



Medical Electronic Systems QwikCheck™ Beads Validation and Training Kit

OVERVIEW

The QwikCheck™ Beads Validation and Training Kit is designed as a proficiency, training, and validation tool for SQA sperm quality analyzers (SQA-Vision and SQA-V). It can be used to validate Accuracy, Precision and Reportable Range per the CLIA Method Validation Regulations (CLIA Final Rules Manual, 2004, ISBN 1-886958-20-3). The regulations disseminated on February 28, 1992 for laboratories to comply with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) included specific quality control (QC) and Validation regulations for laboratories performing moderate and high complexity testing. These regulations also contained specific method validation requirements for modified moderate and high complexity tests and tests developed in-house. The approach in method validation is to perform a series of experiments designed to estimate certain types of analytical errors, e.g., a linearity trial to determine reportable range, a replication trial to estimate imprecision or random error, a comparison of methods trial to estimate inaccuracy or systematic error, and a detection limit trial to characterize analytical sensitivity. Due to the fragile biological nature of sperm, parameters influenced by motion have been omitted from the QwikCheck™ Beads Validation and Training Kit. However, supplemental recommendations and instructions for successfully validating Motility and other motion based parameters have been included in this protocol. After successfully completing this validation, SQA analyzers will be ready for daily use based on Medical Electronic Systems manufacturer's requirements for instrument validation. Depending on State and Local requirements, further validation may be required beyond the CLIA standards.

The QwikCheck™ Beads Validation and Training Kit is also highly recommended as a training tool for running periodic proficiency challenges for all personnel who operate an SQA analyzer. After successfully completing the Accuracy, Precision and Reportable Range testing, users will have extensive knowledge of how to operate the SQA, load the testing capillary, report results and navigate through the various features. In addition routine (annual or semi-annual) laboratory personnel testing using the QwikCheck™ Beads Validation and Training Kit will demonstrate ongoing operator proficiency and the laboratory's commitment to accuracy, precision, and quality of care. The instructions are in two sections: One for the SQA-V and the second for the SQA-Vision.

The tests contained in this kit should all be run following best laboratory practices – a calibrated, positive displacement pipette should be used for all sample processing/dilutions and accuracy is critical to obtain the best results. This is a blind evaluation of the laboratory's proficiency, accuracy and precision.

SQA-V INSTRUCTIONS

SQA-V SYSTEM SET-UP and GENERAL INFORMATION

- Turn on the SQA-V Gold system and the V-Sperm PC and allow the auto-calibration and self-test to complete.
- Print and save the “Service Data Report” per user guide instructions.
- Check the Report to verify the Reference 2 (REF 2) value (it should be above 2900 mV for the best possible results). If the REF 2 value is below 2900 mV, perform a thorough cleaning of the system per user guide instructions with particular attention to cleaning using the wooden handled brush. Run Self Test and generate the “Service Data Report” after cleaning to see that the REF 2 value is in the proper range.
- Set-up the **SQA-V and V-Sperm** default settings as described below.

Go to the **SQA-V Main Menu** and select: **SERVICE > SERVICE DATA**

Go to the **V-Sperm PC** and select: **SET-UP > SQA-V > SQA-V Defaults**. From this screen set:

- ✓ Conc. Standard: 2 (this is mandatory for accurate correlation)
 - ✓ LES: 1US
 - ✓ Printing Options: Automatically print all test results
 - ✓ Printing Options: Automatically print Self-Test Report on Start Up
 - ✓ Controls: Latex Beads
 - ✓ Set-up Control defaults manually from the box of QwikCheck Beads
 - ✓ Or enter “1” in every empty field of QC: LATEX BEADS for Level 1 only
- Save all SQA-V printouts processed during the validation and return them to MES if requested.
 - **The Validation Kit test results will be saved in the PATIENT and CONTROLS archive. Delete these records after completing the Validation Kit testing if desired.**

STEP 1: SQA-V LINEARITY & REPORTABLE RANGE PROTOCOL

Before opening each sample bottle, invert it (upside down) and gently shake the bottle (to remove any beads adhering to the cap liner). When ready to start testing (with the bottle right side up), mix the sample thoroughly, open the cap and aspirate the sample for testing.

Run **LINEARITY & REPORTABLE RANGE** samples on the **FRESH** mode

- **SQA-V LINEARITY & REPORTABLE RANGE** Validation Samples Data Entry and Sample Testing:
 - From the **MAIN MENU** select: **TEST NEW PATIENT**
 - Enter only the mandatory information below. Keep pressing **ENTER** to move through fields that do not require data entry.
 - **Patient ID:** Use the sample # on top of each testing bottle. The bottle number can be used multiple times for repeated tests.
 - **Sample Type:** Select: **FRESH**
 - **WBC CONC:** Select: **< 1 M/ml**
 - Repeatedly press **ENTER** to advance to the Auto-Calibration screen.
 - Wait for Auto-Calibration to complete without touching the system and then run the testing capillary.
 - Record results

NOTE: To run this protocol use the six (6) **Blue lettered "Linearity"** bottles marked **"1"** through **"5"** and the bottle marked **"D"**. Using a calibrated positive displacement pipette, make serial dilutions from bottle **"1"** by following the instructions in the table below. Record results on the data sheet provided in the kit or in the Validation Data Entry form (Excel). The message: "Low Quality Sample testing will take 2 more minutes" will be displayed (SQA-V only) during some tests. This is normal and occurs because there is no motility present.

BOTTLE #	FROM BOTTLE "1"	FROM BOTTLE "D"	DILUTION RATE
1	RUN AS IS ONLY BOTTLE "1"		100/0
2	0.8ml	0.2ml	80/20
3	0.6ml	0.4ml	60/40
4	0.4ml	0.6ml	40/60
5	0.2ml	0.8ml	20/80
D	RUN AS IS ONLY BOTTLE "D"		0/100

STEP 2: SQA-V PRECISION - REPLICATION & DETECTION LIMIT PROTOCOL

Before opening each sample bottle, invert it (upside down) and gently shake the bottle (to remove any beads adhering to the cap liner). When ready to start testing (with the bottle right side up), mix the sample thoroughly, open the cap and aspirate the sample for testing.

Run **PRECISION** samples on the **CONTROL** mode **LEVEL 1**.

- **SQA-V PRECISION** Validation Samples data entry and sample testing:
 - From the MAIN MENU select: **RUN CONTROLS**
 - Select: **LEVEL #1** of Latex Beads and press **ENTER**
 - Follow the onscreen instructions.
 - No data entry is required; disregard the **Status** (Pass/Fail) outcome
 - Record the results.

NOTE: To run this protocol use the four (4) **Green lettered "Precision"** bottles marked "**1**" through "**4**". Run 10 replicates for each sample using the same testing capillary.

One of the samples is a low end control designed to test the lower limit detection (LLD) of the SQA (0.0 M/mL). In addition to the zero level, there are samples above and below normal/abnormal cutoffs (based on WHO references).

- **First level:** Run 10 replicates of sample "**1**" on "Control Mode". Record the results on the enclosed data sheet.
- **Second level:** Run 10 replicates of sample "**2**" on "Control Mode". Record results on the enclosed data sheet.
- **Third level:** Run 10 replicates of sample "**3**" on "Control Mode". Record results on the included data sheet.
- **Forth level:** Run 10 replicates of sample "**4**" on "Control Mode". Record results on the included data sheet.
- **Additional Recommended Validation:** To establish precision for motility based parameters, 2 or 3 fresh human semen samples with motility >30% can be run in replicates of **10** (maximum) in the same manner as above. Running more than 10 replicates is not recommended with live samples as the cells will begin to die in the testing capillary over time and the precision will be adversely affected. **NOTE:** This additional validation must be run on **FRESH** mode.

NOTE: Use high quality fresh human sperm samples and test within 30 minutes of collection to ensure replicate stability.

STEP 3: SQA-V ACCURACY COMPARISON PROTOCOL MANDATORY and OPTIONAL

CLIA recommends running a minimum of 20 samples on the new method (test method) vs. an established method (comparison method) to estimate the inaccuracy or systematic errors of the method. A wide range of test results covering the dynamic range of the system is required to determine systematic errors. Twenty (20) samples covering the entire dynamic range of the system are provided in the QwikCheck™ Beads Validation and Training Kit.

SQA-V MANDATORY ACCURACY COMPARISON PROTOCOL:

Before opening each sample bottle, invert it (upside down) and gently shake the bottle (to remove any beads adhering to the cap liner). When ready to start testing (with the bottle right side up), mix the sample thoroughly, open the cap and aspirate the sample for testing.

- **SQA-V ACCURACY** Validation Samples: Run **ACCURACY** samples on the **FRESH** mode
 - From the **MAIN MENU** select: **TEST NEW PATIENT**
 - Enter only the mandatory information below. Keep pressing **ENTER** to move through fields that do not require data entry.
 - **Patient ID:** Use the sample # on top of each testing bottle. The bottle number can be used multiple times for repeated tests.
 - **Sample Type:** Select: **FRESH**
 - **WBC CONC:** Select: **< 1 M/ml**
 - Repeatedly press **ENTER** to advance to the Auto-Calibration screen. Wait for the auto-calibration to complete – do not touch the screen while it is calibrating.
 - Insert the testing capillary when prompted by the SQA-V and record the results.

NOTE: To run this protocol use the twenty (20) **Red lettered “Accuracy”** bottles marked **“1”** through **“20”**. Run and record all results on the data sheet provided in the kit. The message: “Low Quality Sample testing will take 2 more minutes” will be displayed (SQA-V only) during some tests. This is normal and occurs because there is no motility present.

- Run each sample (**“1”** through **“20”**) and record the results on the enclosed data sheet.
- The “Blind” results will be compared to the target values established by the MES laboratory references.

SQA-V OPTIONAL ACCURACY COMPARISON PROTOCOL:

In addition to running twenty non-motile samples, it is recommended that twenty FRESH HUMAN semen samples of normal quality are run and compared to the current laboratory method (as samples become available). To perform this additional recommended validation, please follow the steps below.

NOTE: When running a human semen validation, all samples must be compared within 30-60 minutes of collection to insure accuracy. It is recommended that all manual (or alternative method) analysis is performed by the same technician to avoid known sample handling discrepancies between multiple technicians which will lower the overall accuracy.

- **SQA-V ACCURACY** Validation Samples: Run **ACCURACY** samples on the **FRESH** mode
 - Set the Conc. Standard of the SQA-V to match the standard manual method used in the lab by going to the **SQA-V: SERVICE > SERVICE DATA**. Then go to: **V-Sperm: SET-UP > SQA-V > SQA-V Defaults**
 - From the **MAIN MENU** select: **TEST NEW PATIENT**
 - Follow the SQA-V User Guide instructions for running FRESH samples. It is not necessary to enter the Birth date, Abstinence in the ENTER PATIENT/SAMPLE DATA screen.
 - Choose **“FRESH”** as the sample type.
 - Follow the on-screen instructions for testing the sample.
- Record results on the data sheet provided in the appendix section of this document or in the Validation Kit Data Entry form (Excel) and **go to STEP 4 of this document for instructions about how to send in the data.**

SQA-VISION INSTRUCTIONS

SQA-Vision SYSTEM SET-UP and GENERAL INFORMATION

- Turn on the SQA-Vision system and allow the auto-calibration and self-test to complete.
- Print and save the “Service Data Report” per user guide instructions.
- Check the Report to verify the Reference 2 (REF 2) value (it should be above 2900 mV for the best possible results). If the REF 2 value is below 2900 mV, perform a thorough cleaning of the system per user guide instructions with particular attention to cleaning using the wooden handled brush. Run Self Test and generate the “Service Data Report” after cleaning to see that the REF 2 value is in the proper range.
- Set-up the **SQA-Vision** default settings as described below.
 - Go to: **SETTINGS > Controls** (User Manual) and select: **Latex Beads Set-up**.
 - ✓ Scan the barcode seen under LATEX BEADS SETUP and then scan the barcode on a box of QwikCheck Beads to automatically set-up the defaults
 - ✓ Or enter “1” in every empty field of QC: LATEX BEADS for Level 1 only
 - Go to: **SETTINGS > Test Patient** (User Manual) and select:
 - ✓ Conc. Standard 2 (this is mandatory for accurate correlation)
 - ✓ LES: US
 - ✓ Low quality counter: Not checked
 - ✓ Debris scan cutoff: No debris scanning
 - ✓ Testing criteria: WHO 5th
 - ✓ Default test type: FRESH
- **Validation Kit test results will be saved in the PATIENT and CONTROLS archive. Delete these records after completing the Validation Kit testing if desired.**

STEP 1: SQA-VISION LINEARITY & REPORTABLE RANGE PROTOCOL

Before opening each sample bottle, invert it (upside down) and gently shake the bottle (to remove any beads adhering to the cap liner). When ready to start testing (with the bottle right side up), mix the sample thoroughly, open the cap and aspirate the sample for testing.

Run **LINEARITY & REPORTABLE RANGE** samples on the **FRESH** mode

- **SQA-VISION LINEARITY & REPORTABLE RANGE** Validation Samples Data Entry and Sample Testing:
 - Go to **TEST PATIENT** (the **FRESH** data entry screen will be opened by default).
 - Enter only the following mandatory information:
 - **Patient ID**: Use the sample # on top of each testing bottle. This bottle number can be used multiple times for repeated tests.
 - **WBC CONC**: Select: **< 1 M/ml**
 - Click: **TEST NOW** and follow the onscreen instructions.
 - Select: **YES** when the message: "Volume not entered semen total will not be reported. Continue?" is displayed
 - Record the results.

NOTE: To run this protocol use the six (6) **Blue lettered "Linearity"** bottles marked **"1"** through **"5"** and the bottle marked **"D"**. Using a calibrated positive displacement pipette, make serial dilutions from bottle **"1"** by following the instructions in the table below. Record results on the data sheet provided in the kit or in the Validation Data Entry form (Excel).

BOTTLE #	FROM BOTTLE "1"	FROM BOTTLE "D"	DILUTION RATE
1	RUN AS IS ONLY BOTTLE "1"		100/0
2	0.8ml	0.2ml	80/20
3	0.6ml	0.4ml	60/40
4	0.4ml	0.6ml	40/60
5	0.2ml	0.8ml	20/80
D	RUN AS IS ONLY BOTTLE "D"		0/100

STEP 2: SQA-VISION PRECISION - REPLICATION & DETECTION LIMIT PROTOCOL

Before opening each sample bottle, invert it (upside down) and gently shake the bottle (to remove any beads adhering to the cap liner). When ready to start testing (with the bottle right side up), mix the sample thoroughly, open the cap and aspirate the sample for testing.

Run **PRECISION** samples on the **CONTROL** mode **LEVEL 1**.

- **SQA VISION PRECISION** Validation Samples data entry and sample testing:
 - Go to **QC/PROFICIENCY > LATEX BEADS**
 - Select: **TEST NOW** on **LEVEL 1** of Latex Beads and follow the onscreen instructions.
 - No data entry is required; disregard the **Status** (Pass/Fail) outcome
 - Record the results.

NOTE: To run this protocol use the four (4) **Green lettered "Precision"** bottles marked "**1**" through "**4**". Run 10 replicates for each sample using the same testing capillary.

One of the samples is a low end control designed to test the lower limit detection (LLD) of the SQA (0.0 M/mL). In addition to the zero level, there are samples above and below normal/abnormal cutoffs (based on WHO references).

- **First level:** Run 10 replicates of sample "**1**" on "Control Mode". Record the results on the enclosed data sheet.
- **Second level:** Run 10 replicates of sample "**2**" on "Control Mode". Record results on the enclosed data sheet.
- **Third level:** Run 10 replicates of sample "**3**" on "Control Mode". Record results on the included data sheet.
- **Forth level:** Run 10 replicates of sample "**4**" on "Control Mode". Record results on the included data sheet.
- **Additional Recommended Validation:** To establish precision for motility based parameters, 2 or 3 fresh human semen samples with motility >30% can be run in replicates of **10** (maximum) in the same manner as above. Running more than 10 replicates is not recommended with live samples as the cells will begin to die in the testing capillary over time and the precision will be adversely affected. **NOTE:** This additional validation must be run on **FRESH** mode.

NOTE: Use high quality fresh human sperm samples and test within 30 minutes of collection to ensure replicate stability.

STEP 3: SQA-VISION ACCURACY COMPARISON PROTOCOL MANDATORY and OPTIONAL

CLIA recommends running a minimum of 20 samples on the new method (test method) vs. an established method (comparison method) to estimate the inaccuracy or systematic errors of the method. A wide range of test results covering the dynamic range of the system is required to determine systematic errors. Twenty (20) samples covering the entire dynamic range of the system are provided in the QwikCheck™ Beads Validation and Training Kit.

MANDATORY ACCURACY COMPARISON PROTOCOL:

Before opening each sample bottle, invert it (upside down) and gently shake the bottle (to remove any beads adhering to the cap liner). When ready to start testing (with the bottle right side up), mix the sample thoroughly, open the cap and aspirate the sample for testing.

Run **ACCURACY** samples on the **FRESH** mode

- **SQA-VISION ACCURACY** Validation Samples data entry and testing:
 - Go to **TEST PATIENT** (the **FRESH** data entry screen will be opened by default).
 - Enter only the following mandatory information:
 - **Patient ID:** Use the sample # on top of each testing bottle. This bottle number can be used multiple times for repeated tests.
 - **WBC CONC:** Select: **< 1 M/ml**
 - Click: **TEST NOW** and follow the onscreen instructions.
 - Select: **YES** when the message: "**Volume not entered semen total will not be reported. Continue?**" is displayed
 - Record the results.

NOTE: To run this protocol use the twenty (20) **Red lettered "Accuracy"** bottles marked "**1**" through "**20**". Run and record all results on the data sheet provided in the kit. The message: "Low Quality Sample testing will take 2 more minutes" will be displayed (SQA-V only) during some tests. This is normal and occurs because there is no motility present.

- Run each sample ("**1**" through "**20**") and record the results on the enclosed data sheet.
- The "Blind" results will be compared to the target values established by the MES laboratory references.

OPTIONAL ACCURACY COMPARISON PROTOCOL:

In addition to running twenty non-motile samples, it is recommended that twenty FRESH HUMAN semen samples of normal quality are run and compared to the current laboratory method (as samples become available). To perform this additional recommended validation, please follow the steps below.

NOTE: When running a human semen validation, all samples must be compared within 30-60 minutes of collection to insure accuracy. It is recommended that all manual (or alternative method) analysis is performed by the same technician to avoid known sample handling discrepancies between multiple technicians which will lower the overall accuracy.

SQA-Vision:

- Set the **Conc. Standard** of the VISION to match the standard manual method used in the lab by going to **SETTINGS > TEST PATIENT** (per user guide).
- Go to the home screen and select: **TEST PATIENT** (**FRESH** data entry screen will be opened by default).
- Follow the SQA-Vision User Guide instructions for data entry/running samples.
- You do not need to enter: Patient Name, Birth date or Abstinence
- Click: **TEST NOW** and follow the onscreen instructions.
- Mix the sample (thoroughly), and fill the testing capillary per instructions in the SQA-Vision User Guide.
- Insert the capillary into the SQA-Vision measurement compartment when prompted.
- Record results on the data sheet provided in the kit or in the Validation Kit Data Entry form (Excel).

STEP 4: REPORTING RESULTS

NOTE: Medical Electronic Systems requests that all data collected during the validation be delivered in electronic format in the file template provided in the enclosed CD. Simply enter all the results into the EXCEL spreadsheet of the template file copied from the disk, attach the file to an email and send to: USA Customers: service@mes-llc.com Other Customers: support@mes-ltd.com

If this is not possible, manually fill in the results in the forms provided in the APPENDIX section. However, the turnaround timeframe for results may be delayed. If electronic reporting is not possible, fax a copy of the enclosed customer report to Medical Electronic Systems via FAX #: USA Customers: 866-557-9064 All other customers: 972-4-637-3984.

The SQA validation results will be compiled and sent to you within 10 business days (if submitted in electronic format). Please contact MES at any time during the validation process by calling our service line @ USA: 866-557-9064. All other customers: 972-4-637-3981 EXT 103 or by writing an e-mail to: USA: service@mes-llc.com or All other customers: support@mes-ltd.com.

REMEMBER, IT ALL STARTED WITH A SPERM!

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APPENDIX I: Mandatory Data Entry Form

Medical Electronic System's SQA-V and SQA-VISION Validation and Training Kit: Mandatory Results			
FACILITY:		LAB TECH:	
		KIT BATCH #	

**STEP 1:
LINEARITY & REPORTABLE RANGE PROTOCOL**

LEVEL	Test Results
First Level	
Second Level	
Third Level	
Forth Level	
Fifth Level	
Sixth Level	

STEP 2:

PRECISION - REPLICATION & DETECTION LIMIT

Replicate #	1st Level	2nd Level	3rd Level	4th Level
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

**STEP 3:
ACCURACY - COMPARISON OF METHODS**

Sample #	Test Results
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	

