Medical Electronic Systems
QwikCheck™ Beads Proficiency and Training Kit

OVERVIEW

The QwikCheck™ Beads Proficiency and Training Kit is designed as a proficiency, training, and validation tool for the SQA sperm quality analyzers (SQA-Vision, SQA-iO and SQA-V) and QwikCheck GOLD. 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 Proficiency 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-Vision, SQA-iO, and SQA-V and QwikCheck GOLD 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 Proficiency and Training Kit is also highly recommended as a training tool for running periodic proficiency challenges for all personnel who operate an SQA-Vision, SQA-iO, SQA-V and QwikCheck GOLD analyzer. After successfully completing the Accuracy, Precision and Reportable Range testing, users will have extensive knowledge of how to operate the system, 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 Proficiency and Training Kit will demonstrate ongoing operator proficiency and the laboratory's commitment to accuracy, precision, and quality of care.

The tests contained in this kit should all be run following best laboratory practices – a calibrated 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.

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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 the “Service Data Report” per user guide instructions.
- Check the Report to verify the Reference 2 (REF 2) value (it should be between 2500 mV – 3500mV for the best possible results). If the REF 2 value is below 2500 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:**
  - ✓ LEVEL 1 Target and Range = 100 +/- 100.
  - ✓ LEVEL 2 Target and Range = 100 +/- 100.
  - ✓ NEGATIVE CONTROL = 0.0.

  Go to: **SETTINGS > Test Patient** (User Manual) and select:
  - ✓ Conc. Standard: 2.
  - ✓ LES: ROW
  - ✓ Debris Scanning: SCAN FOR DEBRIS ON ALL SAMPLES
  - ✓ Low Quality Counter: NOT SELECTED
- **Validation Kit test results will be saved in the PATIENT and CONTROLS archive. Delete these records after completing the Validation Kit testing if desired.**

NOTE: Once you have completed the Validation Kit, please remember to reset your QC settings accordingly.

STEP 1: SQA-VISION LINEARITY & REPORTABLE RANGE PROTOCOL

Before opening each sample bottle, invert it (upside down) to remove any beads adhering to the cap liner. When ready to start testing (with the bottle right side up), mix the sample thoroughly swirling in a circular motion for 30 seconds, 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** and select **FRESH** at the top of the screen.
  - 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 totals will not be reported. Continue?" is displayed.
  - The system will then go through a Calibration process. Wait for this process to be completed. You will hear a beep when completed.
  - Follow instructions on the screen.
  - After the testing phase is completed, the “DEBRIS/ROUND CELL ASSESMENT” will prompt on the screen.
  - Click: **X** on the right top corner.
  - Select: **NONE/FEW <10%** for the Debris Assessment.
  - Select: **CONTINUE**.
  - Record the **CONC. (M/ml)** 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 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 1 and D. No dilution, run as is.

Bottles 2 – 5 are empty. Use the dilution table below and fill with the exact amount for each bottle. Mix thoroughly (30 seconds) for each bottle prior to filling the capillary once the proper dilution amount is added to each bottle.

LINEARITY INSTRUCTIONS			
BOTTLE #	**FROM BOTTLE "1"**	**FROM BOTTLE "D"**	**DILUTION RATE**
1	RUN AS IS ONLY BOTTLE "1"		100/0
2	0.8 ml	0.2 ml	80/20
3	0.6 ml	0.4 ml	60/40
4	0.4 ml	0.6 ml	40/60
5	0.2 ml	0.8 ml	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) to remove any beads adhering to the cap liner. When ready to start testing (with the bottle right side up), mix the sample thoroughly swirling in a circular motion for 30 seconds, open the cap and aspirate the sample for testing.

NOTE: To run this protocol, use the four (4) **Green lettered "Precision"** bottles marked **"1"** through **"4".** Use 1 Capillary to run 10 replicates for each bottle. Ensure a new capillary is used for each bottle.

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

- **Bottle 1:** RUN 10 replicates sample "1" with same capillary on "Control Mode". Record the results.
- **Bottle 2**: RUN 10 replicates sample "2" with same capillary on "Control Mode". Record the results.
- **Bottle 3**: RUN 10 replicates of sample "3" with same capillary on "Control Mode". Record the results.
- **Bottle 4**: RUN 10 replicates of sample "4" with same capillary on "Control Mode". Record the results.

Precision (Using Beads)			
Level Sample #	**# of Replicates to run**	**Run on SQA Control Mode:**	**Record Results**
1	10	LEVEL #1	YES
2	10		
3	10		
4	10	NEGATIVE CONTROL	

Run **PRECISION** samples on the **QC/PROFICENCY** mode**.**

- **SQA VISION PRECISION** Validation Samples data entry and sample testing:

Bottles Marked 1 – 3: Test on LEVEL 1

- Go to **QC/PROFICIENCY > LATEX BEADS**
- Select: **TEST NOW**
- Follow the onscreen instructions.
- Record the **CONC. (M/ml)** results.

Bottle Marked 4: Test on NEGATIVE CONTROL

- Go to **QC/PROFICIENCY > LATEX BEADS**
- Select: **TEST NOW**
- Follow the onscreen instructions.
- Record the **CONC. (M/ml)** results.

OPTIONAL 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 **5** (maximum) in the same manner as above. Running more than 5 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.

Precision (Using Semen with motility > 30%)			
Level Sample #	**# of Replicates to run**	**Run on SQA Mode:**	**Record Results**
1	5	FRESH	YES
2	5		
3	5		
4	5		

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 Proficiency and Training Kit.

MANDATORY ACCURACY COMPARISON PROTOCOL:

Before opening each sample bottle, invert it (upside down) to remove any beads adhering to the cap liner. When ready to start testing (with the bottle right side up), mix the sample thoroughly swirling in a circular motion for 30 seconds, open the cap and aspirate the sample for testing.

NOTE: To run this protocol, use the twenty (20) **Red lettered "Accuracy"** bottles marked **"1"** through **"20"**.

- 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.

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

- **SQA-VISION ACCURACY** Validation Samples data entry and testing:
    - Go to **TEST PATIENT** and select **FRESH** at the top of the screen.
    - 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 totals will not be reported. Continue?" is displayed.
    - The system will then go through a Calibration process. Wait for this process to be completed. You will hear a beep when completed.
    - Follow instructions on the screen.
    - After the testing phase is completed, the "DEBRIS/ROUND CELL ASSESMENT" will prompt on the screen.
    - Click: **X** on the right top corner.
    - Select: **NONE/FEW <10%** for the Debris Assessment.
    - Select: **CONTINUE**.
    - Record the **CONC. (M/ml)** results.

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 ensure 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** 2. 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** and then select **FRESH** at the top of the screen.
- 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).

SQA-iO INSTRUCTIONS

SQA-Vision SYSTEM SET-UP and GENERAL INFORMATION

- Turn on the SQA-iO system.
- Log-in to https://sqa-io.com/
- Once signed in, allow the auto-calibration and self-test to complete.
- Print 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-iO** default settings as described below.

  Go to: **SETTINGS > TEST PATIENT** (User Manual) and select:

  ✓ Conc. Standard: 2.

  ✓ APPEARANCE: Specify sample color.

  ✓ DEBRIS ASSESMENT: Include Debris Assessment (Requires visual assessment)

NOTE: Once you have completed the Validation Kit, please remember to reset your QC settings accordingly.

STEP 1: SQA-iO LINEARITY & REPORTABLE RANGE PROTOCOL

Before opening each sample bottle, invert it (upside down) to remove any beads adhering to the cap liner. When ready to start testing (with the bottle right side up), mix the sample thoroughly swirling in a circular motion for 30 seconds, open the cap and aspirate the sample for testing.

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

- **SQA-iO 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.**
    - **DEBRIS**: Select: **NONE/FEW < 10%**
  - Click: **TEST NOW**
  - Select: **TEST ANYWAY** when the message: "**SAMPLE VOLUME IS MISSING, Semen TOTALS PER EJACULATE will not be reported** " is displayed
  - Follow the on-screen instructions.
  - Record the **CONC. (M/ml)** 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 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 1 and D. No dilution, run as is.

Bottles 2 – 5 are empty. Use the dilution table below and fill with the exact amount for each bottle. Mix thoroughly (30 seconds) for each bottle prior to filling the capillary once the proper dilution amount is added to each bottle.

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

STEP 2: SQA-iO 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.

NOTE: To run this protocol, use the four (4) **Green lettered "Precision"** bottles marked **"1"** through **"4".** Use 1 Capillary to run 10 replicates for each bottle. Ensure a new capillary is used for each bottle.

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

- **Bottle 1:** RUN 10 replicates sample "1" with same capillary on "Control Mode". Record the results.
- **Bottle 2**: RUN 10 replicates sample "2" with same capillary on "Control Mode". Record the results.
- **Bottle 3**: RUN 10 replicates of sample "3" with same capillary on "Control Mode". Record the results.
- **Bottle 4**: RUN 10 replicates of sample "4" with same capillary on "Control Mode". Record the results.

Precision (Using Beads)			
Level Sample #	**# of Replicates to run**	**Run on SQA Control Mode:**	**Record Results**
1	10	LEVEL #1	YES
2	10		
3	10		
4	10	NEGATIVE CONTROL	

Run **PRECISION** samples on the **QC / PROFICIENCY** mode.

- **SQA iO PRECISION** Validation Samples data entry and sample testing:
  - Go to **QC/PROFICIENCY > QwikCheck QC BEADS**
  - SELECT BATCH NUMBER: **080888**

Bottles Marked 1 – 3: Test on LEVEL 1

- Select: **TEST NOW**
- Select: **TEST NOW** when the message: **"PLEASE NOTE: ONLY USE THIS BATCH WITH MES VALIDATION KITS"**
- Follow the on-screen instructions.
- Record the **CONC. (M/ml)** results.

Bottle Marked 4: Test on NEGATIVE CONTROL

- Select: **TEST NOW**
- Select: **TEST NOW** when the message: **"PLEASE NOTE: ONLY USE THIS BATCH WITH MES VALIDATION KITS"**
- Follow the on-screen instructions.
- Record the **CONC. (M/ml)** results.

OPTIONAL 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 **5** (maximum) in the same manner as above. Running more than 5 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.

Precision (Using Semen with motility > 30%)			
Level Sample #	**# of Replicates to run**	**Run on SQA Mode:**	**Record Results**
1	5	FRESH	YES
2	5		
3	5		
4	5		

STEP 3: SQA-iO 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 Proficiency 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-iO 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**
    - **DEBRIS**: Select: NONE/FEW < 10%
  - Select: **TEST NOW**
  - Select: **TEST ANYWAY** when the message: "**SAMPLE VOLUME IS MISSING, Semen TOTALS PER EJACULATE will not be reported** " is displayed.
  - Follow the on-screen instructions.
  - Record the **CONC. (M/ml)** 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 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 between 2500 mV – 3500mV for the best possible results). If the REF 2 value is below 2500 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 QwikCheck GOLD default settings as described below.
- 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: 2ROW
  - ✓ Printing Options: Automatically print all test results.
  - ✓ Printing Options: Automatically print Self-Test Report on Start Up
  - ✓ Controls: Latex Beads.
  - ✓ LEVEL 1 Target and Range = 100 +/- 99.9.
  - ✓ LEVEL 2 Target and Range = 100 +/- 99.9.
  - ✓ NEGATIVE CONTROL = 0.0.
- Save all SQA-V printouts processed during the validation and fill data entry sheet.
- **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.**

NOTE: Once you have completed the Validation Kit, please remember to reset your QC settings accordingly.

STEP 1: SQA-V LINEARITY & REPORTABLE RANGE PROTOCOL

Before opening each sample bottle, invert it (upside down) to remove any beads adhering to the cap liner. When ready to start testing (with the bottle right side up), mix the sample thoroughly swirling in a circular motion for 30 seconds, 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 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 1 and D. No dilution, run as is.

Bottles 2 – 5 are empty. Use the dilution table below and fill with the exact amount for each bottle. Mix thoroughly (30 seconds) for each bottle prior to filling the capillary once the proper dilution amount is added to each bottle.

LINEARITY INSTRUCTIONS			
BOTTLE #	**FROM BOTTLE "1"**	**FROM BOTTLE "D"**	**DILUTION RATE**
1	RUN AS IS ONLY BOTTLE "1"		100/0
2	0.8 ml	0.2 ml	80/20
3	0.6 ml	0.4 ml	60/40
4	0.4 ml	0.6 ml	40/60
5	0.2 ml	0.8 ml	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) to remove any beads adhering to the cap liner. When ready to start testing (with the bottle right side up), mix the sample thoroughly swirling in a circular motion for 30 seconds, open the cap and aspirate the sample for testing.

NOTE: To run this protocol, use the four (4) **Green lettered "Precision"** bottles marked **"1"** through **"4".** Use 1 Capillary to run 10 replicates for each bottle. Ensure a new capillary is used for each bottle.

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

- **Bottle 1:** RUN 10 replicates sample "1" with same capillary on "Control Mode". Record the results.
- **Bottle 2**: RUN 10 replicates sample "2" with same capillary on "Control Mode". Record the results.
- **Bottle 3**: RUN 10 replicates of sample "3" with same capillary on "Control Mode". Record the results.
- **Bottle 4**: RUN 10 replicates of sample "4" with same capillary on "Control Mode". Record the results.

Precision (Using Beads)			
Level Sample #	**# of Replicates to run**	**Run on SQA Control Mode:**	**Record Results**
1	10	Level #1	YES
2	10		
3	10		
4	10	Negative Control	

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

- **SQA-V PRECISION** Validation Samples data entry and sample testing:

Bottles Marked 1 – 3: Test on LEVEL 1

- From the MAIN MENU select: **RUN CONTROLS**
- Select **LEVEL #1** and press ENTER.
- Follow the onscreen instructions.
- Repeat each sample 10 times back-to-back using the same Testing Capillary.
- Record the **CONC. (M/ml)** results.

Bottle Marked 4: Test on LEVEL 1

- From the MAIN MENU select: **RUN CONTROLS**
- Select **NEGATIVE** and press ENTER.
- Follow the onscreen instructions.
- Repeat each sample 10 times back-to-back using the same Testing Capillary.
- Record the **CONC. (M/ml)** results.

OPTIONAL 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 **5** (maximum) in the same manner as above. Running more than 5 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.

Precision (Using Semen with motility > 30%)			
Level Sample #	**# of Replicates to run**	**Run on SQA Mode:**	**Record Results**
1	5	FRESH	YES
2	5		
3	5		
4	5		

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 Proficiency and Training Kit.

SQA-V MANDATORY ACCURACY COMPARISON PROTOCOL:

Before opening each sample bottle, invert it (upside down) to remove any beads adhering to the cap liner. When ready to start testing (with the bottle right side up), mix the sample thoroughly swirling in a circular motion for 30 seconds, open the cap and aspirate the sample for testing.

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 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.
        - Record the **CONC. (M/ml)** results.

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 ensure 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**.

QwikCheck GOLD INSTRUCTIONS

SYSTEM SET-UP and GENERAL INFORMATION

- After powering on the QwikCheck GOLD analyzer, print a copy of the Service Data report.
- Check the Report to verify the Reference 2 (REF 2) value (it should be between 2500 mV – 3500mV for the best possible results). If the REF 2 value is below 2500 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 QwikCheck GOLD default settings as described below.
- From the QwikCheck GOLD MAIN MENU select:
  SERVICE > SET-UP > SYSTEM DEFAULTS. The following settings should be selected for the Validation and Training Kit (you may return them to your specific settings afterwards):
  - ✓ DATE FORMAT
  - ✓ DATE/TIME SETTING
  - ✓ AUTO PRINTING: YES
  - ✓ # LABELS TO PRINT: 1
  - ✓ CONC. STD: 2
- From the QwikCheck GOLD MAIN MENU select:
  SERVICE > SET-UP > CONTROLS. The following settings should be selected for the Validation and Training Kit (you may return them to your specific settings afterwards):
  - ✓ Controls: LATEX BEADS
  - ✓ LEVEL 1 Target and Range = 100 +/- 99.9
  - ✓ LEVEL 2 Target and Range = 100 +/- 99.9
  - ✓ NEGATIVE CONTROL = 0.0

NOTE: Once you have completed the Validation Kit, please remember to reset your QC settings accordingly.

STEP 1: QWIKCHECK GOLD 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.

- **QwikCheck GOLD 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 the **CONC. (M/ml)** 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 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 during some tests. This is normal and occurs because there is no motility present.

Bottle 1 and D. No dilution, run as is.

Bottles 2 – 5 are empty. Use the dilution table below and fill with the exact amount for each bottle. Mix thoroughly (30 seconds) for each bottle prior to filling the capillary once the proper dilution amount is added to each bottle.

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

STEP 2: QwikCheck GOLD PRECISION - REPLICATION & DETECTION LIMIT PROTOCOL

Before opening each sample bottle, invert it (upside down) to remove any beads adhering to the cap liner. When ready to start testing (with the bottle right side up), mix the sample thoroughly swirling in a circular motion for 30 seconds, open the cap and aspirate the sample for testing.

NOTE: To run this protocol, use the four (4) **Green lettered "Precision"** bottles marked **"1"** through **"4".** Use 1 Capillary to run 10 replicates for each bottle. Ensure a new capillary is used for each bottle.

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

- **Bottle 1:** RUN 10 replicates sample "1" with same capillary on "Control Mode". Record the results.
- **Bottle 2**: RUN 10 replicates sample "2" with same capillary on "Control Mode". Record the results.
- **Bottle 3**: RUN 10 replicates of sample "3" with same capillary on "Control Mode". Record the results.
- **Bottle 4**: RUN 10 replicates of sample "4" with same capillary on "Control Mode". Record the results.

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

- **SQA-V PRECISION** Validation Samples data entry and sample testing:
  - From the MAIN MENU select: **RUN CONTROLS**
  - Select **LEVEL #1** for the bottles marked #1 through #3 and **NEGATIVE CONTROL** for bottle #4 and press ENTER.
  - Follow the onscreen instructions.
  - Repeat each sample 10 times back-to-back in the same Testing Capillary.
  - Record the **CONC. (M/ml)** results.

Precision (Using Beads)			
Level Sample #	**# of Replicates to run**	**Run on QwikCheck GOLD Control Mode:**	**Record Results**
1	10	LEVEL #1	YES
2	10		
3	10		
4	10	NEGATIVE CONTROL	

OPTIONAL 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 **5** (maximum) in the same manner as above. Running more than 5 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.

Precision (Using Semen with motility > 30%)			
Level Sample #	**# of Replicates to run**	**Run on QwikCheck GOLD Mode:**	**Record Results**
1	5	FRESH	YES
2	5		
3	5		
4	5		

STEP 3: QwikCheck GOLD 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 Proficiency and Training Kit.

QwikCheck GOLD MANDATORY ACCURACY COMPARISON PROTOCOL:
Before opening each sample bottle, invert it (upside down) to remove any beads adhering to the cap liner. When ready to start testing (with the bottle right side up), mix the sample thoroughly swirling in a circular motion for 30 seconds, open the cap and aspirate the sample for testing.

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 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.
  - **QwikCheck GOLD 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 system.
    - Record the **CONC. (M/ml)** results.

QwikCheck GOLD 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 ensure 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.

- **QwikCheck GOLD ACCURACY** Validation Samples: Run **ACCURACY** samples on the **FRESH** mode.
    - Set the Conc. Standard of the system to match the standard manual method used in the lab by going to the **QwikCheck GOLD: SERVICE > SET-UP > SYSTEM DEFAULTS.**
    - From the **MAIN MENU** select: **TEST NEW PATIENT**
    - Follow the QwikCheck GOLD User Guide instructions for running FRESH samples. Skip parameters that are not necessary to enter in the ENTER PATIENT/SAMPLE DATA screen.
    - Choose "**FRESH**" as the sample type.
    - Follow the on-screen instructions for testing the sample.
    - Record the **CONC. (M/ml)** results.

- 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**.

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 USB Thumb Drive. 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: North America, Puerto Rico and Australia Customers: service@mes-llc.com Other Customers: Michelle@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 number provided by your Distributor: **North America, Puerto Rico, and Australia**: 310-670-9066 **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 **North America, Puerto Rico, and Australia:** 310-670-9066. **All other customers:** 972-4-637-3981 EXT 103 or by writing an e-mail to: **North America, Puerto Rico and Australia: service@mes-llc.com** or **All other customers**: **Michelle@mes-ltd.com**.

REMEMBER, IT ALL STARTED WITH A SPERM! WWW.MES-GLOBAL.COM

PPENDIX I: Mandatory Data Entry Form

Medical Electronic System's SQA Validation and Training Kit: Mandatory Results					
FACILITY:		LAB TECH:		KIT BATCH #	
DEVICE NAME:		DEVICE SN#			

Enter information and results in the white fields above and below:

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	

SQA Validation and Training Kit Data Entry_Mandatory_7_FEB_2016

APPENDIX II: OPTIONAL Data Entry Form

Medical Electronic System's SQA Validation and Training Kit: Optional Results

FACILITY:		LAB TECH:		KIT BATCH #	
DEVICE NAME:		DEVICE SN#			

Enter information and results in the white fields above and below:

1. PRECISION-REPLICATION & DETECTION LIMIT: Using Semen Samples

Semen Sample #1		
Count M/ml	Motility %	Morphology %

Semen Sample #2		
Count M/ml	Motility %	Morphology %

Semen Sample #3		
Count M/ml	Motility %	Morphology %

2. ACCURACY - COMPARISON OF METHODS: Using Semen Samples

Sample #	SQA SEMEN ANALYZER			MANUAL OR CURRENT METHOD		
	Count M/ml	Motility %	Morphology %	Count M/ml	Motility %	Morphology %
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

Product Regulatory Information - QwikCheck™ Beads Proficiency and Training Kit

Manufacturer's Name	MES Medical Electronic Systems
Manufacturer's Address	20 Alon Hatavor Street, Zone 6, Caesarea Industrial Park, Israel 3088900
Product Part #	A-CA-00691-00
Storage and handling conditions	Store the QwikCheck™ Beads Proficiency and Training Kit @ 15-30°C (60-86°F). Open vial beads can be stored @ 15-30°C (60-86°F) for 30 days. The expiration date assumes that QwikCheck™ Beads Proficiency and Training Kit is stored in its original containers and the bottles are tightly capped to prevent evaporation.
Number of tests included	1 round of testing for product validation
IVD Test Kit	

Australian Sponsor	Acrapack Pty Ltd, Anne Jones 7/ 84 Poinciana Avenue, Tewantin QLD Australia 4565 Email: anne@acrapack.onmicrosoft.com