available in the U.S.

- **POST VAS** -Fresh sample designated as post-vasectomy and tested within an hour of collection will report Motile, Immotile and Total Sperm in M/ml and per ejaculate. Samples analyzed for **presence or absence** of sperm, without motility can be analyzed within 24 hours of collection using the Manual option.

Enter patient and sample data in the TEST PATIENT screen seen below. Mandatory fields are indicated by an asterisk *, and an error message will appear if empty. The Collected/Received Date and time will be filled automatically according to the current Date and time of the test and can be edited.

PLEASE NOTE: Although sample volume is not mandatory, semen parameters related to sample volume will not be presented if the volume is not entered. The accuracy of the operator is relied upon to correctly measure sample volume.

OPTIONAL 1 and OPTIONAL 2 are 'open' fields to input any desired information.



After entering patient data, select the type of test to be run:

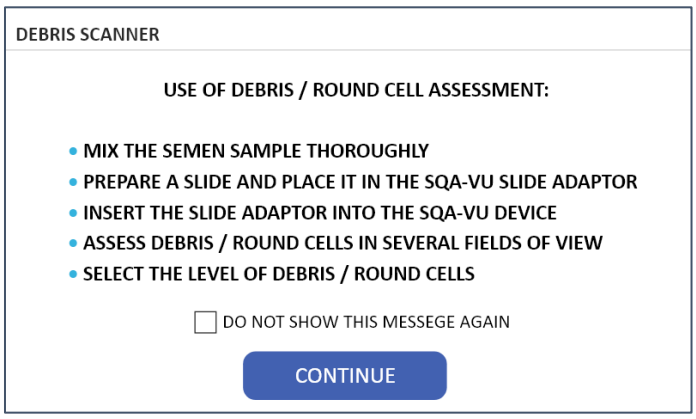
Sample Handling and Testing Options:

- **Sample Handling:** Samples need to be completely liquefied and run within one hour of collection so that motility parameters are reported accurately. Always maintain samples at room temperature prior to and during testing; Excessive heat and/or cold will shock sperm cells and affect motility. See Appendix section for semen collection, capillary filling, and sample testing guidelines.
    - Temperature Control: Maintain sample at room temperature (20-25°C / 68-77°F). Do not heat as excessive heat will deplete sperm resources and cold will shock sperm cells and affect motility.
    - Sample Collection: See Appendix section for guidelines about semen sample collection and for instructions on how to fill the testing capillary and insert it into the SQA-iO.
    - Sample Liquefaction: Samples need to be completely liquefied and run within one hour of collection as motility parameters can decline over time. QwikCheck Liquefaction vials can be used to liquify semen samples prior to aspirating into the testing capillary, if needed.
- **Measuring Sample Volume:**
    - When to measure: After sample liquefaction and before testing, measure according to laboratory procedures.
    - Entering sample volume into the SQA-iO: Enter volume in the "Test Patient" screen of the SQA-iO.
- **WBC / pH:** Assess pH and WBC prior to testing using QwikCheck WBC/pH test strips.
- **1:2 (1+1) Dilution:** 0.3 to 0.5 ml of sample required. Dilute sample 1:2 (1+1) using the QwikCheck™ Dilution kit reagent. 1+1 dilution requires equal amounts of sample and diluent (i.e. If the total sample volume is 0.4 ml, add 0.4 ml of dilution media). Operator sample dilution errors will result in inaccurate results.
- **Low Volume Sample /10 microliter:** Fill only the tip (motility channel) of the capillary using 10µl of sample. A limited test report with motility parameters only will be provided.
- **WASHED samples**: select to run NORMAL or LOW VOLUME (10µl samples).

Debris / Round Cells Scan (requires SQA-VU device)

If automated test results fall below the pre-set **Debris/Round Cell Scan** cutoffs established in **SETTINGS,** this feature is activated for all samples, the **Debris/Round Cell Scanner** will automatically open during the testing cycle.

- Using a Fixed Coverslip Slide or standard slide 1" x 3" with a 22X22 mm coverslip, estimate the % debris/round cells compared to the % of spermatozoa based on:
    - NONE/FEW: <10% (for every 10 sperm 1 or less piece of non-sperm debris)
    - MODERATE: 11-30% (for every 10 sperm there are 1-3 non-sperm debris)
    - MANY: 31-99% (for every 10 sperm there are 3-9 non-sperm debris)
    - GROSS: >100% (for every 10 sperm there are 10 or more non-sperm debris)
- The sample preparation instruction screen below will be displayed prior to activating the **Debris/Round Cell Scanning** screen.

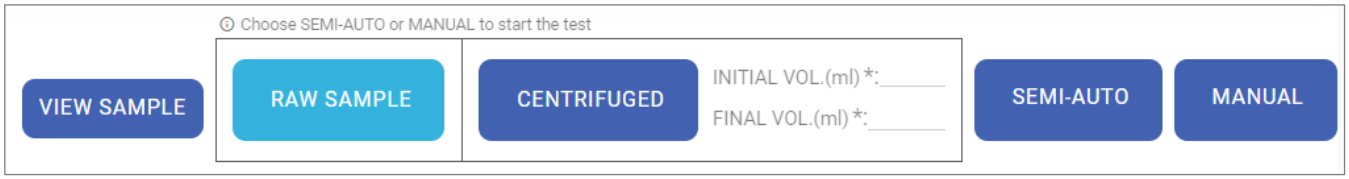


Post Vasectomy Testing (requires SQA-VU device)

From the Main Menu, select TEST PATIENT > POST VAS.

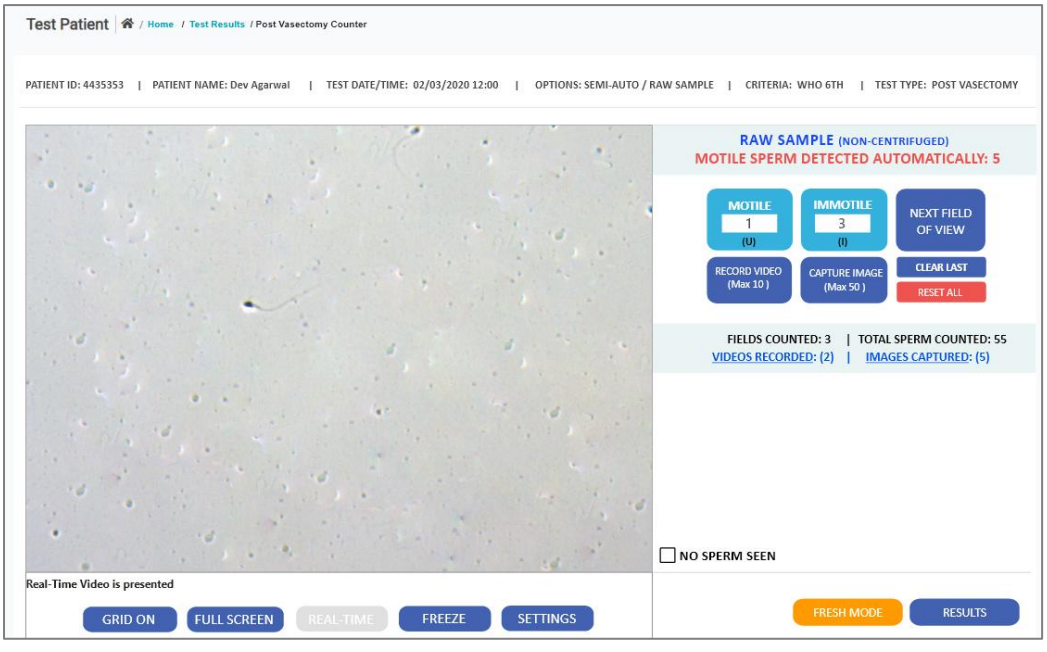
Current WHO guidelines recommend running a non-centrifuged semen sample first to search for Motile and Non-Motile spermatozoa. If no sperm cells are found, the sample should be centrifuged and re-tested. Two modes are available for testing POST VAS samples: SEMI-AUTO and MANUAL.

- Enter patient/sample information into the POST VAS data entry screen (below).
- Select RAW SAMPLE or CENTRIFUGED button to specify the sample type.
- If CENTRIFUGED is selected: Enter Initial Volume (before centrifugation) and Final Volume (after centrifugation). A warning will be shown if the Initial Volume used for centrifugation exceeds the ejaculate Volume or if the Final Volume exceeds Initial Volume.
- Click the **SEMI-AUTO** or **MANUAL** button in the lower right-hand corner of the **POST VAS** screen:



SEMI-AUTO test: Detects the presence of motile sperm

- Fill the testing capillary and insert into the measurement chamber when the **Insert Testing Capillary** pop-up is displayed to begin the test. This semi-automated test takes approximately 5 minutes to run and is highly sensitive to motion. Please do not disturb the SQA-iO device or the testing capillary during the testing cycle or the results may be impacted.
- At the end of the automated test, the **POST-VAS Counter** with sample preparation instructions will open. The number of motile sperm detected will be displayed.
- Count spermatozoa in the entire fixed coverslip slide by turning the Field of View knob and clicking the Motile/Immotile buttons (one click per each cell).
- Enter # of slides counted (several slides can be counted in one testing round).
- Select "No Sperm Seen" if no sperm cells were found and click on the **RESULTS** button.
- Click FRESH MODE if many sperm cells are seen and a normal test can be run.
- Capture **Images** and/or **Video** clips if desired (Max 10).
- Select: **RESULTS** in the **POST-VAS Counter** when manual counting is completed.

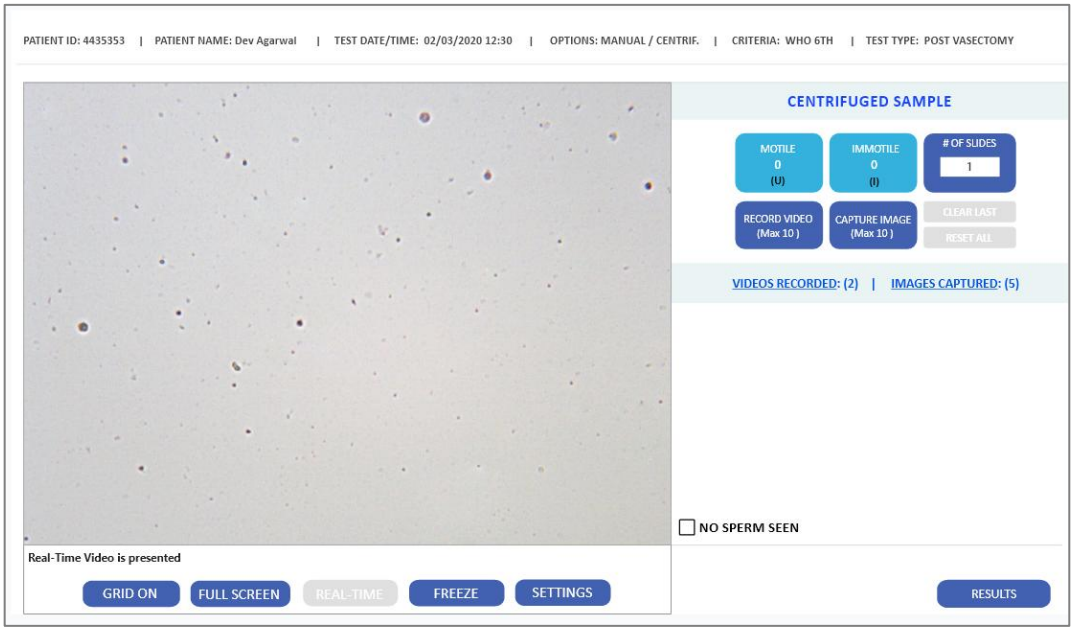


- The test results displayed will be based on both automated and manual assessment.
- If no manual data is entered and the **RESULTS** button is clicked, only automated results will be reported.

MANUAL test:

- The manual test requires only **visual assessment** and will therefore bypass the auto-calibration and capillary detection processes and open the **Post-VAS Counter** immediately. Credit codes will not be reduced.
- Select "No Sperm Seen" if no sperm cells were found and click on the **RESULTS** button.
- Capture **Images** and/or **Video** clips if desired (Max 10).
- Select: **RESULTS** in the **POST-VAS Counter** when manual counting is completed.

Please note: The **MANUAL** Post Vas mode can also be used to report a Qualitative Result of "Present or Absent" sperm cells within 24 hours of collection. A note should be made that Motility was not assessed in this case.

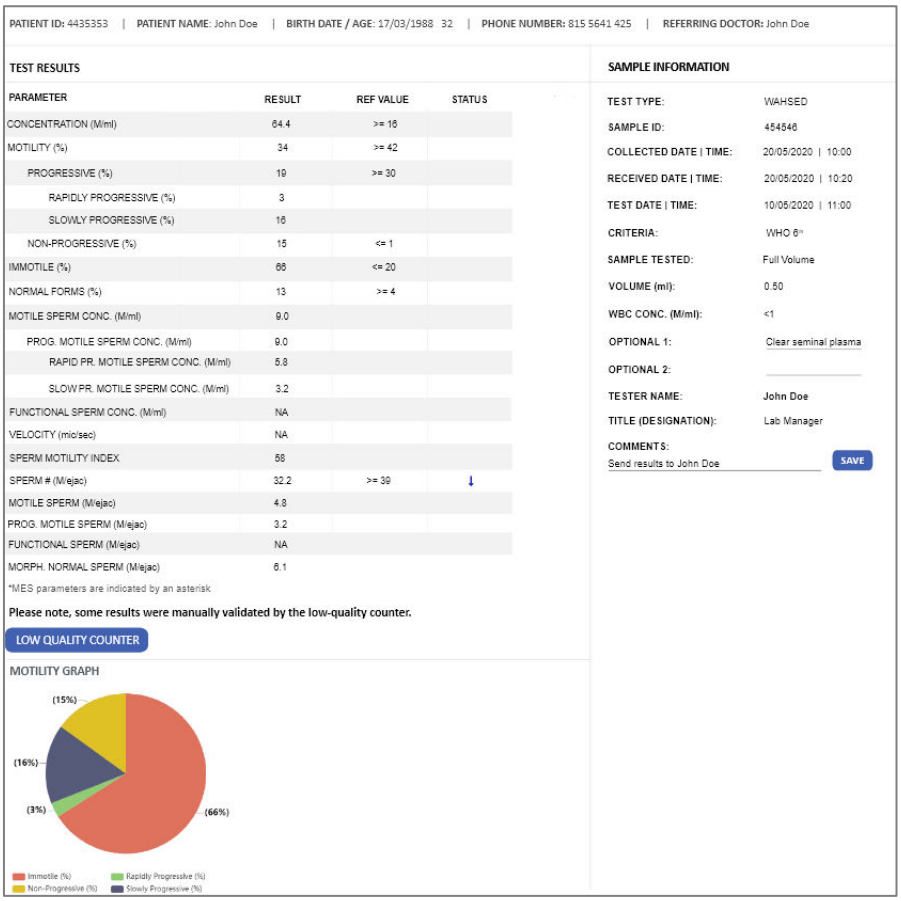


Test Patient – Test Results

Click **TEST NOW** and insert the testing capillary when prompted. 0.6 ml of sample is required. Do not move the device during testing. After approximately 75 seconds, all sperm parameter results will be displayed. An indicator arrow will appear if the results are high or low based on the laboratory's approved reference values and protocols for results interpretation. If there is no arrow, the test results are either in the normal range or there is no reference value for the parameter.

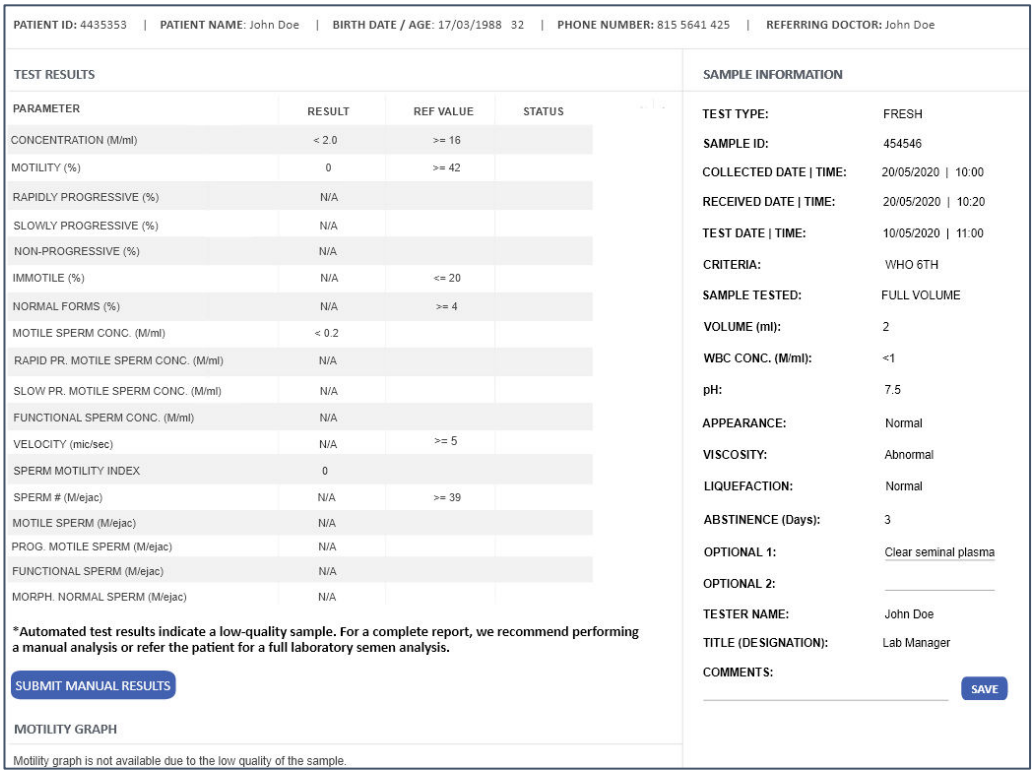
Test Results: The table above will be displayed after testing **FRESH** and **WASHED** semen samples with normal testing volume, 10 µl or diluted 1:2 (1+1). Five navigation options are available from the TEST RESULTS screen:

- **RETEST:** Select to run a second test on the same patient.
- **VIEW REPORT:** Click to view the patient's test report.
- **DOWNLOAD REPORT:** Click to download and print the patient's test report.
- **Requires an SQA-VU device:**
    - **MORPHOLOGY (Normal Forms):** Connect the SQA-VU to manually assess Normal/Abnormal sperm.
    - **CAPTURE:** Attach up to 10 images / videos to the report. The capture option allows image/video viewing, deleting, downloading.
- **REPORT EDITS:** After testing, click on PATIENT NAME/REFERRING DOCTOR/BIRTHDATE or AGE to edit.



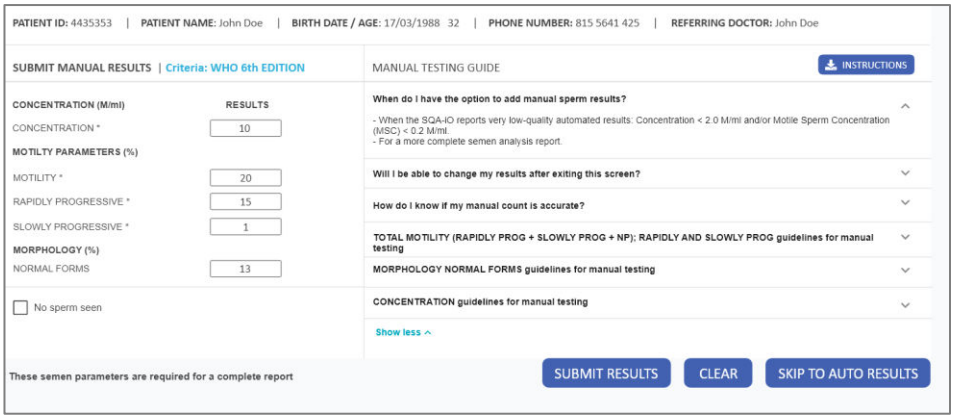
Low Quality – Test Results

Low quality test results may be reported as < (less than) or > (greater than) when one or more of the parameters falls below the SQA-iO dynamic range. Only Sperm Concentration, Total Motile, Motile Sperm Concentration and SMI values will be reported automatically due to the limited number of sperm cells, very low motility and/or poor morphology. Manual results can be entered to provide a full report if desired.



Low Quality – Manual Results

For non-VU users, manual results can be added to the test report to supplement the motility values reported in the automated low-quality test. A proficient semen analysis laboratory with equipment to test sperm concentration, motility, and morphology, is required. Please note that the accuracy and precision of the manual results will rely on the proficiency of the operator and accurate reporting is the operator's responsibility.



NORMAL FORMS (Morphology) are not included in the LOW-QUALITY report unless manually assessed.

* Motility and Concentration results cannot be submitted after leaving the manual assessment or test results page. Normal forms can be added at any time from the Patient Data Archive if manual results were entered for the other parameters.

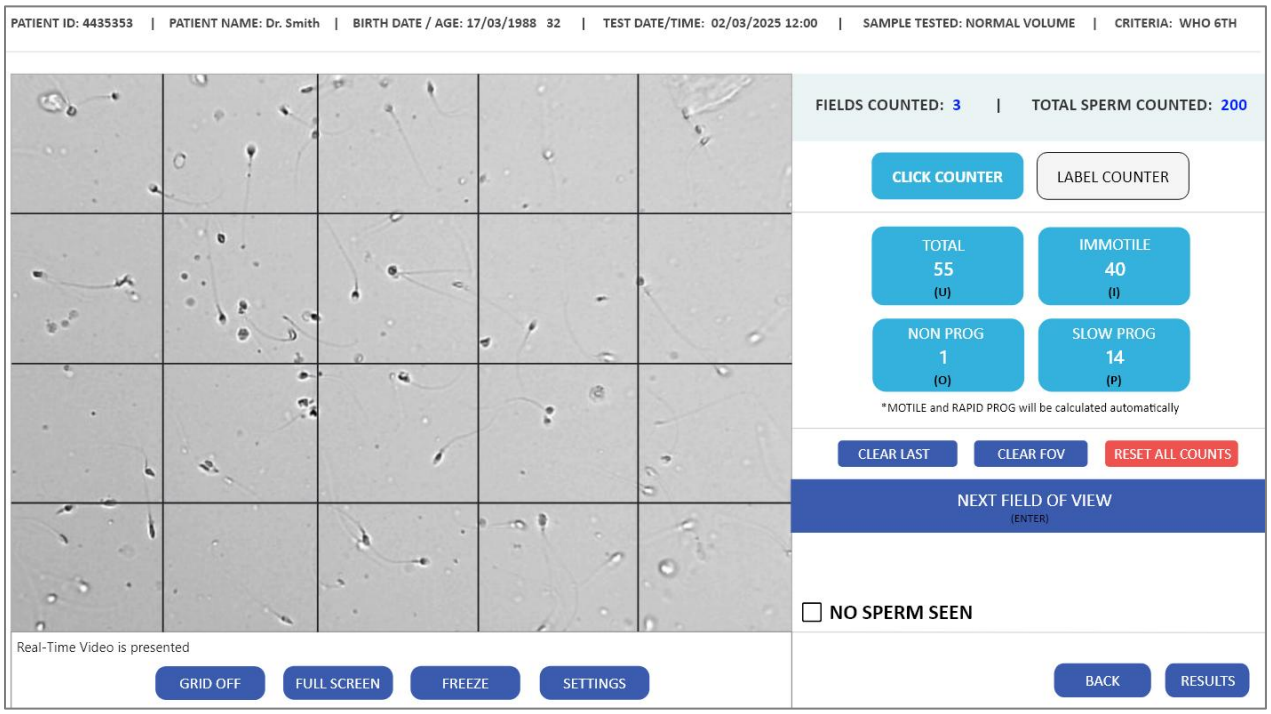
Low Quality counter (requires SQA-VU device)

- When "Open the Low-quality counter automatically" is marked in the settings and an SQA-VU device is connected, the counter will automatically activate when a low-quality sample is run.

- Use a Fixed Coverslip Slide to assess the number of Total, Immotile, Slowly Progressive and Non Progressive Spermatozoa in the field of view.

- Click NEXT FIELD OF VIEW and turn the Visualization Field of View Stage knob to move to a new field of view and assess additional sperm cells. Activate GRID ON, FULL SCREEN and FREEZE functions for easier counting.

• During the process of counting, the Number of FIELDS COUNTED and TOTAL SPERM COUNTED will be shown on the screen. Use the FREEZE option to accurately assess the total number of sperm cells.



• Click on the NO SPERM SEEN checkbox if no spermatozoa are found in all fields of view.

• Once you have completed the manual assessment, click the RESULTS button to view the results and report.

Test Patient – Semen Analysis Report

Test reports format options are available in SETTINGS:

- Graph report: Two-page report with Motility Graph, editable header/footer and signature section with the option to include additional information, add the company Head letter and edit or remove email address.
- Standard report: One-page report with editable header/footer re-sizing and the option to add the company Head letter and edit or remove email address.
- Flexible report - Can be customized by downloading and modifying an HTML template.

Graph Report – page 1

Medical Electronic Systems
5000 West Street LA.
CA 90000 University Laboratory

PHONE: 837-6029-686
EMAIL: mes@gmail.com
SITE: www.mes.com

SQA-iO AUTOMATED SEMEN ANALYSIS RESULTS

SQA-iO MES - Signal Processing Technology

PATIENT INFORMATION

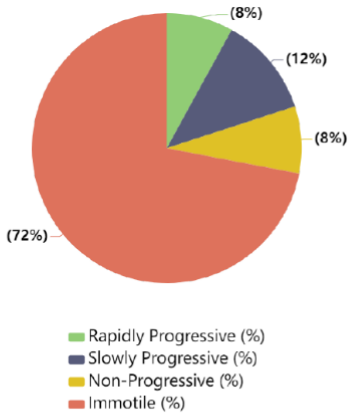
FIRST NAME:	John	LAST NAME:	Doe
PATIENT ID:	4435353	AGE:	32
REFERRING DOCTOR:	J Smith	PHONE NUMBER:	546-6784-222

SAMPLE INFORMATION

SAMPLE ID:	454546	pH:	7.5
SAMPLE TYPE:	FRESH	APPEARANCE:	NORMAL
COLLECTED DATE / TIME:	13/02/2022 | 10:30	VISCOSITY:	NORMAL
RECEIVED DATE / TIME:	13/02/2022 | 11:00	LIQUEFACTION:	0-30 Minutes
TEST DATE / TIME:	13/02/2022 | 11:19	ABSTINENCE (days):	7
CRITERIA:	WHO 6TH	OPTIONAL 1:	Very clear seminal plasma
VOLUME (ml):	5	OPTIONAL 2:	QwikCheck used for liquefaction
WBC CONC. (M/ml):	<=1		

PARAMETER	RESULT	UNITS	REF VALUE	
CONCENTRATION	24.7	M/ml	>=16	
MOTILITY	28	%	>=42	↓
PROGRESSIVE	20	%		
RAPIDLY PROGRESSIVE	8	%		
SLOWLY PROGRESSIVE	12	%		
NON-PROGRESSIVE	8	%	<=1	↑
IMMOTILE	72	%	<=20	↑
NORMAL FORMS	3	%	>=4	↓
MOTILE SPERM CONC.*	7.0	M/ml		
PROG. MOTILE SPERM CONC.*	4.9	M/ml		
RAPID PR. MOTILE SPERM CONC.*	1.9	M/ml		
SLOW PR. MOTILE SPERM CONC.*	3.1	M/ml		
FUNCTIONAL SPERM CONC.*	0.4	M/ml		
VELOCITY (VCL)*	31	mic/sec	>=5	
SPERM MOTILITY INDEX*	27	---		

MOTILITY GRAPH



* MES parameters are indicated by an asterisk

Signature: _____ Tester Name: John Doe Title (Designation): Lab Technician

SQA-iO Device SR: 10111 | Conc. Standard 1 | 20/05/2020 11:30:01 | AVG 55.81 | AW 15427 | CNT 330 | OD 1.126

Standard report

PHONE: 837-6029-686
EMAIL: MES@gmail.com
WEBSITE: www.mes-global.com

MES GLOBAL
5000 West Street LA.
CA 90000 University Laboratory

SQA-iO AUTOMATED SEMEN ANALYSIS RESULTS

PATIENT INFORMATION

FIRST NAME:	John	LAST NAME:	Doe
PATIENT ID:	4435353	BIRTH DATE | AGE:	17/03/1988 | 32

SAMPLE INFORMATION

SAMPLE ID:	454546	TEST RUN BY:	J. Smith
TEST TYPE:	FRESH	APPEARANCE:	NORMAL
COLLECTED DATE / TIME:	20/05/2023 | 10:00	VISCOSITY:	ABNORMAL
RECEIVED DATE / TIME:	20/05/2023 | 10:20	LIQUEFACTION:	0-30 Minutes
TEST DATE / TIME:	20/05/2023 | 11:00	CRITERIA:	WHO 6th
ABSTINENCE (days):	3	SAMPLE TESTED:	NORMAL VOLUME
OPTIONAL 1:	QwikCheck used for liquefaction	OPTIONAL 2:	Very clear seminal plasma

PARAMETER	RESULT	UNITS	REF.VALUE	STATUS
VOLUME	6	ml		
pH:	4	---		
WBC CONC.	<1	M/ml		
CONCENTRATION	6.0	M/ml	>=16	↓
MOTILITY	34	%	>=42	↓
PROGRESSIVE	11	%	>=30	
RAPIDLY PROGRESSIVE	3	%		
SLOWLY PROGRESSIVE	16	%		
NON-PROGRESSIVE	15	%	<=1	
IMMOTILE	66	%	<=20	
NORMAL FORMS	3	%	>=4	↓
MOTILE SPERM CONC.*	2.0	M/ml		
PROG. MOTILE SPERM CONC.*	1.0	M/ml		
RAPID PR. MOTILE SPERM CONC.*	0.2	M/ml		
SLOW PR. MOTILE SPERM CONC.*	1.0	M/ml		
FUNCTIONAL SPERM CONC.*	N/A	M/ml		
VELOCITY (VCL)*	N/A	mic/sec	>=5	
SPERM MOTILITY INDEX*	0	---		
SPERM #	18.0	M/ejac	>=39	↓
MOTILE SPERM*	6.1	M/ejac		
PROG. MOTILE SPERM*	3.4	M/ejac		
FUNCIONAL SPERM*	N/A	M/ejac		
MORPH. NORMAL SPERM*	0.5	M/ejac		

*MES parameters are indicated by an asterisk

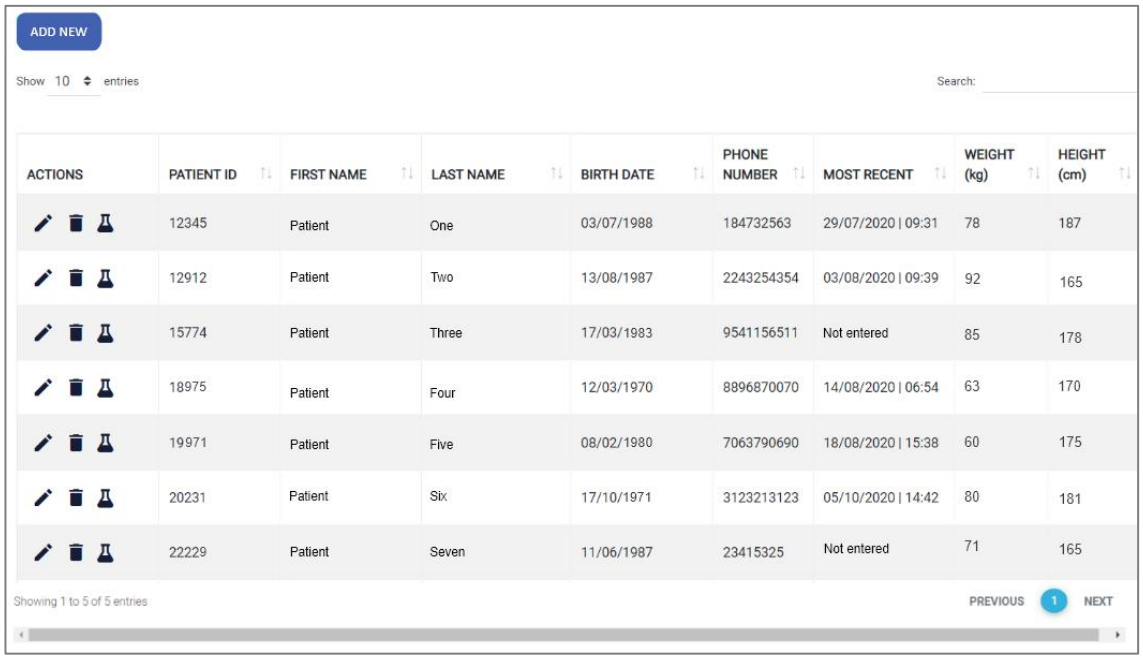
COMMENTS: Very clear seminal plasma, QwikCheck device used for liquefaction of this sample.

FAC ID#: Z9XQWR | SN#: 10111 | [MA] | Conc. Standard 1 | 20/05/2020 11:30:01 | AVG 55.81 | AW 15427 | CNT 330 | OD 1.126

CE

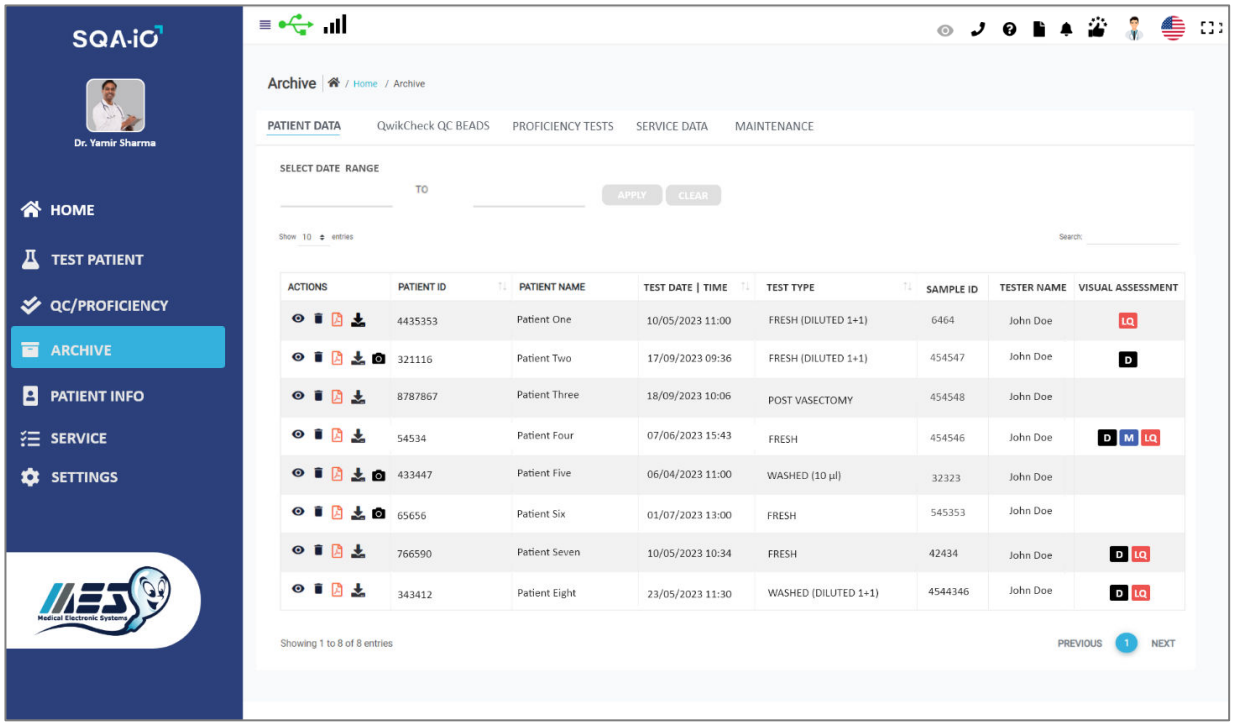
Patient Information

- **ADD NEW** patients by accessing the PATIENT INFORMATION screen.
- **Click ACTION** to edit or delete patient information.
- **SORT** by clicking on the column header.



Archive

- Click **ARCHIVE** for a list of all patient's test results.
- **SORT** by selecting the patient and then clicking on the ACTION button for date range, view, delete, or reports.



SECTION 6: QC / CONTROLS and Proficiency

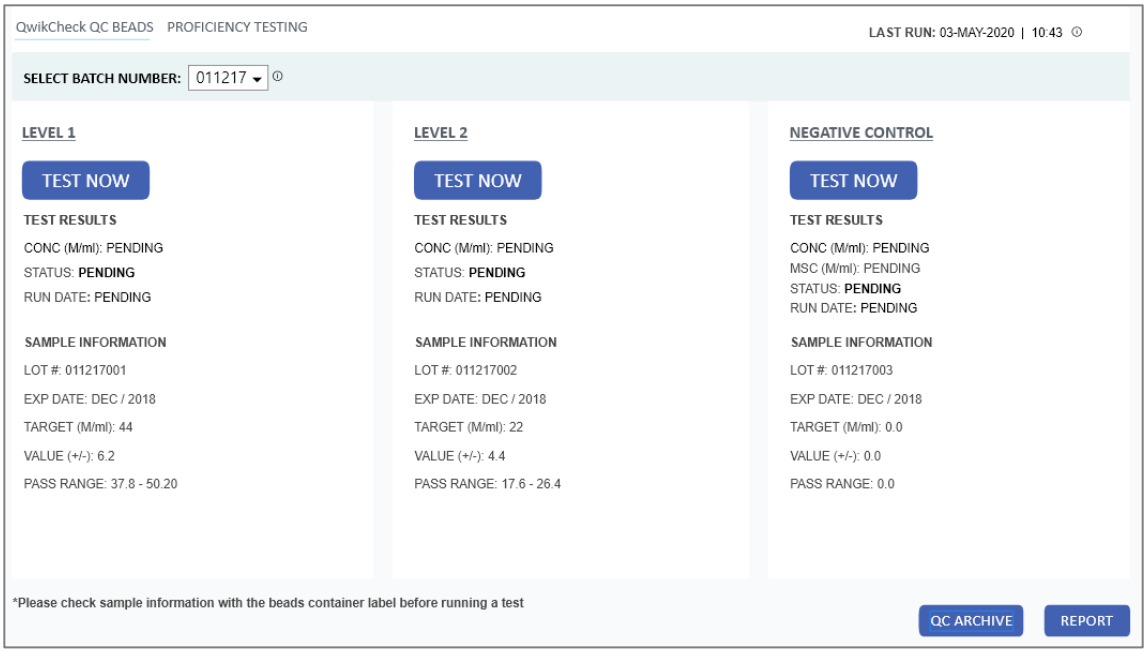
Select QC/Proficiency from the navigation panel to run three levels of QwikCheck Beads quality control samples or perform Proficiency testing. When running QwikCheck Beads controls or Proficiency samples please follow the instructions in the package insert. Also, be sure to:

- Use a separate, new capillary for each beads level.
- Mix the samples gently before aspirating into the testing capillary.
- Do not return beads solution to the container after testing – this will contaminate the samples AND beads adhere to the capillary walls so the concentration of the beads will be altered.

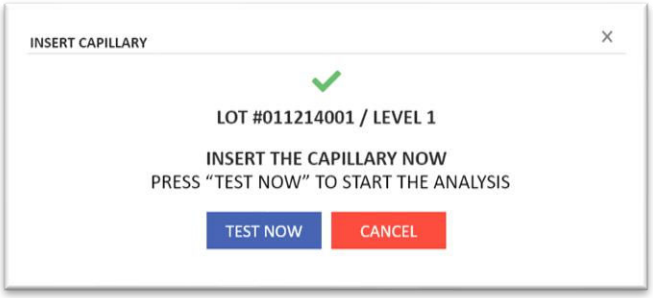
Testing QC Controls

The screen below will be activated when entering QC/Proficiency > QC from the navigation panel. If controls have never been run, all TEST RESULTS and SAMPLE INFORMATION will be shown as PENDING.

- **SELECT BATCH NUMBER:** From the drop-down menu, find the batch number that corresponds to the batch number on the outside label of the QwikCheck beads box that will be tested.
- **SAMPLE INFORMATION:** All three levels of beads will automatically be filled when the batch is selected.
- **LAST RUN:** If previous tests have been run, the last test date and time is shown.
- **TEST NOW:** Select TEST NOW when the testing capillaries are prepared for each test.

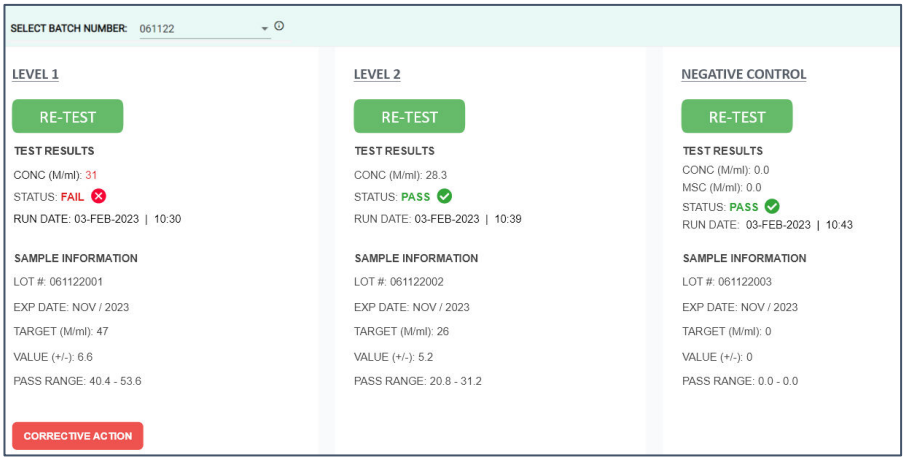


Follow the on-screen instructions for capillary preparation and insertion.

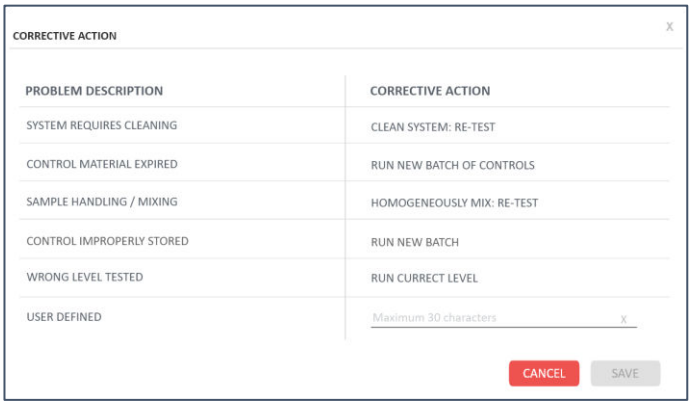


Results and Corrective Action:

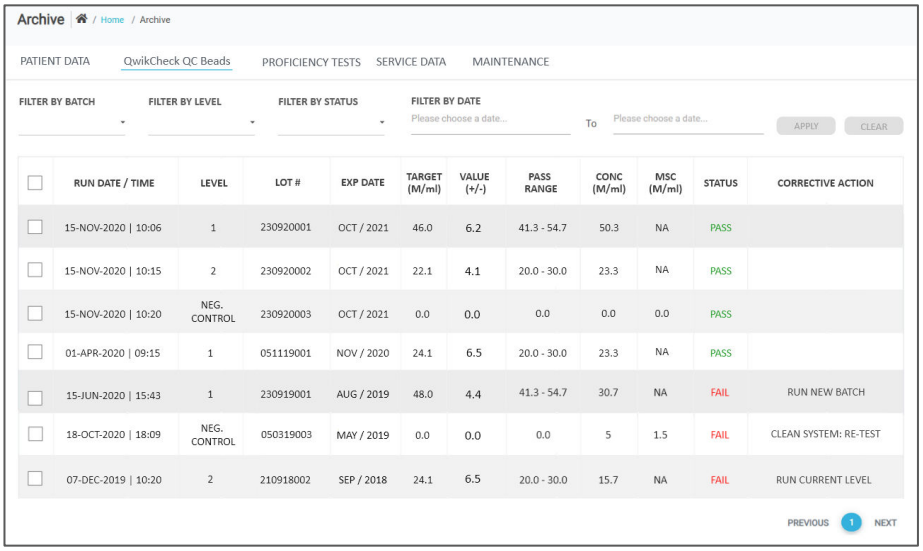
- **RESULTS:** Control testing takes about 20 seconds per test. Results are displayed automatically and, if out of range, a CORRECTIVE ACTION alert will be shown. Select the CORRECTIVE ACTION button to identify what caused the out-of-range results.
- **RE-TEST:** This button will appear after the first test was performed. Select it to test the sample again with no extra charge of credit code. The re-test option is time limited.



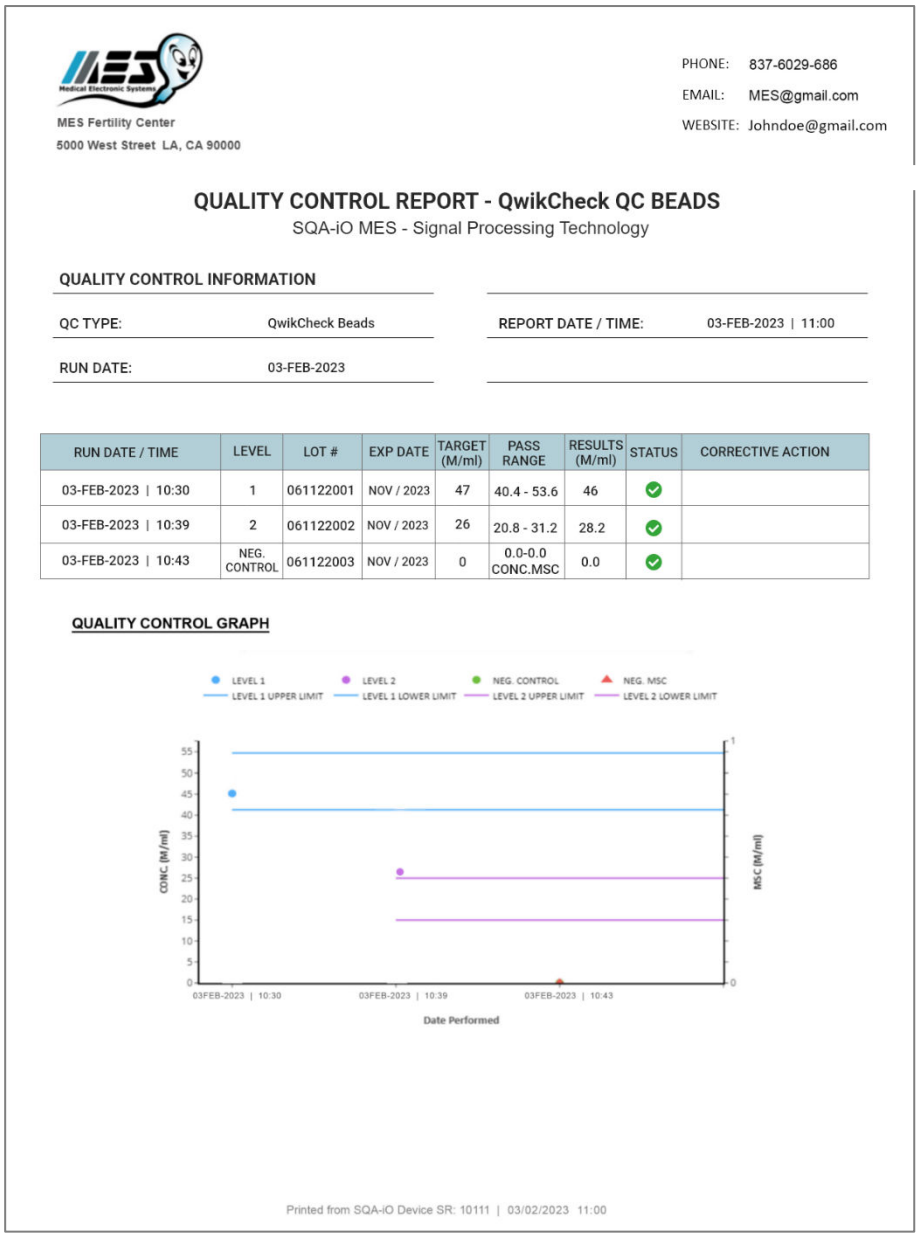
- **CORRECTIVE ACTIONS** are listed below and once selected, will appear on the QC Report and will be saved in the QC archive. Use the USER DEFINED option if none of the actions listed describe the problem.



- **QC ARCHIVE:** Select from the TESTING or ARCHIVE screen to view all QC tests. Many options for selecting and presenting results are available from this screen and results can be exported.



- **QC/Controls Test Report:** After testing, select REPORT to print a final report with QC results and graph.



MES Fertility Center
5000 West Street LA, CA 90000

PHONE: 837-6029-686
EMAIL: MES@gmail.com
WEBSITE: Johndoe@gmail.com

QUALITY CONTROL REPORT - QwikCheck QC BEADS

SQA-iO MES - Signal Processing Technology

QUALITY CONTROL INFORMATION

QC TYPE:	QwikCheck Beads	REPORT DATE / TIME:	03-FEB-2023 | 11:00
RUN DATE:	03-FEB-2023		

RUN DATE / TIME	LEVEL	LOT #	EXP DATE	TARGET (M/ml)	PASS RANGE	RESULTS (M/ml)	STATUS	CORRECTIVE ACTION
03-FEB-2023 | 10:30	1	061122001	NOV / 2023	47	40.4 - 53.6	46	✓	
03-FEB-2023 | 10:39	2	061122002	NOV / 2023	26	20.8 - 31.2	28.2	✓	
03-FEB-2023 | 10:43	NEG. CONTROL	061122003	NOV / 2023	0	0.0-0.0 CONC.MSC	0.0	✓	

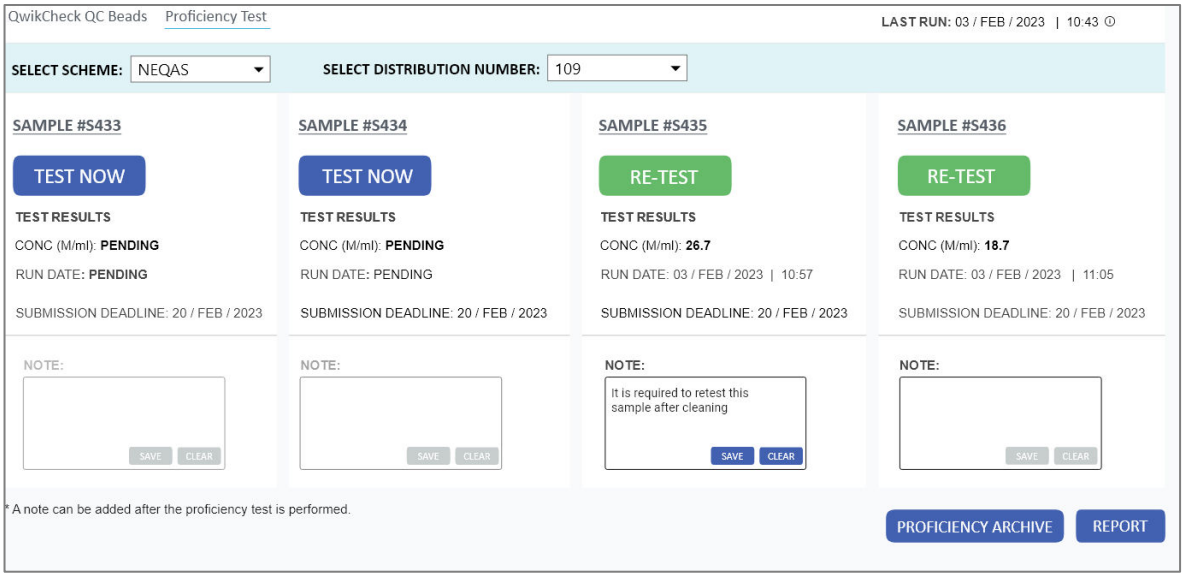
QUALITY CONTROL GRAPH

Printed from SQA-iO Device SR: 10111 | 03/02/2023 11:00

Testing Proficiency Samples

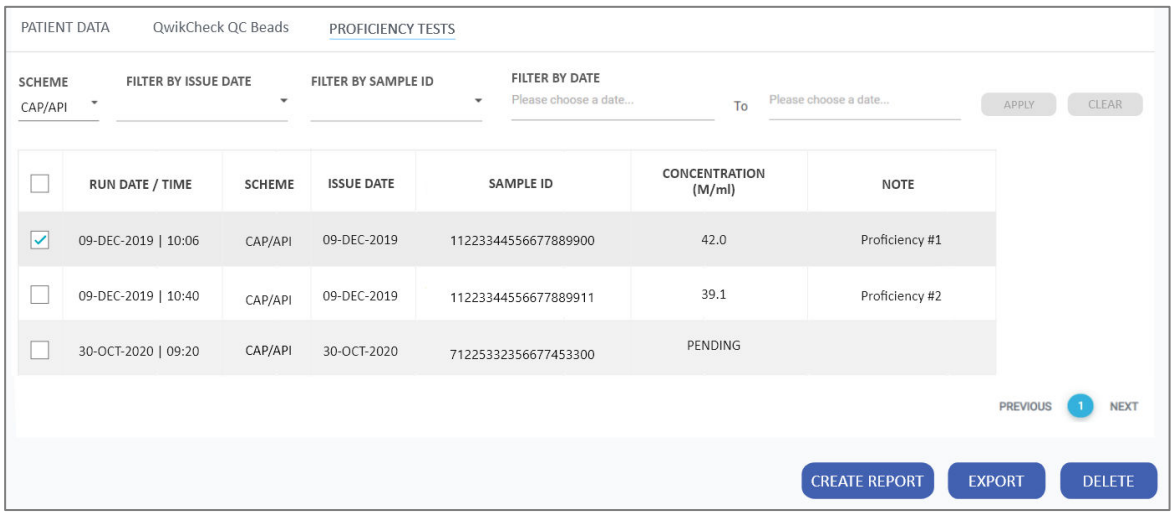
- Select QC/Proficiency from the navigation panel, then activate the Proficiency Testing tab to view the screen displayed below.
- **SCHEMES**: There are four different schemes available to select from:
  - NEQAS
  - QuaDeGa
  - CAP/API
  - iPRO
- **SELECT SCHEME:** From the drop-down menu, select the scheme in which the lab is enrolled.
- **SELECT DISTRIBUTION NUMBER:** For NEQAS and QuaDeGa, the distribution number can be found on the box labeling. Select the corresponding distribution number from the drop-down menu.
- **ENTER ISSUE DATE/BATCH NUMBER:** For CAP/API and iPRO, the issue date/Batch number can be found on the box labeling. Enter the information in the provided field.

- **SAMPLE INFORMATION:** NEQAS and QuaDeGa sample ID's will be shown automatically when the distribution number is selected. For CAP/API, manually enter the sample IDs found on the box labeling.
- **LAST RUN:** If previous tests have been run, a notification of the last date and time is shown.
- **TEST NOW:** Select TEST NOW when the testing capillaries are prepared for each test. Follow the on-screen instructions for capillary insertion.
- **RE-TEST:** This button will appear after the first test was performed. Select it to test the sample again with no extra charge of credit code.
- **SUBMISSION DEADLINE:** The date the proficiency results must be reported.
- **NOTE:** Enter sample testing notes after testing, if desired. Click SAVE to display notes on the report/archive or CLEAR to remove the notes.

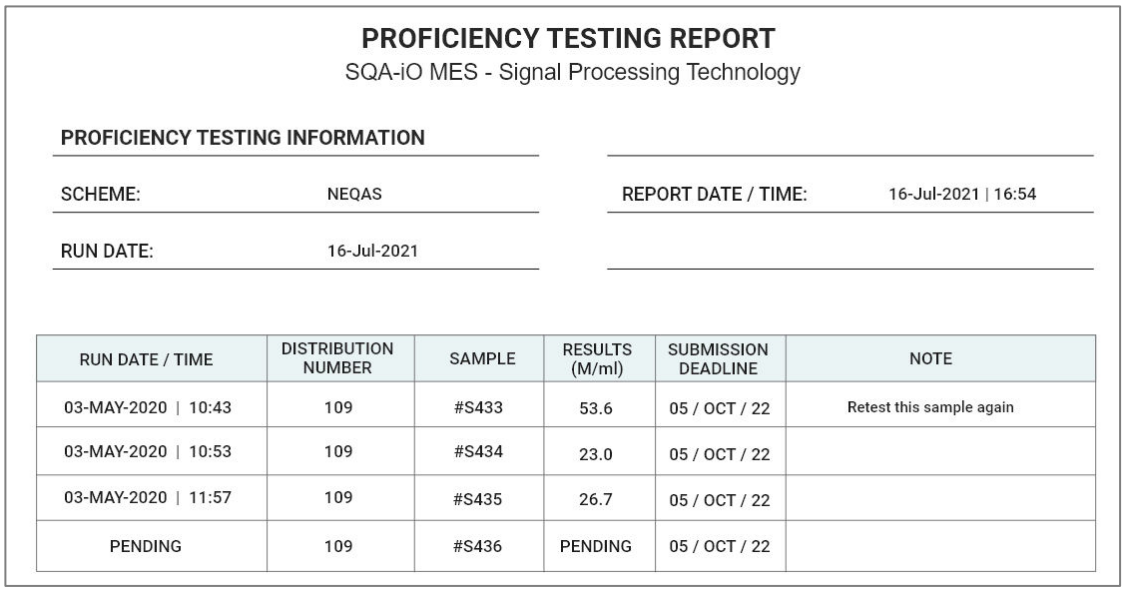


Proficiency Results:

- **RESULTS:** Proficiency testing takes about 20 seconds per test. Concentration Results are displayed automatically. If the results indicate the SQA-iO was not cleaned effectively before testing, the results will be displayed in red, and a re-test option will be available after cleaning the device.
- **PROFICIENCY ARCHIVE:** Select this option from the TESTING or ARCHIVE screen to view all Proficiency Tests. Options for filtering, presenting/deleting or exporting results are available.



- **TEST REPORT:** After completing a test, select the REPORT button to view the final Report.



PROFICIENCY TESTING REPORT

SQA-iO MES - Signal Processing Technology

PROFICIENCY TESTING INFORMATION

SCHEME: NEQAS

REPORT DATE / TIME: 16-Jul-2021 | 16:54

RUN DATE: 16-Jul-2021

RUN DATE / TIME	DISTRIBUTION NUMBER	SAMPLE	RESULTS (M/ml)	SUBMISSION DEADLINE	NOTE
03-MAY-2020 | 10:43	109	#S433	53.6	05 / OCT / 22	Retest this sample again
03-MAY-2020 | 10:53	109	#S434	23.0	05 / OCT / 22	
03-MAY-2020 | 11:57	109	#S435	26.7	05 / OCT / 22	
PENDING	109	#S436	PENDING	05 / OCT / 22	

SECTION 7: SQA-iO Test Credits

The SQA-iO cannot operate without test credits. Each new test kit or SQA Testing Capillaries box contains a unique TEST CREDIT CODE. Enter this code into the SQA-iO when opening a new test kit or when you receive an alert that test credits are low. From the Home page SELECT:

- **ORDER SUPPLIES** to request SQA-iO supplies from your distributor.
- Click on **CREDIT CODES** if you need to load more tests.

SQA-iO supplies can also be ordered through **CONTACT US** using the convenient drop-down menu **by direct contact with your local distributor.**

SECTION 8: Set-up the SQA-iO Default Settings

Various levels of default SETTINGS can be implemented in the SQA-iO based on the user's permission status. Each user will have different permissions and his own login credentials (email and password).

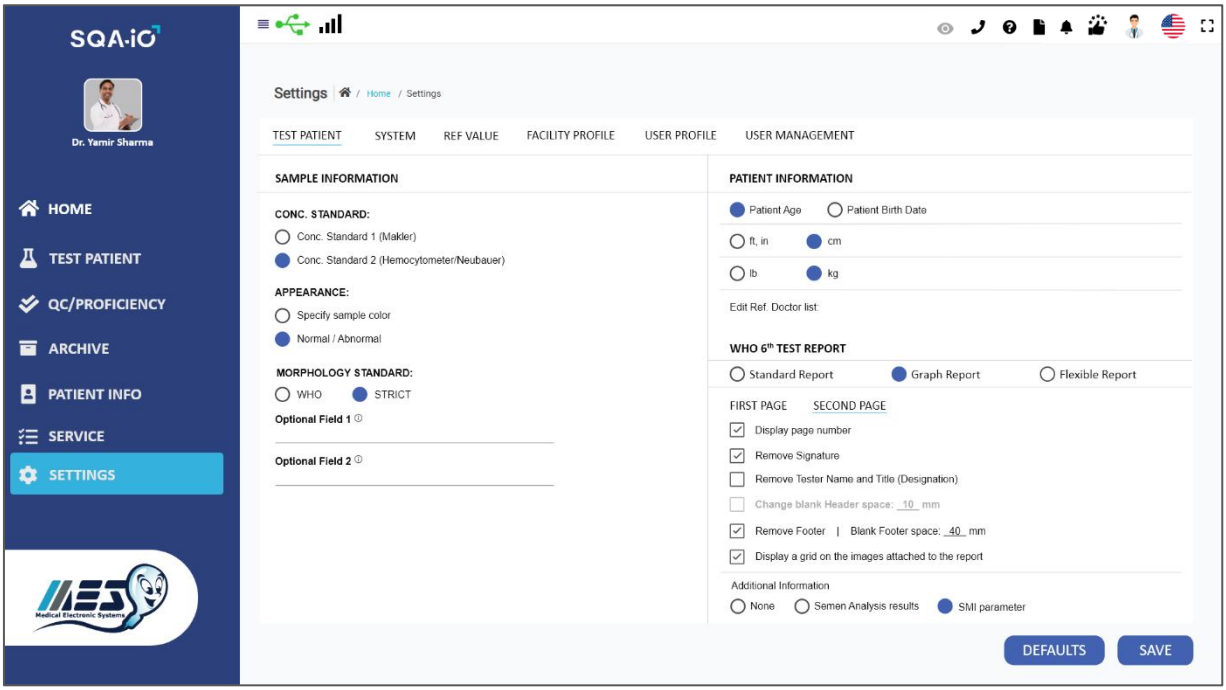
TYPES OF USERS: Three types of users are described below along with their permission rights.

- **BASIC** – Can view and modify the User Profile.
- **EDITOR** – Can change the User Profile, Reference Values and Test Patient defaults.
- **ADMIN** – Has access rights and can view/modify all Settings options and can add new, remove, or edit other user accounts. Admin users are limited to two per account.

TEST PATIENT (Editor Level Permission): Select **Settings -> Test Patient** to define the defaults for sample testing.

- **CONC. STANDARD**: Select "Standard 1" for 10-20-micron counting chambers (Makler) that do not require sample dilution; Select "Standard 2" for hemacytometers OR Neubauer.
- **APPEARANCE**: Use to select the color or Normal/Abnormal sample appearance.
- **MORPHOLOGY STANDARD**: Set the Morphology Standard to strict or WHO based on the lab morphology assessment data. The default option is strict for both editions.

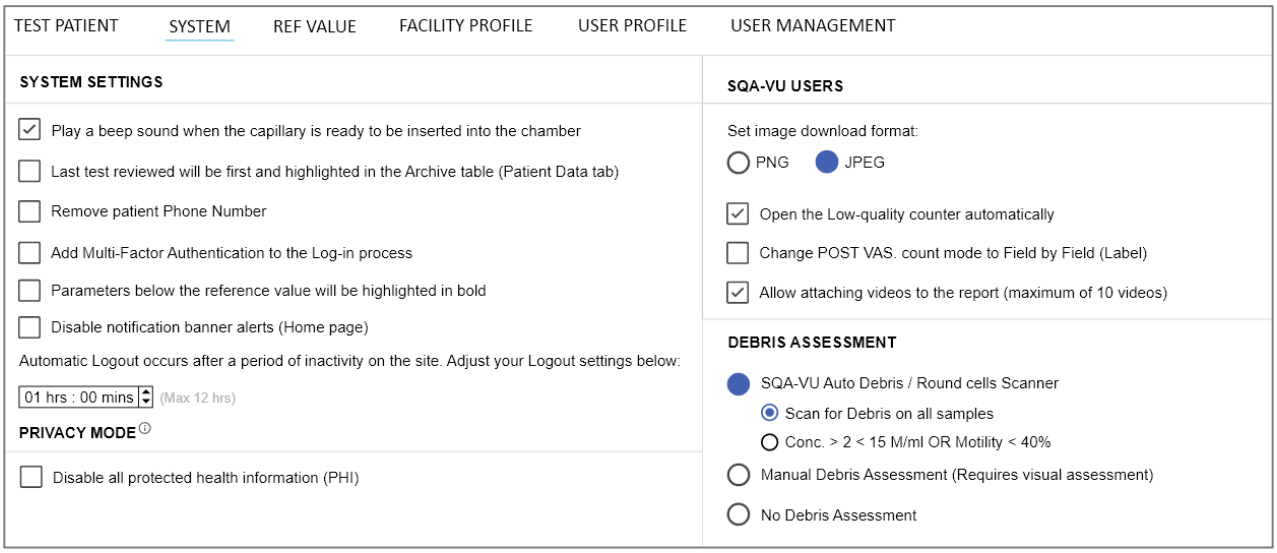
- **OPTIONAL FIELDS**: Enter any labeling desired in any one of these fields. They will appear as labeled on the test report and on the data entry/patient testing screen.



SYSTEM (Editor Level Permission): Select **Settings -> System** to define the system defaults.

- **SYSTEM SETTINGS:**
  - Beep sound: Turn on or off beep that indicates when to insert capillary after auto calibration.
  - Archive: The page of the last test run / reviewed will appear first when opening the Archive and the last run/reviewed test will be highlighted.
  - MULTI-FACTOR Authentication: The log-in process will include an additional email delivery step with a unique six-digit code.
  - Highlight parameters: Parameters below the reference value will be highlighted in bold.
  - Disable notification banner alerts: Eliminate notifications from Home page.
  - Automatic Logout: Define time for the automatic log-out up to 12 hours.
- **PRIVACY MODE:**
  - Disable protected information (PHI): Select this option to disable data input fields and remove all personal patient identification information from the SQA-iO interface and reports.
- **SQA-VU USERS SETTINGS**: Any operator can adjust:
  - Image format: Change the IMAGE download format from PNG (default) to JPEG.
  - Low Quality Counter: Select to automatically open a manual counting screen for all low-quality samples.
  - Post-vas Counter: Set the counting mode to Field-by-Field (Label) instead of Click.
  - Allow attaching videos: Select this option to attach recorded videos through a link accessible from the test report. Each link remains valid for 5 years.
- **DEBRIS ASSESSMENT:**
  - Select options for activating sample Debris Assessment:
    - SQA-VU Auto Debris / Round cells Scanner
    - Manual Debris Assessment (Requires visual assessment)
    - No Debris assessment

    *See the Debris Assessment Protocol in the Appendix section of this guide.



REF. VALUE (Editor and Admin Permission): Select WHO 5th of 6th edition testing criteria for reference values. The manufacturer's factory defaults are pre-set to WHO 6th criteria. Or, set custom reference values by un-checking the box.

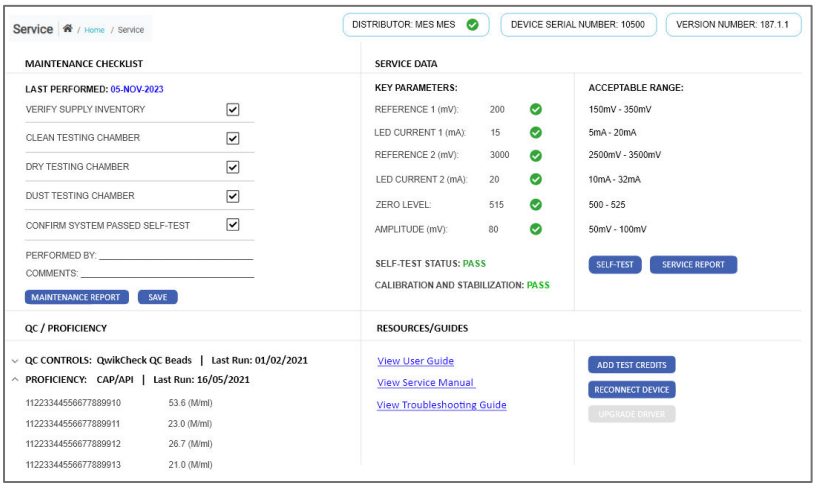
FACILITY PROFILE (Administrator Permission): Select to customize the SQA-iO test report logo and facility information.

USER PROFILE (All Users): View personal profile information, change password, set-up test report signature and upload a personal profile picture.

SECTION 9: Service

Enter this screen to view/access the:

- **DISTRIBUTOR**: Link to your distributor for service and support by their unique ID number.
- **MAINTENANCE CHECKLIST**: Document and track the device maintenance and cleaning schedule.
- **MAINTENANCE REPORT:** Displays the most recent maintenance checklist.
- **SERVICE REPORT**: Provides technical information about the device.
- **SERVICE DATA/KEY PARAMETERS**: Check to confirm that the SQA-iO device is ready for testing.
- **User Guide, Service Manual and Troubleshooting Guide**: Links provided to review or download.
- **RECONNECT DEVICE**: The system will reboot the device. Click to solve connectivity issues.
- **UPGRADE DRIVER**: Recommended to improve system performance.



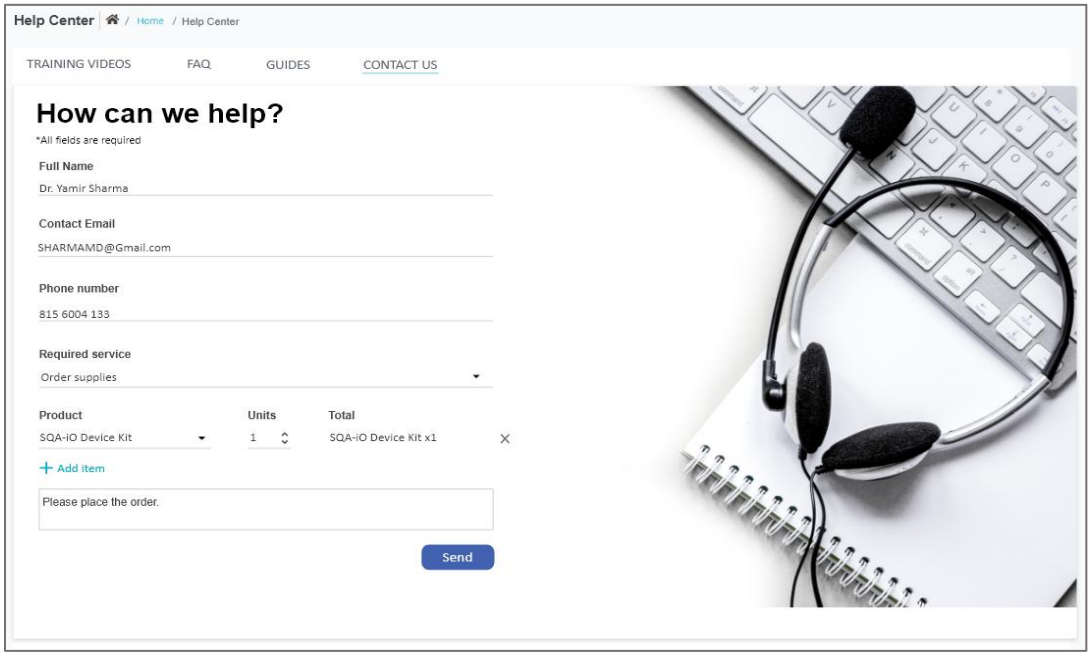
SECTION 10: Help Center / Contact Us

TRAINING VIDEOS: Provide step-by-step instructions on the different features and processes of the SQA-iO.

FAQ: Presents different troubleshooting questions and answers to solve technical problems.

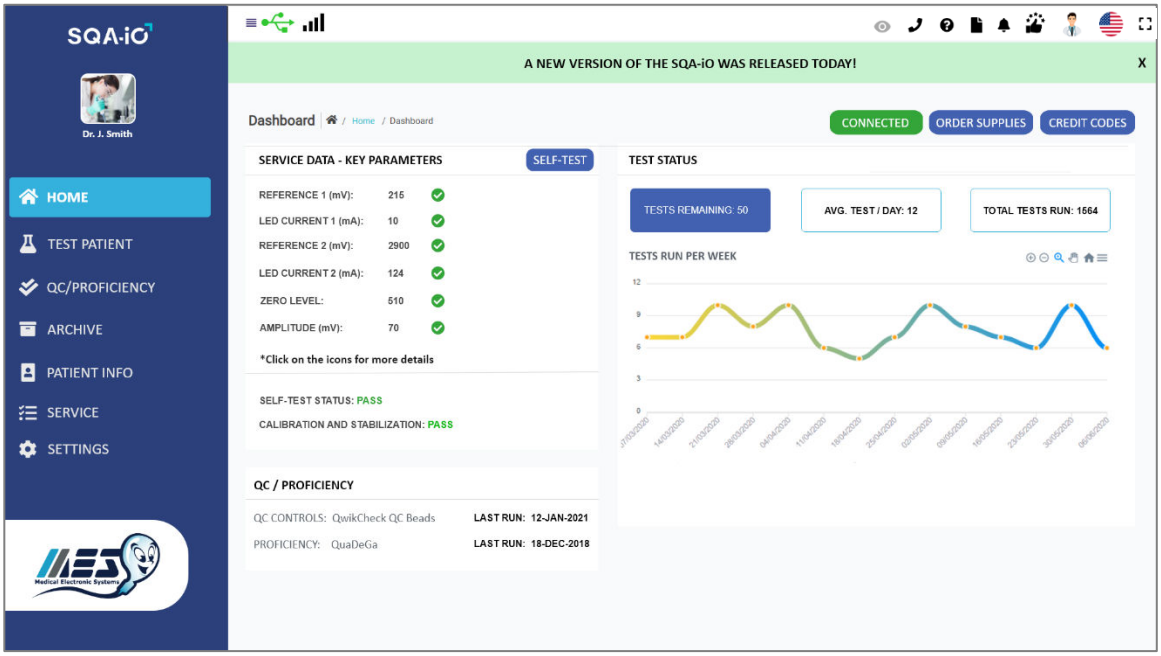
GUIDES: Displays all SQA-iO guides for viewing or downloading.

CONTACT US: Click the phone icon at the top righthand corner of the screen or access from the Help Center to order new test kits or request support. Use the drop-down menu and message box to contact your local distributor.

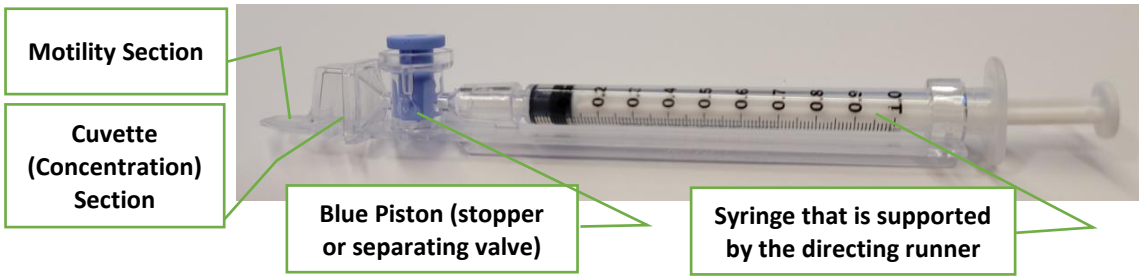


SECTION 11: Notifications

The notification system is designed to deliver timely updates, alerts, and important announcements. New notifications will be displayed as a green banner on the Home page, as a list within the dedicated notification center, and via a bell icon located in the interface header. For users who prefer a more streamlined experience, the banner can be disabled through the settings page.



APPENDIX 1: Filling the Testing Capillary with a Normal Volume Sample



Sample size, collection and preparation instructions:

1. A minimum of 0.6 ml. of semen is required for the SQA testing capillary.
2. Self-collected the sample without using lubricants/creams or partners.
3. Test the sample after liquefaction and within 1 hour of collection for optimal results.
4. Maintained at room temperature 20-25°C / 68-77°F (do not heat or refrigerate).
5. Measure sample volume according to laboratory protocols.
6. Before filling the capillary, mix the liquefied sample gently by rotating the sample collection container.
7. *WARNING:* ***Do not shake or use a pipette to mix the sample otherwise air bubbles will form and test results will be inaccurate.***
8. Carefully check that the liquefied, fully mixed semen is **free** of air bubbles.

Fig. 1: Filling

Filling the capillary… Ready to test:

1. Push the syringe pump fully into the syringe and then place only thin part of the capillary into the bottom of the sample (Fig 1).
2. Pull the syringe pump back slowly while keeping the tip of the capillary well below the sample level and below any surface bubbles. Continue to aspirate the sample until it appears in the Luer adaptor (Fig. 1 & 2).
3. Check the capillary after filling (Fig. 2), visually confirm that the sample has **completely** filled the cuvette and thin section of the capillary (without a meniscus). Tap on the syringe to make sure there are no air bubbles in the sample. If air bubbles still appear below the Luer adaptor, fill again with a **small** quantity of semen to draw the air bubbles into the syringe.
4. Wipe the tip of the capillary with a **Kimwipe** quickly (to avoid wicking) (Fig. 3). Also wipe the exterior of the capillary if any spillage occurred, in order to keep the SQA-iO clean. Visually **confirm** that the capillary chambers are still full after cleaning. If not, slightly push in the piston of the syringe to re-fill the capillary section.
5. Slowly push in the blue separating valve until it is level with the plastic (Fig. 4).
6. Insert the testing capillary into the SQA-iO **all the way** with the blue valve down (Fig 5)

Fig. 2: Inspect for bubbles

Fig. 3: Wipe the tip

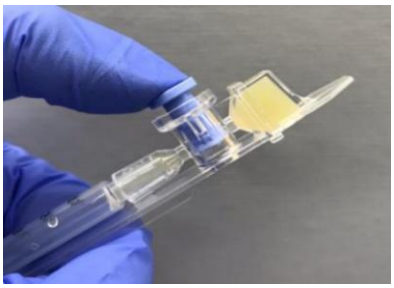


Fig. 4: Push-in the blue valve

Fig. 5: Insert capillary into SQA-iO

APPENDIX 2: Filling the Testing Capillary with a LOW Volume Sample

Sample size and preparation:

1. A **minimum** of 10 microliters of semen can be tested by filling ONLY the thin section of the testing capillary. Only semen motility parameters will be reported.
2. The sample must be maintained at room temperature (do not heat or refrigerate), tested within 1 hour of collection and be fully liquified.
3. After liquefaction, gently mix the sample by rotating it in the container.
4. Carefully check that the liquified, fully mixed semen is free of air bubbles.

WARNING: ***Do not shake or use a pipette to mix the sample otherwise air bubbles will form and test results will be inaccurate.***

Fig. 1: Fill the tip

Fill the SQA-iO testing capillary:

1. **Push the syringe piston in fully**. Place only the thin part of the capillary into the bottom of the sample (Figure 1).
2. **Pull the piston back slowly** without withdrawing the capillary from the sample.
3. **Fill only the (thin) capillary chamber** with 10 microliters of semen (Figure 1). Aspirate the sample until it just appears in the cuvette section while keeping the tip of the capillary well below the sample level and well below the level of any bubbles covering the liquid.
4. Withdraw the capillary tip from the semen sample and visually inspect to ensure that the sample has completely filled the thin section (no meniscus).
5. Wipe the tip of the capillary with a **Kimwipe** quickly (to avoid wicking). Also wipe the exterior of the capillary if any spillage occurred, in order to keep the SQA-iO clean.
6. Visually **confirm** that the thin section of the capillary is still full after cleaning. If not, **slightly** push in the piston of the syringe until a small drop appears on the capillary tip and then re-fill the capillary tip with more sample.

Remove the blue separating valve:

- Detach the entire syringe from the hub (Figure 2)
- Use the syringe or capillary jig to push-out the blue separating valve from the capillary (Figure 3)
- Completely remove the blue separating valve (Figure 4)
- Insert the testing capillary into the SQA-iO

Fig 2:Detach the syringe

Fig 3:Push the valve out

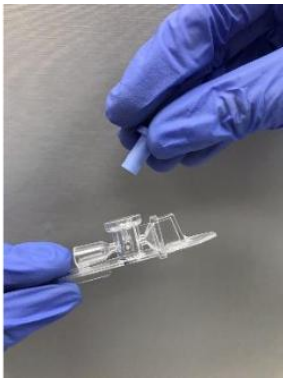


Fig 4:Remove the blue

PLEASE NOTE: Test Low Volume samples as soon as the capillary is filled.

APPENDIX 3: Cleaning the SQA-iO

When to clean: AT LEAST WEEKLY

- Or if SELF-TEST or any other failure occurs
- Or if System becomes contaminated with semen

Cleaning kit components:

- Long cleaning brush (provided in the SQA-iO TEST KIT)
- Fibrous material cleaning paddles (single use)
- Sponge-tipped drying paddles (single use)
- Cleaning fluid (single drop dispenser)


Fig.1 Long Cleaning Brush

CLEANING: STEP 1

1. Insert the long brush supplied in your TEST KIT (bristle side down) into the chamber of the SQA-iO in the same way a testing capillary would be inserted (Fig 1 and 2).
2. Pull the brush out, applying downward pressure to sweep or '**dust off**' the optics (you will feel a 'shelf' in the back/top section of the chamber) – (Fig 2 and 3)
3. **Monitor the system's "REF. 2" parameter. It should be between 2,800 and 3,200 mV if possible.**


Fig. 2 Clean the chamber


Fig. 3 "Dust off"

CLEANING: STEP 2

2. Use a **Fibrous material** cleaning paddle (Fig 4) supplied in your TEST KIT.
   - Moisten with only ONE drop of cleaning fluid.
   - Shake off excess fluid.
   - Insert into the measurement compartment fibrous material facing **down** and move the cleaning paddle in and out 5 times (Fig 5).
   - Then, insert into the measurement compartment fibrous material facing **up** and move the cleaning paddle in and out 5 times (Fig 5).
3. Dry the testing chamber using a sponge-tipped drying paddle that is supplied in your TEST KIT.
   - Insert it into the testing chamber and leave it for 10 – 15 seconds (Fig 6).
   - Leave the drying paddle in place, DO NOT move it in and out.


Fig. 4 Fibrous cleaning paddle


Fig. 5 Insert cleaning paddle down and up


Fig. 6 Dry the testing chamber with sponge

APPENDIX 4: Reference Range Values of Semen Parameters

WHO 5th		WHO 6th		
SEMEN PARAMETER	**REFERENCE RANGE***	**SEMEN PARAMETER**	**REFERENCE RANGE***	**SOURCE**
CONCENTRATION (M/ml)	≥ 15	CONCENTRATION (M/ml)	≥ 16	WHO
TOTAL MOTILE PR + NP (%)	≥ 40	TOTAL MOTILITY (%)	≥ 42	WHO
PROGRESSIVE PR (%)	≥ 32	PROGRESSIVE (%) (RAPIDLY + SLOW PROG)	≥ 30	WHO
NON-PROGRESSIVE NP (%)	N/A	NON-PROGRESSIVE (%)	≤1	WHO
IMMOTILE IM (%)	N/A	IMMOTILE (%)	≤ 20	
MOTILE SPERM CONC. (M/ml)	≥ 6	MOTILE SPERM CONC. (M/ml)	≥ 7	MES
PROG. MOTILE SPERM CONC. (M/ml)	≥ 5	PROG. MOTILE SPERM CONC. (M/ml) (RAPIDLY + SLOW)	≥ 5	MES
NORMAL FORMS (%)	≥ 4	NORMAL FORMS (%)	≥ 4	WHO
SPERM MOTILITY INDEX**	≥ 80	FUNCTIONAL SPERM CONC. (M/ml)	≥ 0.2	WHO
		SPERM MOTILITY INDEX**	≥ 80	MES
SPERM # (M/ejac)	≥ 39	SPERM # (M/ejac)	≥ 39	MES
MOTILE SPERM (M/ejac)	≥ 16	MOTILE SPERM (M/ejac)	≥ 16	MES
		PROG. MOTILE SPERM (M/ejac)	≥ 12	MES
		FUNCTIONAL SPERM (M/ejac)	≥ 0.5	MES
		MORPH NORMAL SPERM (M/ejac)**	≥ 2	MES
		VELOCITY** (VCL) (mic/sec)	≥ 5	MES

* The reference values established above are based on WHO 5th/6th edition manual data or MES (for proprietary semen parameters). Each laboratory/clinic can establish their own requirements and cut-offs for semen parameters.

** Semen parameters not reported in U.S. market

APPENDIX 5: Product Performance Data:

Accuracy:

The SQA-iO WHO 6th accuracy vs. the SQA-V PREDICATE is established using Passing-Bablok regression analysis. The trendline slope, intercept and correlation Accuracy results are shown in Table 1 below.

Table 1. SQA-iO Intended User vs. SQA-V Expert User (n = 165)

Parameter	Intercept	CI	Slope	CI	Correlation	CI
CONCENTRATION, M/ml	-1.5	-2.0 to -0.7	1.0	1.0 to 1.0	1.0	0.98 to 0.99
MOTILITY, %	-3.0	-3.1 to -1.7	1.0	1.0 to 1.0	1.0	0.95 to 0.97
PROGRESSIVE MOTILITY, %	-0.8	-1.0 to 0.0	0.9	0.9 to 1.0	1.0	0.97 to 0.98
RAPIDLY PROGRESSIVE, %	0.1	0.0 to 0.3	1.0	0.9 to 1.0	0.9	0.90 to 0.94
SLOWLY PROGRESSIVE, %	-0.8	-1.0 to 0.0	1.0	0.9 to 1.0	0.9	0.86 to 0.93
NON-PROGRESSIVE, %	-1.9	-3.0 to -1.0	1.2	1.0 to 1.3	0.8	0.71 to 0.83
IMMOTILE, %	3.0	1.0 to 5.0	1.0	1.0 to 1.0	1.0	0.95 to 0.97
MSC, M/ml	-0.9	-1.7 to -0.6	1.0	1.0 to 1.0	1.0	0.98 to 0.99
PMSC, M/ml	-0.4	-0.7 to -0.3	1.0	0.9 to 1.0	1.0	0.99 to 1.00
RAPID PMSC, M/ml	0.0	-0.1 to 0.0	1.0	1.0 to 1.0	1.0	0.96 to 0.98
SLOW PMSC, M/ml	-0.1	-0.4 to -0.1	1.0	0.9 to 1.0	1.0	0.98 to 0.99
MORPHOLOGY, % (n = 155)	0.0	0.0 to 0.1	1.0	0.9 to 1.0	1.0	0.96 to 0.98
FSC, M/ml (n = 155)	-0.1	-0.1 to 0.0	0.9	0.9 to 1.0	1.0	0.97 to 0.99

Precision:

Table 1: SQA-iO Sperm Concentration Precision

Concentration			Within-Run		Between-Run		Between-Day		Between-Operator/ Lot/Instrument		Total	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	40	8.5	0.63	7.4%	0.61	7.2%	0.25	2.9%	0.60	7.1%	0.62	7.3%
2	40	34.5	1.66	4.8%	1.70	4.9%	0.77	2.2%	1.31	3.8%	1.76	5.1%
3	40	45.4	3.25	7.2%	3.30	7.3%	1.66	3.7%	3.09	6.8%	3.46	7.6%
4	40	58.5	3.12	5.3%	3.07	5.2%	1.04	1.8%	2.11	3.6%	3.04	5.2%
5	40	62.2	2.42	3.9%	2.38	3.8%	1.42	2.3%	2.30	3.7%	2.64	4.2%
6	40	181.6	5.25	2.9%	5.35	2.9%	3.42	1.9%	3.83	2.1%	5.87	3.2%
7	40	227.6	5.87	2.6%	6.25	2.7%	5.45	2.4%	3.48	1.5%	7.58	3.3%
8	40	212.9	3.74	1.8%	4.42	2.1%	4.87	2.3%	2.67	1.3%	5.79	2.7%

Table 2: SQA-iO Motility Precision

Motility			Within-Run		Between-Run		Between-Day		Between-Operator/ Lot/Instrument		Total	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	40	0.0	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%
2	40	77.0	2.82	3.7%	2.74	3.6%	1.20	1.6%	2.59	3.4%	2.87	3.7%
3	40	62.3	2.62	4.2%	2.59	4.2%	0.74	1.2%	2.27	3.7%	2.54	4.1%
4	40	80.6	0.99	1.2%	1.00	1.2%	0.46	0.6%	0.83	1.0%	1.01	1.3%
5	40	58.0	3.83	6.2%	4.65	7.7%	3.23	5.6%	2.60	4.5%	6.99	12.1%
6	40	43.9	1.81	4.1%	1.99	4.5%	1.18	2.7%	1.37	3.1%	2.04	4.6%
7	40	30.7	2.29	7.5%	2.52	8.3%	2.22	7.2%	0.94	3.1%	3.03	9.9%
8	40	49.9	1.52	3.0%	1.77	3.5%	1.52	3.0%	1.28	2.6%	2.05	4.1%

Table 3: SQA-iO Motile Sperm Concentration (MSC) Precision

MSC			Within-Run		Between-Run		Between-Day		Between-Operator/ Lot/Instrument		Total	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	40	2.0	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%
2	40	26.5	1.31	5.0%	1.36	5.1%	1.05	4.0%	0.68	2.6%	1.60	6.0%
3	40	27.9	1.40	5.0%	1.55	5.5%	1.03	3.7%	1.08	3.9%	1.67	6.0%
4	40	47.0	2.99	6.4%	2.99	6.4%	1.13	2.4%	2.27	4.8%	2.97	6.3%
5	40	35.5	1.42	4.0%	1.56	4.4%	0.77	2.2%	1.27	3.6%	1.54	4.3%
6	40	79.4	2.87	3.6%	3.54	4.5%	2.41	3.0%	1.09	1.4%	3.60	4.5%
7	40	69.3	4.26	6.2%	5.05	7.3%	4.29	6.2%	1.37	2.0%	5.85	8.4%
8	40	106.2	3.43	3.2%	4.48	4.2%	5.30	5.0%	2.18	2.1%	6.12	5.8%

Table 4: SQA-iO Progressively Motile Sperm Concentration (PMSC) Precision

PMSC			Within-Run		Between-Run		Between-Day		Between-Operator/ Lot/Instrument		Total	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	40	0.0	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%
2	40	23.2	1.11	4.8%	1.14	4.9%	0.94	4.1%	0.74	3.2%	1.38	6.0%
3	40	24.2	1.27	5.2%	1.35	5.6%	0.83	3.4%	0.90	3.7%	1.41	5.8%
4	40	42.2	2.80	6.6%	2.81	6.7%	1.16	2.8%	2.11	5.0%	2.82	6.7%
5	40	31.5	1.78	5.6%	1.86	5.9%	0.76	2.4%	1.11	3.5%	1.92	6.1%
6	40	70.3	2.64	3.8%	3.34	4.8%	2.34	3.3%	0.92	1.3%	3.40	4.8%
7	40	51.0	4.60	9.1%	5.34	10.6%	5.20	10.2%	2.51	4.9%	6.54	12.8%
8	40	93.4	3.58	3.8%	4.39	4.7%	5.32	5.7%	2.21	2.4%	6.14	6.6%

Table 5: SQA-iO Normal Morphology Precision

Normal Morphology			Within-Run		Between-Run		Between-Day		Between-Operator/ Lot/Instrument		Total	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	40	0.0	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%
2	40	15.4	0.87	5.7%	0.87	5.7%	0.33	2.2%	0.78	5.1%	0.92	6.0%
3	40	11.2	1.00	9.0%	1.00	8.9%	0.25	2.2%	0.89	8.0%	0.98	8.8%
4	40	16.5	0.78	4.7%	0.83	5.0%	0.37	2.2%	0.59	3.6%	0.85	5.1%
5	40	10.2	0.58	5.7%	0.61	6.0%	0.41	4.0%	0.45	4.4%	0.66	6.5%
6	40	7.2	0.35	4.8%	0.39	5.4%	0.19	2.6%	0.26	3.6%	0.41	5.6%
7	40	3.6	0.42	11.9%	0.46	13.0%	0.39	10.7%	0.22	6.2%	0.55	15.1%
8	40	8.5	0.48	5.6%	0.53	6.3%	0.51	6.0%	0.35	4.2%	0.68	8.0%

Analytical sensitivity (limits of blank and detection/quantitation):

The defined limit of blank (LoB), Limit of Detection (LoD) and limit of Quantitation (LoQ) of the SQA-iO system for sperm concentration is as follows:

- Limit of Blank (LoB) = 0 M/mL
- Limit of Detection (LoD) = 1.73 M/mL
- Limit of Quantitation (LoQ) = 6.8 M/mL

APPENDIX 6: SQA-iO Warranty

Warranty Sperm Quality Analyzer SQA-iO

Medical Electronic Systems ("MES") warrants that the SQA-iO Sperm Quality Analyzer will be free from defects in workmanship and materials for a period of twelve (12) months from date of the first, initial installation. If a device is resold or re-installed after the first, initial installation, the warranty will continue (or expire) based on the first, initial installation date.

If, during the one-year warranty period, the device is shown to MES's reasonable satisfaction to be defective, MES shall, at its option, replace or repair such a device without charge for parts or labor. The foregoing remedy shall be purchaser's sole and exclusive remedy under this warranty.

The warranty is subject to the following conditions:

- Proper cleaning is followed based on the manufacturer's guidance AND evidence of such scheduled cleaning (weekly) and proper maintenance of the device per the manufacturer's guidelines is provided from the system records.
- No modifications or alterations are made to the SQA-iO device or related testing supplies.
- The SQA-iO is not used, operated, opened by anyone other than the purchaser.
- The SQA-iO is not serviced by anyone or any other entity other than MES or its designee.
- The SQA-iO is used, as labeled for human semen testing only, transported in its original box, stored in the proper temperature range and only manufacturer supplied testing supplies are used for testing, service and maintenance.

If the above conditions are not met or proper maintenance/cleaning records are not provided, this warranty shall be void and of no further force or effect. EXCEPT FOR THE FOREGOING WARRANTIES, THE PRODUCTS ARE SOLD AS-IS AND WITHOUT ANY OTHER WARRANTY OF ANY NATURE WHATSOEVER. MES HAS NOT MADE AND DOES NOT MAKE ANY OTHER REPRESENTATION, WARRANTY, GUARANTY, OR COVENANT, EXPRESS OR IMPLIED, WITH RESPECT TO THE DESIGN, CONDITION, DURABILITY, SUITABILITY, FITNESS FOR USE, FITNESS FOR A PARTICULAR PURPOSE, OR MERCHANTABILITY OF THE SQA IN ANY RESPECT. UNDER NO CIRCUMSTANCES AND IN NO EVENT, WHETHER AS A RESULT OF BREACH OF CONTRACT OR WARRANTY, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY) OR OTHERWISE, INCLUDING BUT NOT LIMITED TO INACCURATE RESULTS OR OPERATOR ERROR, SHALL MES BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES. IN NO EVENT SHALL MES'S LIABILITY WITH RESPECT TO THE PRODUCT EXCEED THE PURCHASE PRICE FOR SUCH PRODUCT.

APPENDIX 7: SQA-VU Visualization Device

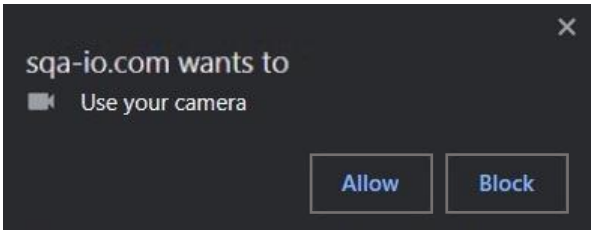
SECTION 1: Overview

The SQA-VU visualization system works specifically with the SQA-iO sperm quality analyzer to visualize sperm samples and capture Motility videos and Morphology images for manual assessment and integration into the test report and SQA-iO patient archive. It is not a standalone device.

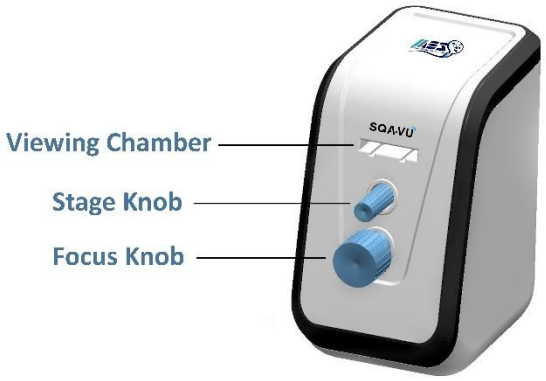
SECTION 2: Connect and Operate the SQA-VU

Register / Login to your SQA-iO account: www.sqa-io.com

1. Connect the SQA-VU to the same computer as the SQA-iO, using the supplied USB cable.
2. Click **ALLOW** to permit the SQA-VU to access the camera (the SQA-VU will not work without this permission).



3. Access the SQA-VU visualization displays from the:
   - **TEST PATIENT** page click the **VIEW SAMPLE** button.
   - **ARCHIVE** click the camera icon for a specific test/patient.
   - **TEST RESULTS** click the **CAPTURE** or **MORPHOLOGY** button.
4. Prepare a semen sample using a standard slide and 22X22mm coverslip or an SQA-Vision fixed coverslip slide (for optimal quality).
5. Place the slide into the SQA-VU slide adaptor. Insert into the **Viewing Chamber** of the SQA-VU device.
6. Use the **Focus Knob** to visualize the sample clearly. Use the **Stage Knob** to move to additional fields of view.
7. These options are available for assessing the sample:
   - **GRID ON** for easier counting
   - **REAL-TIME** for viewing the sample on the screen.
   - **FREEZE** to accurately count the total number of sperm cells.
   - **FULL SCREEN** to view the sample on a **larger display.**
   - **SETTINGS** to adjust the video settings to your preference.
   - **NO SPERM SEEN** can be checked if no spermatozoa were found in all fields of view.



8. Capture images and Videos
   - Click the icon on the image / video to attach it to the REPORT (up to 10 can be attached).
   - View and/or download video attachments by clicking the report link "CLICK HERE TO VIEW ALL ATTACHED VIDEOS", which will navigate to the MES Video Viewer site.
   - Click the **MANAGE VIDEOS** / **MANAGE IMAGES** header to view, delete or download.
9. Remove the slide adaptor and unplug the SQA-VU from the computer when not in use.

SECTION 3: Device Specifications, Operating Conditions and Cautions

Device Specifications:

- Dimensions: 20 X 16 X 11 cm
- Weight: 1.40 kg
- Power supply: USB powered 5 VDC
- SQA-VU device power consumption: 2.5 [Watt] max
- Recommanded browsers for optimal performance: Chrome, Microsoft Edge

System Requirements:

- Recommended browsers for optimal performance: Chrome, Microsoft Edge
- Operating System: PC with WIN 8 Professional x 32 or above
- Recommended Hardware:
    - CPU: Intel Core I5 & Above
    - RAM: 8GB
    - Video card: Powerful graphics card to support HD resolution (1280x960)
    - Screen resolution: 1280x960
    - Hard drive: 400GB of free space to store downloaded videos & images
- One free available USB port
- Internet Connection: 5mb per second

Visualization Compartment:

- White LED illumination system with luminous intensity 35000 mcd
- Objective: Standard, x20, chromatic aberration correction
- Focus knob
- Digital CCD
- Field of View Stage knob

Video/image resolution:

- Video: 1280 x 960 pixels, 40 FPS capture of high-resolution videos
- Image: 2560 x 1920 pixels

Operating Temperature and Humidity:

The SQA-VU is designed to operate at the WHO recommended ROOM TEMPERATURE controlled environment of 20-25ºC (68-77ºF), which is optional for semen testing.

Note: Although the SQA-VU can operate at a higher ambient temperature range of (15-38ºC), extreme ambient temperature may impact the accuracy of the semen test results.

Operational Environmental conditions:

The SQA-VU system is intended for indoor use, mains supply fluctuations ±10%, Overvoltage Category I, Pollution Degree II.

Caution when device is not in use:

Remove the slide adaptor and unplug the SQA-VU from the computer when not in use.

APPENDIX 8: Assessing Debris/Round Cells in Semen Samples

Overview:

The SQA-iO Debris/Round Cell Scanner (automated and manual versions) enables analysis of non-sperm particulates (debris) and cells such as leukocytes and immature germ cells (round cells) as one collective group and categorized as None/Few, Moderate, Many, or Gross according to their combined % of presence in the semen sample compared to sperm cells.

How to use the Debris Scan Feature:

1. Activate the Debris Scanner in Settings:

- Navigate to "SETTING" from the Main Menu, then choose "SYSTEM."
- Choose "Scan for Debris on All Samples" under the DEBRIS ASSESSMENT section.
- This will automatically open the Debris Scanner after each Semen Analysis performed on the SQA-iO (on all samples with Conc. > 2 M/ml).

2. Prepare the Testing Slide:

- After the Semen Analysis is completed, follow the Debris Scanner Pop-Up Instructions:
  - Thoroughly mix the semen sample by swirling for 30 seconds.
  - Place 10µl of semen sample near the front inch of a 1X3 inch laboratory slide
  - Cover with a 22mm x 22mm Coverslip.
  - Insert the Slide into the Visualization System using the SQA-Vu Slide Adapter.

3. Automated Scanning for Debris:

1. Adjust the focus knob until the semen sample is clearly seen (debris or sperm can be used for reference).
2. Select a random field of view by turning the Field of View adjustment knob Clockwise or Counterclockwise.
3. Click "AUTO ANALYZE" to automatically categorize the Debris in the field of view.
4. Turn the Field of View adjustment knob to a new Randomized Field and click "AUTO ANALYZE."
5. Repeat this process for a Minimum of 5 Fields of View.
6. Click "RESULTS" when your Debris Assessment is complete.

4. Manual Debris Assessment:

1. Adjust the focus knob until the semen sample is clearly seen (debris or sperm can be used for reference).
2. Select a random field of view by turning the Field of View adjustment knob Clockwise or Counterclockwise.
3. On each field of view, count only debris/round cell particles **without tails** that are **the size of sperm heads or larger are counted.**
4. Next, count the # sperm cells in the image.
5. Debris level (%) is calculated: Divide the # debris by the # sperm cells then multiply by 100 for %.
6. The absolute number of debris/round cells is only important for determining the % of debris vs. sperm to classify the debris level by category (refer to table below).

Reporting Debris / Round Cell Results

- The Debris/Round Cells Assessment will report one of four categories and include in the test report.
- Categories are classified based on the % of debris/round cells to spermatozoa.

#	Debris Category	% Range of Debris/Round Cells vs Sperm	Example
1	None/Few	Less than 10%	# Sperm 50 and # Debris 1 = 2%
2	Moderate	11 to 30%	# Sperm 50 and # Debris 10 = 20%
3	Many	31 to 99%	# Sperm 50 and # Debris 30 = 60%
4	Gross	≥ 100%	# Sperm 50 and # Debris 60 = 120%

- Click "VIEW REPORT" or "DOWNLOAD REPORT" to generate a PDF Test Report.
- Click "CAPTURE" button to view samples at any time
- The Debris/Round Cell scanner feature is disabled for concentrations < 2 M/ml.
- Results with selected images are permanently saved in the archive and may be transferred to LIS / EMR systems.

Summary:

Categorizing and reporting the presence of Debris and Round Cells in the semen sample provides valuable clinical insight for providers. In combination with Medical Electronic Systems WBC (White Blood Cell) test strip assessment, valuable information is provided on the presence of non-sperm cellular material in the Semen Sample. Images and Videos captured during the assessment are save in the archive.

Appendix 9: Warnings and Regulatory Information

Warnings and Precautions:

- Maintenance Schedule: Clean the measurement compartment at least weekly using ONLY manufacturer's cleaning supplies provided in the test kit.
- Semen is considered a biologically hazardous material and is subject to laboratory protocols for handling and disposing of such materials in specially marked hazardous waste containers.
- Indoor Use

Cybersecurity Controls:

- Operate the SQA-iO software interface in a controlled environment of the laboratory, accessible to trusted, authorized personnel only.
- Carefully read the entire SQA-iO IFU before initial use to ensure optimal results.
- The SQA-iO USB port is intended to connect the SQA-iO device only. Do not connect any USB devices such as a mouse or a keyboard to the USB port of the SQA-iO.

EMC Related Information

- Intended Use: the SQA-iO is designed and tested to comply with applicable Electromagnetic Compatibility (EMC) standards for use in the electromagnetic environment specified below.
- EMC Compliance: the SQA-iO complies with the requirements of IEC 60601-1-2 general requirements for basic safety and essential performance related with electromagnetic compatibility of Medical Devices. Compliance has been verified through testing under specific conditions. To maintain compliance, follow the guidelines provided in this Instruction for Use.
- No SQA-iO deviations were found from the reference standard or allowances during the SQA-iO EMC testing.
- Electromagnetic Environment: The SQA-iO is intended for use in an indoor environment where radiated RF disturbances are controlled. The intended user of the SQA-iO device should ensure that it is used in such an environment.
- Operate the device away from any source of vibrations such as a centrifuge.
- Use of Accessories: Only use accessories and cables provided or approved by the manufacturer. The use of unauthorized accessories may result in increased emissions or decreased immunity of the device. Specifications of the accessories (PC) required for the safe performance of the SQA-iO are included in Section 1 of the Instruction for Use.
- Interference Caution and Reporting: The user should be aware that electromagnetic emissions from nearby equipment or devices may affect the proper operation of the SQA-iO.
- If electromagnetic interference is suspected to impact the performance of the SQA-iO, report the issue to the manufacturer through CONTACT US, and to the relevant regulatory authority (such as US FCC-Federal Communication Committee). Provide details of the interference, equipment involved, and operating conditions.
- The SQA-iO complies with both emission and immunity requirements.
- The SQA-iO device communicates with the user's PC via a single USB port. There are no RF wireless functions applied by the SQA-iO device.
- Maintenance instructions to ensure that the SQA-iO remains safe and performs to EM disturbances as intended: Disconnect the device if not in use for an extended period of time.
- FCC warning: The SQA-iO operator is required to cease operating the device if the Commission or its representative find that the device is causing harmful interference. Operation cannot resume until the condition causing the harmful interference has been corrected.
- NOTE: "Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Symbols:

CE mark

Symbol for **"IN VITRO DIAGNOSTIC MEDICAL DEVICE"**

Symbol for **"The intended use of a prescription IVD product"**