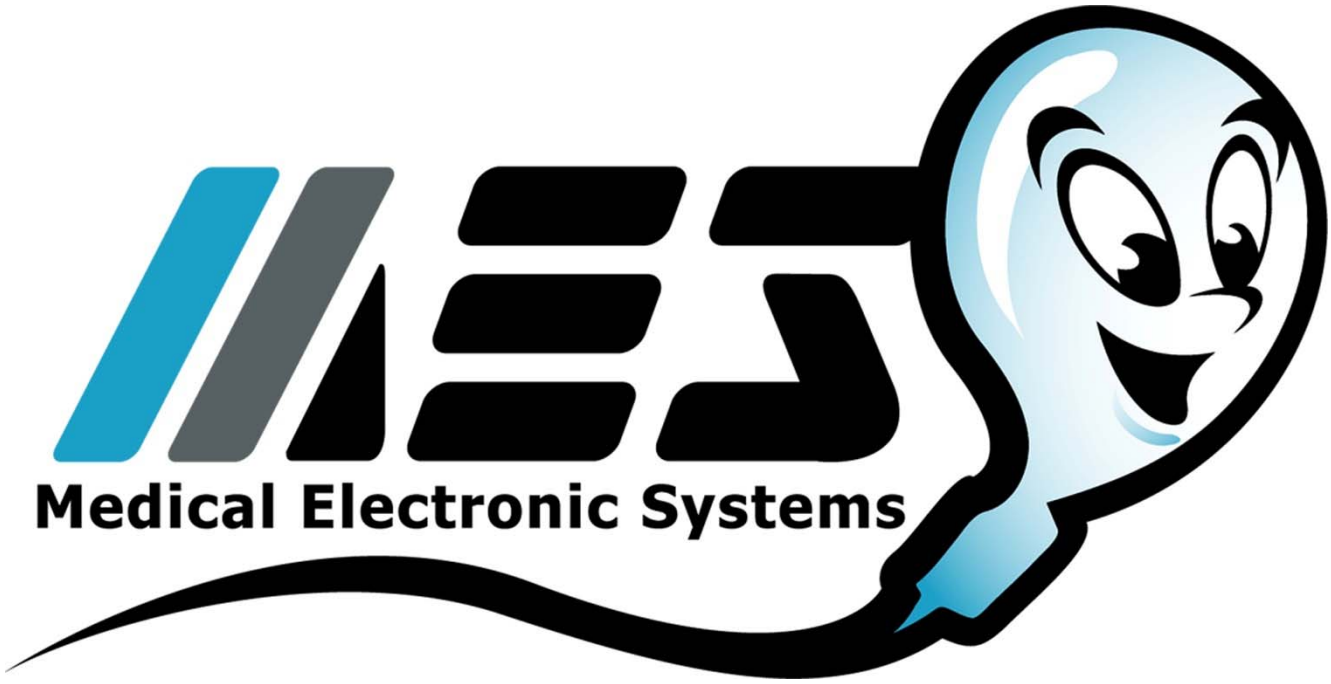
SQA-VISION
Semen Analysis Handbook



Remember, it ALL Started with a Sperm!

SQA-V HANDBOOK TABLE OF CONTENTS

MEDICAL ELECTRONIC SYSTEMS
5757 W. Century Blvd. Suite 805
Los Angeles, CA. 90045
"Remember, it ALL Started with a Sperm!"

SQA-VISION INTRODUCTION AND PRE-INSTALLATION GUIDE

Medical Electronic Systems is looking forward to installing your instrument and we want to provide you with some basic information on the system and request some from you in order to make the process as smooth and efficient as possible.

Before the Training:
Once training is scheduled, please send your MES point of contact a copy of your standard operating procedure (SOP) for semen analysis. The procedure will be reviewed by MES to ensure that all potential discrepancies in standards, ranges, and procedures are addressed during the on-site training. Your SOP can also be e-mailed to service@mes-llc.com if you do not have the contact details of your trainer.

Space and Connection Requirements:
The SQA-VISION instrument and included All-in-One PC will require a space of approximately 40" wide x 20" deep x 20" high. The counter should be clean, sturdy and 100% isolated from vibrations (printers, centrifuges, etc.) One standard grounded electrical outlet within 24" of the instrument is also required. There are no further liquid, venting or drainage requirements for the system.

Training Format and Time:
Training is conducted in a "train the trainer" format whereby 1 or 2 key personnel are thoroughly instructed on the use of the instrument and supported during the ongoing training of other users. The key operator(s) will serve as the key points of contact with MES and should take the lead on validation and implementation. Installation of the system typically takes about 45 minutes and training will take around 2 hours.

Necessary Materials for Installation / Training:

- 40" wide x 20" deep x 20" high worth of clean, sturdy and vibration free counter space.
- Copy of customers standard operating procedure (SOP)
- Kimwipes
- 10 microliter and 5 microliter pipettes with tips
- 1" x 3" standard lab slides
- 22 x 22mm cover slips
- 8 ½ x 11" standard white printer paper
- Lab gloves
- Enthusiasm for Learning!

MES Contact Information:
Medical Electronic Systems, LLC
5757 W. Century Blvd Suite 805
Los Angeles, CA. 90045
Phone: 866-557-9064
Fax: 310-670-9069
sales@mes-llc.com | service@mes-llc.com | www.mes-global.com

MEDICAL ELECTRONIC SYSTEMS CONTACT INFORMATION

Medical Electronic Systems would like to welcome you to the world of Automated Semen Analysis. Your new SQA-VISION instrument will save time while increasing accuracy, peace of mind and moral in the laboratory. This SQA-VISION handbook was designed to simplify the learning curve associated with bringing your analyzer online and provide necessary documentation to accelerate the transition to this new technology. Please review the information contained in this handbook and feel free to contact MES with any additional questions or requests.

MES America Contact Information:

Medical Electronic Systems, LLC
5757 W. Century Blvd. Suite 805
Los Angeles, CA. 90045

Phone: 866-557-9064
Fax: 310-670-9069
Website: www.mes-global.com

Sales:
Phone: 310-670-9066 x301
E-Mail: sales@mes-llc.com

Service:
Phone: 310-670-9066 x305
E-Mail: service@mes-llc.com

www.mes-global.com

www.youtube.com/mesvision

www.twitter.com/MESemenAnalysis

www.facebook.com/mesglobal

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SQA-VISION Training Checklist | Facility Name: _____ Date: _____

STEP	TOPICS COVERED	INITIALS
1	**Trainer Introduction and Company Overview** • Name / Title of Trainer • Contact Information for Medical Electronic Systems • www.mes-global.com Training Resource • User Guide & Handbook Overview • Company Overview • Upgrades to Come!	☐
2	**Powering the System ON and OFF** • 2 Parts to the VISION (Testing Unit and Touchscreen PC) • Powering ON the Testing Unit + PC and Logging In • Auto Calibration / Self-Test Report / Possible Errors • Self-Test Report Archive • Powering the System OFF at the End of Each Day	☐
3	**Introduction – SQA-VISION Testing Unit** • Front Panel (Testing Chamber vs. Visualization Chamber) • Front Panel (Focus Knob, Field of View Knob, Zoom In/Out, Keypad) • Back Panel (Serial Number, Data Cords, Power Cable) • Testing Unit Service Menu • I-Button Port / I Button Loading	☐
4	**Introduction – SQA-VISION PC Interface** • Home Screen Overview – Key Parameters, System Status, QC, Backup, Test Stats • Home Screen Shortcuts – Report, Maintenance, Refresh • Top Menu Buttons – Minimize, Timer, Help, Exit, Home • Software Version / Date / Time • Offline Mode • VISION Main Menu Overview • Test Patient • QC / Proficiency • Visualization • Archive • Service • Settings	☐
5	**Introduction – Testing Capillary** • SQA-VISION Testing Capillary Overview • Motility Channel vs. Concentration Channel • Stopper Valve • Syringe / Plunger • Technology Overview • Sample Mixing / Liquefaction Importance • Capillary Cleaning Importance • Bubbles and "Wicking Meniscus"	☐

STEP	TOPICS COVERED	INITIALS
6	**Settings** • Controls • Proficiency • Test Patient • Visualization • System • QwikLink / LIS Interface	
7	**Quality Control and Proficiency** • Latex Beads – 90 Day Expiration, Room Temp • Stabilized Sperm • Proficiency – CAP Code for SQA Platforms: SC1 • Mixing and Running the Sample • Corrective Action • QC Frequency Setup • QC Archive and Reports	
8	**Test Patient** • Testing Modes • Fresh | Post Vas | Washed | Swim Up | Gradient | Frozen | Longevity | Manual • Data Entry Process / Mandatory Fields • Optional Fields • WBC / pH Test Strips • Dilution Option for Short Samples • 20 Microliter Mode • Comments Entry – Before and After Test • Sample Mixing / Sample Viscosity (Washed Mode Correction) / Sample Liquefaction • Loading the Capillary and Running the Sample • Visualization Options (Online) • Low Quality Counter | Debris Scanner | Morphology | Vitality | Capture • Slide and Stain Options • Post Vas and Longevity Test Flows • Additional Data Entry • Results Overview – WHO Version, Cutoffs • Reporting / Archiving	
9	**Visualization (Offline)** • Morphology | Vitality | Capture • Offline vs. Online • Touch to Mark vs. Click Counter • Saving and Archiving Offline Visualization	
10	**Clinical Comparison, Validation, Technical Bulletins, Procedures** • Important Technical Bulletins: http://www.mes-global.com/Technical-Bulletins • Room Temperature During the Testing Process – No Sample Heating • Sample Mixing – Transfer Pipette • Sample Liquefaction - High Viscosity Sample Treatment • Azoospermic and Low Concentration Samples – Low Quality Scanner • Extreme Amounts of Debris – Debris Scanning • "Watery Sample" Recommendation (Washed Mode) • Initial Validation and 6 Month Mini-Validation and Calibration Confirmation • WHO Manual For Semen Analysis – VISION SOP • Software Updates • CAP Proficiency Survey – Code **SC1**	

STEP	TOPICS COVERED	INITIALS
11	**Archive** • Patient Data • Latex Beads (Daily QC) • Stabilized Sperm • Proficiency • Maintenance • Service Data • Visualization	☐
12	**Maintenance** • Self-Test Key Parameters (Home Screen + Maintenance Section) • Daily Maintenance Checklist • Daily Cleaning (Wooden Brush) • Weekly Cleaning (Cleaning Capillaries and Fluid) • Average Test Per Day • QC Status • I Button Status • Backup Status • Real Time Service Parameter Analysis	☐

ADDITIONAL NOTES:

Trainer and Trainee acknowledge that all topics contained in this checklist were covered during the SQA-V system training:

FACILITY: _____ DATE: _____

TRAINER NAME: _____ TRAINER SIGNATURE: _____

TRAINEE NAME: _____ TRAINEE SIGNATURE: _____

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Medical Electronic Systems SQA-VISION Validation Recommendations

OVERVIEW

This Medical Electronic Systems Validation Recommendation template was designed to help validate the Accuracy, Precision and Reportable Range of the SQA-V Gold sperm quality analyzer per the New 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) 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. Test sites performing unmodified, FDA approved, moderate complexity testing could accept the manufacturer's performance specifications and were not required to perform any method validation. On January 24, 2003, the Centers of Medicare and Medicaid Services (CMS) issued the final CLIA rules (CLIA Final Rules Manual, 2004, ISBN 1-886958-20-3). These rules bring ALL non-waived (moderate and high complexity) testing under uniform QC requirements, including validation of methods. Minimum QC now is two levels per day rather than per run. The approach in method validation is to perform a series of experiments designed to estimate certain types of analytical errors, e.g., a linearity experiment to determine reportable range, a replication experiment to estimate imprecision or random error, a comparison of methods experiment to estimate inaccuracy or systematic error, and a detection limit experiment to characterize analytical sensitivity. These SQA-VISION Validation Instructions provide recommendations for validation of the SQA-VISION per CLIA 2003 (USA) standards for non-waived systems. After completion of this validation, your SQA-VISION instrument will be ready to use in daily operation based on Medical Electronic Systems manufacturer requirements for instrument validation. Depending on your State and Local requirements further validation may be required beyond these recommendations so please check with your local regulatory agencies.

➔ MES MANUFACTURERS VALIDATION KIT

Medical Electronic System's Manufacturers a Validation Kit designed as a proficiency, training, and validation tool for the SQA line of sperm quality analyzer. It can be used to validate Concentration Accuracy, Precision, Lower Limit Detection and Reportable Range (Linearity) per CLIA Method Validation Regulations. Due to the fragile biological nature of sperm, parameters influenced by motion have been omitted from the Manufacturers Validation Kit. Supplemental recommendations and instructions for successfully validating Motility, and other motion based parameters are included with the kit. After successfully completing the MES Manufacturers Validation Kit users will have extensive knowledge of the SQA-VISION's operation, capillary loading technique, reporting, and more. In addition, annual or semi-annual personnel re-testing using the Validation Kit will demonstrate ongoing operator proficiency and the laboratory's commitment to accuracy, precision, and quality of care. Product Code: A-CA-00691-00 / mes-global.com/sqa-validation-kit. For additional information or to order this product please contact MES: Phone: 310-670-9066 / sales@mes-llc.com.

SQA-VISION Validation Instructions

SETUP

- Power on the SQA-VISION testing unit and PC then allow the calibration and self-test to complete.
- Confirm that all Key Parameters are passing and in range.
- Recommended Test Patient Settings:
    - CONC. Standard = 2
    - LES = ROW
    - Low Quality Counter = Checked
    - Debris / Round Cell Scan Cutoff = No Debris Scanning
    - Testing Criteria = WHO 5th (unless the current method is based on a different WHO version)
    - For assistance setting the defaults, please refer to the Help Menu of the Vision, the User Guide, or contact MES: (866-557-9064 / service@mes-llc.com).

1. COMPARISON OF METHODS EXPERIMENT (ACCURACY) OVERVIEW

MES recommends running a minimum of 20 patient specimens by the new method (test method) and an established method (comparison method) to estimate the inaccuracy or systematic error of the method. At the same time, it is stated that the actual number of specimens tested is less important than the quality of those specimens. Twenty specimens that are carefully selected on the basis of their observed concentrations will likely provide better information than the a hundred specimens that are randomly received by the laboratory. The quality of the experiment and the estimates of systematic errors will depend more on getting a wide range of test results than a large number of test results.

Based on these comments, MES recommends running 20 selected patient semen samples representing high, medium and low sperm concentrations using the SQA-VISION and a manual or backup method. NOTE: Samples can be diluted and combined to achieve target qualities and increase the number of observable samples.

NOTE: Results may be sent to MES for analysis (service@mes-llc.com). It is recommended that you send the first 5 comparison samples for an initial overview before completing the remainder of the validation. This will allow for any necessary troubleshooting or modification of technique. A data entry sheet is also available from MES upon request.

To achieve an accurate comparison, please review these requirements and recommendations closely:

- The SQA-VISION analyzes semen samples strictly according to WHO Manual criteria and accurate validation will be difficult if WHO recommendations are not followed closely by the manual or backup method. Please contact MES to request a free copy of the WHO Manual for Semen Analysis if you don't already have one. service@mes-llc.com. MES currently recommends WHO 5th edition criteria for manual analysis.
- Everything must be run at ROOM TEMPRATURE by both methods. Samples should never be incubated, pre heated or tested on a heated stage.
- All samples should be run within 1 hour of collection – no exceptions during validation. Samples should be run on the SQA-VISION first as the testing cycle is much faster. Manually, motility should be run first to decrease associated time variables.
- All samples need to be fully liquefied and well mixed. Use the QwikCheck Liquefaction Kit on stubborn, viscous, and agglutinated / aggregated samples. This is a critical point for both accurate concentration and motility comparison.
- After the automated testing cycle, samples should be visualized using the "Debris" scanning option on the SQA-VISION results screen. Select the debris % according to the instructions and options provided in the Debris Scanning interface.

- When counting fields manually do not ignore agglutinated or aggregated sperm. The system counts all sperm, so if you ignore the large clumps it will affect the comparison. This is a common mistake with manual analysis – there is a tendency to ignore fields that are clumped and agglutinated in search of "easier" fields to count.

- The SQA-VISION analyzes Morphology according to WHO 3rd, 4th or 5th edition criteria. It is critically important that WHO standards be followed for the Manual or backup method as well. For clarification or questions on WHO criteria, please contact MES directly for support: service@mes-llc.com.

- It is common to overestimate sperm motility (manually), but this can often be avoided by reversing the order of analysis (Non Progressive and Immotile first), using an eyepiece reticle, and being aware of, and avoiding, to the extent possible, potential sources of bias **(see Section 7.13.3) – WHO 5th ed. manual, p. 24).**

- **Section 7.13.3 (WHO 5th ed. manual, p. 200-201)** Practical hints when experiencing difficulty assessing motility:

1. Make the preparation immediately before assessing. Read only after any drifting has stopped to reduce bias in overall motility.
2. Select the field randomly and do not deliberately select fields with high or low numbers of motile spermatozoa. NOTE: One way to do this is to avoid looking through the oculars until a field has been selected.
3. Do not wait for motile spermatozoa to enter the field before starting to count.
4. Analyze quickly; analyze only a small portion of the grid at one time, depending on sperm concentration.
5. Spend less time examining one area of the grid, to avoid counting spermatozoa that swim into the area during analysis.
6. Count progressive, non-progressive and immotile spermatozoa in two stages. If there are problems with the technique, reverse the order of analysis (Review Table 7.4 below):

Table 7.4 Sources of variation (error) in assessing sperm motility and proposed solutions

Procedure	Prevention	Control
Improper mixing of specimen before aliquot is removed	Training, SOP	Replicate sampling and assessment, IQC
Waiting too long after slide is prepared before analysis (spermatozoa quickly lose vigour)	Training, SOP	Replicate sampling and assessment, IQC
Improper temperature of stage warmer (e.g. too high temperature will kill spermatozoa)	Training, SOP, equipment maintenance	IQC
Microscope not properly cleaned or aligned. Improper magnification	Training, SOP, equipment maintenance	IQC, EQC
Lack of eyepiece grid for guidance	Equipment	IQC (control chart)
Analysing around the edges of the coverslip (the spermatozoa die or become sluggish around the outer 5mm of the coverslip)	Training, SOP	Replicate assessment, IQC
Making the assessment too slowly (other spermatozoa swim into the defined area during the assessment period)	Training, SOP	IQC
Malfunction of multikey counter	Equipment maintenance	IQC, EQC
Errors in calculating percentages if not counted in multiples of 100	Training, SOP	IQC, EQC
Subjective bias (i.e. consistently too high % motile or too low % motile)	Training, SOP	IQC, EQC
Preparative procedures that reduce motility (e.g. temperature change, vigorous mixing, contamination with toxins)	SOP	IQC
Non-random selection of fields for analysis. Delay in analysis (e.g. waiting until motile spermatozoa swim into the field or grid to begin analysis)	Training, SOP	IQC, EQC

2. REPLICATION & DETECTION LIMIT EXPERIMENT (PRECISION)

Quality Control - Running a minimum of 10 replicate determinations on at least two levels of positive control materials is recommended to estimate the imprecision or random error of the method. For the Detection Limit Experiment, a "blank" (negative control) material is analyzed in 10 replicates. MES QwikCheck Beads (Positive Levels and Negative Control) are recommended for this experiment.

- Set the SQA-VISION control information in the Settings section.
- Run 10 replicates of two bead levels from the QC / Proficiency section of the main menu. Do not discharge and refill the capillary between tests; re-run the same aliquot in the same capillary.
- Run 10 replicates of the Negative Control. NOTE: Make sure you choose the "Negative Control" level (not 1 or 2). Record both the Concentration and MSC results on the data entry spreadsheet.

Live Samples - It is also recommended that 2 live samples be run on the systems Fresh "Test Patient" mode to observe Motility and Morphology precision. NOTE: Only 5 replicates of each sample should be run (using the same aliquot in the same capillary). Sample stability may be effected by the time gap associated with running 10 replicates.

- Select "Fresh" from the Test Patient tab. Enter the required sample information and test the sample. On the results screen you will see the option to "Re-Test". Choose this option to avoid delays between replicates.
- Record your results and return them to MES for analysis.

3. LINEARITY & REPORTABLE RANGE EXPERIMENT

Centrifuge multiple semen samples and decant the supernatant to achieve a sample concentration of at least 400 M/ml in 3 ML of total volume (1,200 million sperm total). Load and run all samples on Fresh mode according to standard SQA-VISION testing procedures

- Prepare six samples by diluting of the Pooled semen sample using MES QwikCheck Dilution media in the following proportions: **100/0, 80/20, 60/40, 40/60, 20/80 and 0/100**.
- **First level:** Run concentrated specimen on "Fresh Mode" to establish the upper range of the linearity curve. Record the results. NOTE: Target is 400 M/mL but a result close to that is acceptable.
- **Second level:** Mix 0.8 mL from First Level and 0.2 mL of QwikCheck Diluent. This will create an 80/20 dilution. Run and record results.
- **Third level:** Mix 0.6 mL from First Level and 0.4 mL of QwikCheck Diluent. This will create a 60/40 dilution. Run and record results.
- **Fourth level:** Mix 0.4 mL from First Level and 0.6 mL of QwikCheck Diluent. This will create a 40/60 dilution. Run and record results.
- **Fifth level:** Mix 0.2 mL from First Level and 0.8 mL of QwikCheck Diluent. This will create a 20/80 dilution. Run and record results.
- **Sixth level**: Run QwikCheck Dilution media as is for a 0/100 dilution. Run and record results on the enclosed data sheet.
- Record all results and return to MES for analysis.

CONCLUSION – Results may be returned to MES for analysis at any time: service@mes-llc.com

SQA-V VALIDATION STUDY DATA ENTRY SHEET

Facility:	
Date:	
Conducted By:	
Serial Number:	

LINEARITY & REPORTABLE RANGE RESULTS

Sample #	Dilution	Result
1	100/0	
2	80/20	
3	60/40	
4	40/60	
5	20/80	
6	0/100	

REPLICATION AND DETECTION LIMITS (PRECISION) RESULTS

Replicate #	Level 1	Level 2	ZL CONC.*	ZL MSC*
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

* Please include the Concentration and MSC results from the zero level.

LIVE SAMPLE #1 PRECISION

Count	Motility	Morph.

LIVE SAMPLE #2 PRECISION

Count	Motility	Morph.

COMPARISON OF METHODS EXPERIMENT (ACCURACY) RESULTS

Sample #	SQA-V GOLD SEMEN ANALYZER			MANUAL OR CURRENT METHOD		
	Count	Motility	Morph.	Count	Motility	Morph.
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

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SQA-VISION Gold Semiannual Validation/ Proficiency/ QC Recommendations

OVERVIEW

Providing the best patient care requires laboratory staff and pathologists to strive for the highest levels of performance. In order to meet these standards, maintain user proficiency, and confirm the correct operation of the SQA-VISION Automated Sperm Quality Analyzer, MES had developed a series of recommendations to be performed on a semiannual basis. These recommendations include:

1. Semiannual Instrument Calibration Confirmation

It is recommended that twice per year, the SQA-VISON calibration be checked against the original factory calibration parameters. Although there are acceptable calibration ranges for the SQA-VISION, the system parameters may be close to the high or low end of the range and proactive maintenance will ensure continued uninterrupted use and optimal clinical performance.

2. Semiannual College of American Pathologists (CAP) Proficiency Challenge

Medical Electronic Systems SQA analyzers (Spermalite and VISION) are part of the CAP semen analysis proficiency challenge and as an automated method has a specific sample set that is peer reviewed against other SQA users. MES recommends this survey as an unbiased appraisal of user proficiency and system performance. Please contact CAP directly for more information and for ordering details: http://www.cap.org/apps/cap.portal. **NOTE: The code of the SQA analyzer is SC1.**

3. Semiannual System Mini-Validation and Motility / Morphology Confirmation

It is highly recommended that the facility confirm the precision and lower limit detection ability of the SQA-VISION by completing an abbreviated validation study on a semiannual basis. Organizations providing semen analysis proficiency testing programs (CAP, NEQAS) require laboratories to show proficiency and quality control across three main semen analysis parameters: Sperm concentration, motility and morphology. To date, the QC / proficiency testing samples provided by these organizations do not address motility or morphology due to natural limitations associated with shipping live samples. This recommended precision / lower limit detection study in conjunction with the SQA-VISIONS daily calibration / self-test, and daily zero level MSC confirmation can be used to demonstrate ongoing motility and morphology verification. For additional motility / morphology QC information please contact MES directly to request a technical bulletin (service@mes-llc.com). As necessary, tt is also suggested that 5 samples be compared to a backup method on an annual or semi-annual basis if required.

Manufacturers Validation Kit (OPTIONAL)

MES Manufacturers an optional "Validation Kit" designed as a proficiency, training, and validation tool for the SQA-VISION. It can be used to validate Concentration Accuracy, Precision, Lower Limit Detection and Reportable Range (Linearity) per CLIA Method Validation Regulations. Product Code: A-CA-00691-00 / www.mes-global.com/sqa-validation-kit.

Semiannual Instrument Calibration Confirmation

Twice per year, MES recommends sending us the "Service Data Report" of your SQA-VISION for a calibration confirmation. To print your Service Data Report and return it to MES, please follow these instructions:

- Right after powering the SQA-VISION "On" click on "REPORT" to the right of the home screen box.
- Print this report.
- Fax the report to MES (310-670-9069) or scan and e-mail it to service@mes-llc.com. Please include an e-mail address and your contact information with the Self-Test report so that we may return the confirmation.
- Your SQA-V calibration parameters will be compared to the initial calibration parameters recorded during the manufacturing process and presented back to you in report format

Semiannual College of American Pathologists (CAP) Proficiency Challenge

Medical Electronic Systems SQA analyzers (Spermalite and VISION models) are part of the CAP semen analysis proficiency challenge and as an automated method has a specific sample set that is peer reviewed against other SQA users. MES recommends this survey as an unbiased appraisal of user proficiency and system performance. **NOTE: The CAP proficiency material is run under the Proficiency mode in the QC / Proficiency Tab NOT on Fresh mode.**

System Setup:

- From the home screen, navigate to "Settings" then "Proficiency".
- Enter a sample ID, date, and note if necessary.
- Confirm that "CAP" is selected as the Proficiency Type.
- Click "Apply" to save the settings.

Running Stabilized Sperm CAP Proficiency Material on the SQA-V:

- From the home screen, select "QC / Proficiency", then "Proficiency".
- Choose your level, then load the SQA testing capillary and insert it into the testing chamber per the onscreen instructions.
- Repeat this process for Level 2.
- If a result is reported as "0", re-run the sample on the system's Fresh mode (under "Test Patient"). See **NOTE** below.
- Record your test results and submit them to CAP.
- Please contact MES with any questions or assistance running your CAP samples: service@mes-llc.com or 886-557-9064.

Semiannual System Mini-Validation and Motility / Morphology QC Confirmation

PRECISION: Quality Control Material - Running a minimum of 5 replicate determinations on at least two levels of positive control materials is recommended to estimate the imprecision or random error of the method. For the Detection Limit Experiment, a "blank" (negative control) material is analyzed in 5 replicates. MES QwikCheck Beads (Positive Levels and Negative Control) are recommended for this experiment.

- Set the SQA-VISION control information in the Settings section.
- Run 5 replicates of two bead levels from the QC / Proficiency section of the main menu. Do not discharge and refill the capillary between tests; re-run the same aliquot in the same capillary.
- Run 5 replicates of the Negative Control. NOTE: Make sure you choose the "Negative Control" level (not 1 or 2). Record both the CONC. and MSC results on the data entry spreadsheet.

PRECISION: Live Semen Samples - It is also recommended that 2 live samples be run on the system's Fresh "Test Patient" mode to observe Motility and Morphology precision. NOTE: Only 5 replicates of each sample should be run (using the same aliquot in the same capillary). Sample stability may be effected by the time gap associated with running more than 5 replicates.

- Select "Fresh" from the Test Patient tab. Enter the required sample information and test the sample. On the results screen you will see the option to "Re-Test". Choose this option to avoid delays between replicates.
- Record your results and return them to MES for analysis.
- Save all printouts processed during the validation and return them to Medical Electronic Systems for your full validation report per the instructions in the CONCLUSION section. Fax: 310-670-9069 / service@mes-llc.com.

ACCURACY (Optional) – If required, MES recommends running a minimum of 5 patient specimens on the SQA-VISION and an established method (comparison method). The patient semen samples should represent high, medium and low sperm concentrations. NOTE: Samples can be diluted and combined to achieve target qualities and increase the number of observable samples.

To achieve an accurate comparison, please review these requirements and recommendations closely:

- The SQA-VISION analyzes semen samples strictly according to WHO Manual criteria and accurate validation will be difficult if WHO recommendations are not followed closely by the manual or backup method. Please contact MES to request a free copy of the WHO Manual for Semen Analysis if you don't already have one. service@mes-llc.com. MES currently recommends WHO 5th edition criteria for manual analysis.
- Everything must be run at ROOM TEMPRATURE by both methods. Samples should never be incubated, pre heated or tested on a heated stage.
- All samples should be run within 1 hour of collection – no exceptions during validation. Samples should be run on the SQA-VISION first as the testing cycle is much faster. Manually, motility should be run first to decrease associated time variables.
- All samples need to be fully liquefied and well mixed. Use the QwikCheck Liquefaction Kit on stubborn, viscous, and agglutinated / aggregated samples. This is a critical point for both accurate concentration and motility comparison.
- Run the samples on the "Fresh" mode under the Test Patient tab per SOP or User Guide instructions.
- After the automated testing cycle, samples should be visualized using the "Debris" scanning option on the SQA-VISION results screen. Select the debris % according to the instructions and options provided in the Debris Scanning interface.
- When counting fields manually for comparison do not ignore agglutinated or aggregated sperm. The system counts all sperm, so if you ignore the large clumps it will affect the comparison. This is a common mistake with manual analysis – there is a tendency to ignore fields that are clumped and agglutinated in search of "easier" fields to count.

- The SQA-VISION analyzes Morphology according to WHO 3rd, 4th or 5th edition criteria. It is critically important that WHO standards be followed for the Manual or backup method as well. For clarification or questions on WHO criteria, please contact MES directly for support: service@mes-llc.com.

- It is common to overestimate sperm motility (manually), but this can often be avoided by reversing the order of analysis (Non Progressive and Immotile first), using an eyepiece reticle, and being aware of, and avoiding, to the extent possible, potential sources of bias **(see Section 7.13.3) – WHO 5th ed. manual, p. 24).**

- **Section 7.13.3 (WHO 5th ed. manual, p. 200-201)** Practical hints when experiencing difficulty assessing motility:

1. Make the preparation immediately before assessing. Read only after any drifting has stopped to reduce bias in overall motility.
2. Select the field randomly and do not deliberately select fields with high or low numbers of motile spermatozoa. NOTE: One way to do this is to avoid looking through the oculars until a field has been selected.
3. Do not wait for motile spermatozoa to enter the field before starting to count.
4. Analyze quickly; analyze only a small portion of the grid at one time, depending on sperm concentration.
5. Spend less time examining one area of the grid, to avoid counting spermatozoa that swim into the area during analysis.
6. Count progressive, non-progressive and immotile spermatozoa in two stages. If there are problems with the technique, reverse the order of analysis (Review Table 7.4 below):

Table 7.4 Sources of variation (error) in assessing sperm motility and proposed solutions

Procedure	Prevention	Control
Improper mixing of specimen before aliquot is removed	Training, SOP	Replicate sampling and assessment, IQC
Waiting too long after slide is prepared before analysis (spermatozoa quickly lose vigour)	Training, SOP	Replicate sampling and assessment, IQC
Improper temperature of stage warmer (e.g. too high temperature will kill spermatozoa)	Training, SOP, equipment maintenance	IQC
Microscope not properly cleaned or aligned. Improper magnification	Training, SOP, equipment maintenance	IQC, EQC
Lack of eyepiece grid for guidance	Equipment	IQC (control chart)
Analysing around the edges of the coverslip (the spermatozoa die or become sluggish around the outer 5mm of the coverslip)	Training, SOP	Replicate assessment, IQC
Making the assessment too slowly (other spermatozoa swim into the defined area during the assessment period)	Training, SOP	IQC
Malfunction of multikey counter	Equipment maintenance	IQC, EQC
Errors in calculating percentages if not counted in multiples of 100	Training, SOP	IQC, EQC
Subjective bias (i.e. consistently too high % motile or too low % motile)	Training, SOP	IQC, EQC
Preparative procedures that reduce motility (e.g. temperature change, vigorous mixing, contamination with toxins)	SOP	IQC
Non-random selection of fields for analysis. Delay in analysis (e.g. waiting until motile spermatozoa swim into the field or grid to begin analysis)	Training, SOP	IQC, EQC

CONCLUSION – Results may be returned to MES for analysis at any time: service@mes-llc.com

SQA-V SEMIANNUAL VALIDATION STUDY DATA ENTRY SHEET

Facility:	
Date:	
Conducted By:	
Serial Number:	

LOWER LIMIT DETECTION RESULTS

Sample #	Conc. Value	MSC Value
1		
2		
3		
4		
5		

PRECISION & SENSITIVITY - SAMPLE #1

Sample #	Conc. M/mL	Motility %	Morphology %
1			
2			
3			
4			
5			

PRECISION & SENSITIVITY - SAMPLE #2

Sample #	Conc. M/mL	Motility %	Morphology %
1			
2			
3			
4			
5			

ACCURACY COMPARISON (OPTIONAL)

Sample #	Concentration (M/ml)		Motility %		Morphology %	
	SQA-V	Manual	SQA-V	Manual	SQA-V	Manual
1						
2						
3						
4						
5						

Semen Analysis: SOP (Standard Operating Procedure)

LABORATORY TEST #: *(enter)*

SPECIMEN TYPE: *Live Human Semen*

REVISION DATE: April 13, 2017

INSTRUMENTATION: *SQA-Vision Semen Quality Analyzer*

VENDOR: *Medical Electronic Systems LLC*

METHOD: *Mixed Technology*

DISCIPLINE: *(enter)*

CLINICAL SIGNIFICANCE

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

TEST PRINCIPLE

The SQA-Vision is an automated sperm analyzer with powerful visualization system used as an accessory tool. The system performs a highly reliable 70-second semen analysis that follows the WHO (3rd, 4th or 5th Edition) guidelines for analyzing Sperm Concentration, Motility, Normal Morphology and many other parameters. The SQA-Vision can run the following sample / test types: FRESH, POSTVASECTOMY, WASHED, SWIM-UP, DENSITY GRADIENT, FROZEN, LONGEVITY and MANUAL, and it runs assayed QwikCheck-beads (latex) for QC purposes and stabilized sperm for proficiency testing.

In addition to automated testing, the SQA-Vision visualization system magnifies samples x1188 to x1725. The patient/sample data and additional semen testing results such as WBC's, pH, volume, viscosity, liquefaction status, etc. are entered in the SQA-Vision PC screen. Test results and patient/sample data are saved automatically in the PC archive upon completion of the test and included in one patient report. Semen pictures and video clips can be attached to patient records for documentation purposes. A LIS interface is part of the SQA-Vision software and supports the data transfer to the facility receiving site.

SPECIMEN REQUIREMENTS

Specimen type:	Semen
Specimen volume:	Entire ejaculate or entire semen volume of the processed sample
Minimum volume:	>0.5 ml (to test a 'neat' sample) or 0.5-0.3 ml to test a diluted 1:2 (1+1) sample
Maximum ejaculation to test time:	1 hour

Provide the patient with the instructions: *Patient Instructions for Semen Collection* (Refer to Appendix 1) and verify that they have followed the instructions summarized below:

- 2-7 days abstinence from ejaculation prior to specimen collection
- Collect sample by masturbation only
- Lubricants, spermicides and other contaminants are not to be used
- The entire specimen must be collected into a clean container (preferably supplied by the physician's office or the laboratory)
- The specimen container should be clearly labeled with the patient name and identifying information
- Transport the specimen to the laboratory right after collection (if collected off-site)
- Keep the sample at room temperature during transportation. Do not heat or cool the sample or the container

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

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

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

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

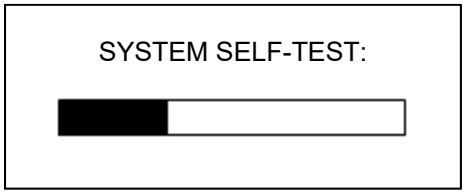
REAGENTS and SUPPLIES

- SQA-Vision Sperm Analyzer (testing device + all-in-one touch screen PC)
- SQA-Vision Capillaries (Catalog # 4021) Medical Electronic Systems LLC
- SQA-Vision Cleaning Kit (Catalog # 0115) Medical Electronic Systems LLC
- Vision™ Fixed Coverslip Slides (Catalog # A-CA-01082-00) Medical Electronic Systems, LLC
- Microscope slides, glass, 1” x 3”
- Coverslips, 22 x 22 mm
- QwikCheck™ Pre-Stained Morphology Slides (Catalog # VS-CA-01108-00) Medical Electronic Systems, LLC
- QwikCheck™ Test Strips for semen WBC and pH (Catalog # 0700) Medical Electronic Systems, LLC
- QwikCheck™ Liquefaction Kit (Catalog #0900) Medical Electronic Systems, LLC
- QwikCheck™ Dilution Kit (Catalog #0800) Medical Electronic Systems, LLC
- QwikCheck™ Beads (Catalog # 0200) Medical Electronic Systems, LLC
- QwikCheck™ Vitality Kit (Catalog # A-CA-01057-00) Medical Electronic Systems, LLC
- QwikCheck™ Beads Validation and Training Kit

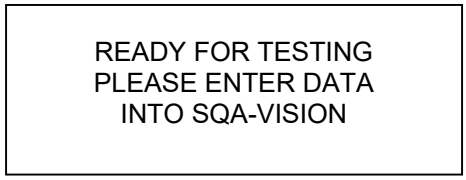
GETTING STARTED

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

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



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



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

- Double click the SQA-Vision icon on the PC desktop to open the screen below:

- Enter the User Name: **administrator**
- Enter the password: **fertility** and press **ENTER**
- The HOME screen (below) will be displayed.

QUALITY CONTROL

Standardizing semen analysis in the laboratory with an automated system will improve accuracy and precision. Proficiency testing surveys (CAP Survey) and periodic intra-laboratory testing will further benchmark the accuracy and precision of the laboratory to other peer groups.

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

Basic instructions:

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

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

1. Select: **QC/PROFICIENCY>LATEX BEADS** from the **MAIN MENU** of the SQA-Vision.
2. Click: **TEST NOW** on the desired Level of LATEX BEADS to be tested to open the sample preparation instructions screen.

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

PROCEDURE NOTES AND PRECAUTIONS

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

Enter Patient and Sample Data into the SQA-Vision:

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

QwikCheck™Test Strips for Semen Analysis Leucocytes and pH:

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

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

QwikCheck™Liqefaction:

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

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

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

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

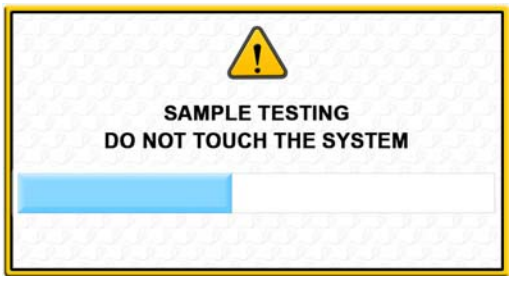
- **Low Volume Sample Instructions**: Aspirate 20 µl of sample into only the thin motility section of the testing capillary. Follow the onscreen instructions (above) and the guidelines in the Appendix section of this User Guide: “Filling the SQA-VISION Capillary with a Low Volume Sample”.
- **Non-Diluted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

QwikCheck™Dilution:

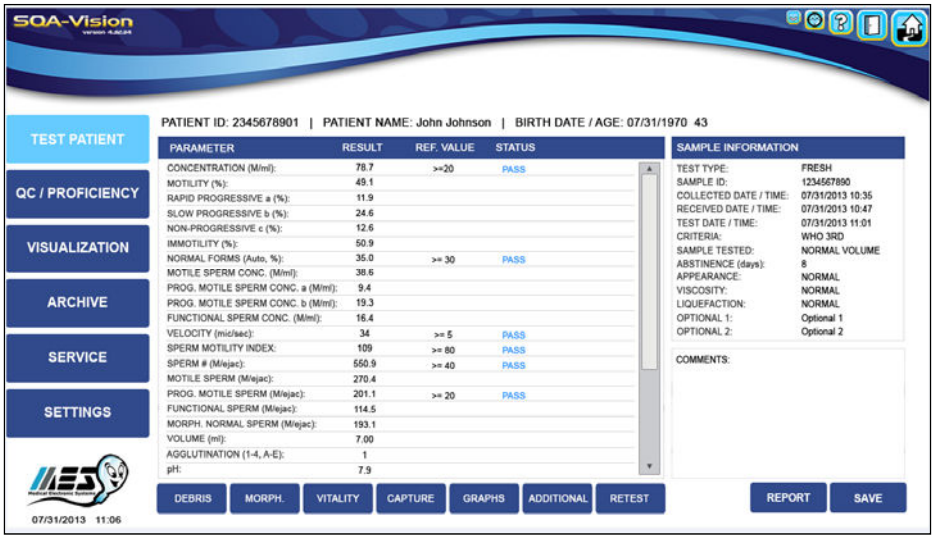
- Measure the volume of the neat semen sample.
- Dilute 1:2 (1+1) with QwikCheck-Dilution
- Thoroughly mix the sample in order to evenly distribute the spermatozoa throughout the sample without introducing bubbles (do not us a pipette to mix)
- Fill a testing capillary in the usual manner (Normal Volume)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

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

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



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



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

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

CALCULATION OF RESULTS

No calculations required

REPORTING RESULTS

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

DAILY MAINTENANCE AND BACKUP

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

REPORTABLE RANGE OF THE SQA-VISION

Reportable range of the SQA-Vision automated results

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

SEMEN PARAMETERS AND WHO RANGES REPORTED BY THE SQA-VISION

SEMEN PARAMETER	REFERENCE VALUE*	SOURCE
Concentration (Count)	≥15 M/ml	WHO 5th manual
Total Motile (PR+NP)	≥40 %	WHO 5th manual
Progressive (PR)	≥32 %	WHO 5th manual
Non-progressive (NP)	-	-
Immotile (IM)	-	-
Normal Forms (morphology)	≥4%	WHO 5th manual
Motile Sperm Concentration (MSC)	≥6 M/ml	MES
Progressively Motile Sperm Concentration (PMSC)	≥5 M/ml	MES
Functional Sperm Concentration (FSC)	-	-
Velocity (Average path velocity – VAP)	≥5 mic./sec.	MES
Sperm Motility Index (SMI)	≥80	MES
Sperm #	≥39 M	WHO 5th manual
Motile Sperm	≥16 M	MES
Progressively Motile Sperm	≥12 M	MES
Functional Sperm	-	-
Morphologically Normal Sperm	≥2 M	MES

*** The reference values established above are based on WHO 5th edition manual data or MES (for proprietary semen parameters).**

LIMITATIONS OF THE PROCEDURE

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

REFERENCES

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

APPENDIX SECTION

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

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

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

The information below will automatically be updated:

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

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

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

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

Step 1: Enter the following information from the product labeling:
- **LOT#** - number identifying the control media lot
- **EXP. DATE** – control media expiration date (MM=month, YY=year)

Step 2: Enter the **TARGET VALUE** and **+/- RANGE:**
- Enter 00 for the target value
- Enter 0.0 for the +/- range

Step 3: Save settings

Step 4: Establish the target value and +/- range for each level:
- Fill a testing capillary and run 10 replicates in the **QC/PROFICIENCY** mode following the onscreen instructions
- Calculate the mean target value. Based on laboratory protocols determine the +/- range (Example: 2SD)
- Open Controls Settings again and update the **TARGET VALUE** and **+/- RANGE** for the control

Refer to the User Guide for the details on the other settings.

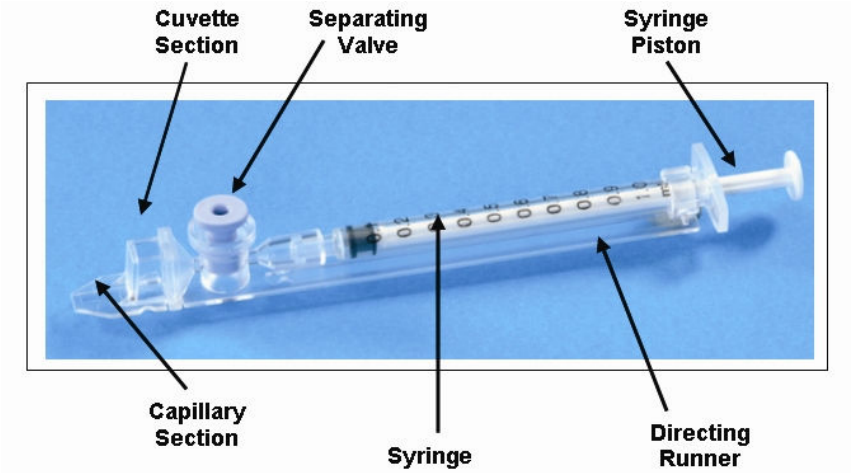
Appendix 2: Adding I-Button Tests

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

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

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

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



Sample size, collection container and preparation:

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

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

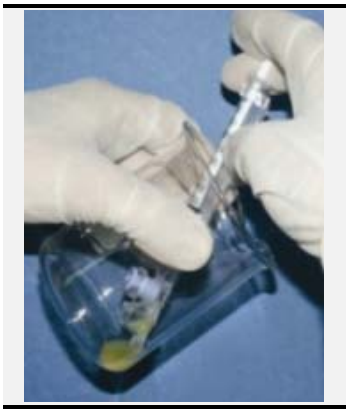


Figure 1

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

Filling the capillary:

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

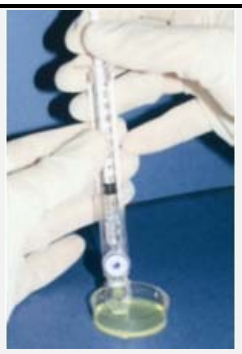


Figure 2

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

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

Figure 3 Inspect for bubbles

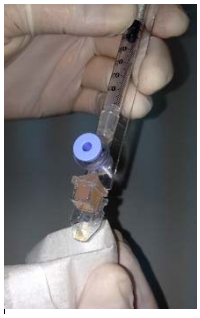


Figure 4 Wipe the tip

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

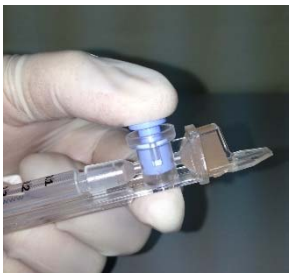


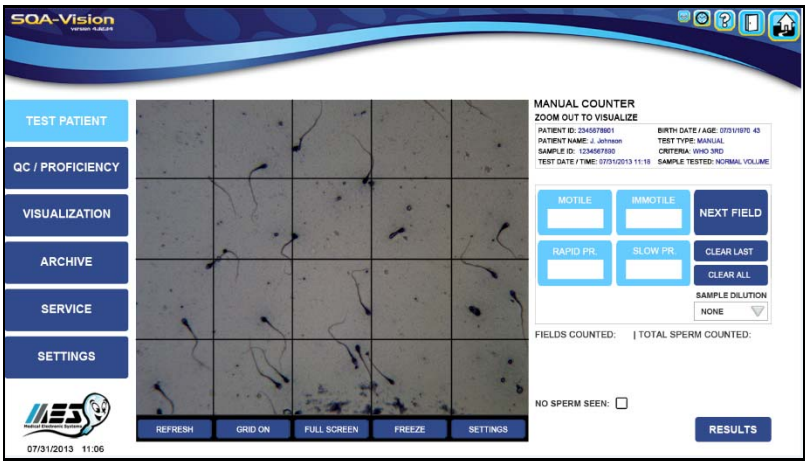
Figure 5 Push-in the piston

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

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

Appendix 4: Using the SQA-Vision Visualization System

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



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

Appendix 5: SQA-Vision Cleaning Instructions

When to clean:

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

Cleaning kit components:

Blue Dot capillaries (fig 1)
Sponge-tipped drying capillaries (fig 2)
Cleaning brush - wooden-handled (fig 4)
Cleaning fluid

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

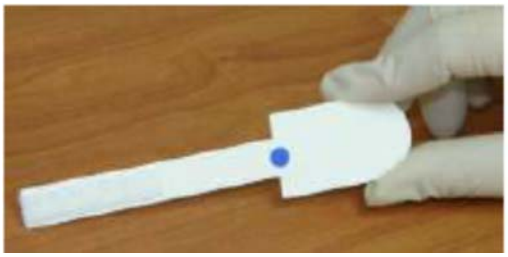


Figure 1

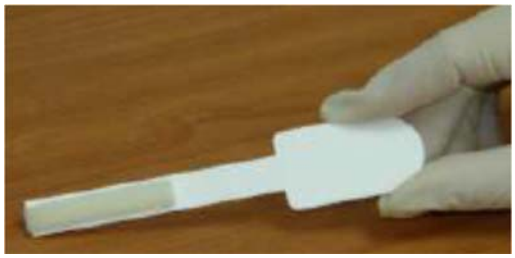


Figure 2

CLEANING: STEP 1

1. Use a **BLUE DOT** fibrous material capillary (fig 1)
   - Moisten with **ONE** drop of cleaning fluid, shaking off excess fluid.
   - Insert into the measurement compartment - fibrous material facing up and **BLUE DOT** down. Move back and forth a few times. Repeat with the material facing down.
2. Use a sponge-tipped drying capillary to dry the same compartment (fig 3). Insert the sponge and hold for a few seconds. Then, withdraw the sponge tip. Do not go back and forth more than 2 times.

Figure 3

Figure 4

CLEANING: STEP 2

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

Figure 5

Appendix 6: Sample Mixing, Semen Liquefaction, and Viscosity

BACKGROUND:

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

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

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

Box 2.3 Thorough mixing of semen

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

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

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

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

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

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

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

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

Appendix 7: Testing Sperm Samples at Room Temperature

BACKGROUND:

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

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

OVERVIEW:

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

INSTRUCTIONS:

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

MANUFACTURER’S RECOMMENDATION:

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

APPROVAL AND REVIEW

PREPARED BY: _____

DATE: _____

DISCIPLINE DIRECTOR APPROVAL: _____

DATE: _____

DEPARTMENTAL DIRECTOR (or DESIGNEE) APPROVAL (at site): _____

DATE: _____

IMPLEMENTATION DATE (at site): _____

SUPERSEDES SOP DATED: _____

DATE SOP RETIRED (at site): _____

DEPARTMENTAL DIRECTOR (OR DESIGNEE) ANNUAL REVIEW:

SIGNATURE	TITLE	DATE

TECHNICAL BULLETIN: SAMPLE MIXING, SEMEN LIQUEFACTION, AND VISCOSITY

For SQA-V GOLD, QwikCheck GOLD and SQA-Vision Systems | Wednesday, January 14th, 2015

BACKGROUND:

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

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

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

Box 2.3 Thorough mixing of semen

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

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

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

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

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

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

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

Washing Low (Decreased) Viscosity Semen Samples:

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

TECHNICAL BULLETIN: TESTING SPERM SAMPLES at ROOM TEMPERATURE

For SQA-V GOLD, QwikCheck GOLD and SQA-Vision Systems | Wednesday, January 14th, 2015

BACKGROUND:

Room temperature is a general term describing common indoor temperatures. It is usually in the range of 20 °C (68 °F or 293 K) to 25 °C (77 °F or 298 K). http://en.wikipedia.org/wiki/Room_temperature

OVERVIEW:

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

INSTRUCTIONS:

The SQA-V GOLD is calibrated at room temperature and has been developed to operate at room temperature conditions, so there is no heating stage on the device. When performing a validation of the SQA-V based on comparing the test results to manual results, the manual results should be performed at room temperature as well.

MANUFACTURER'S RECOMMENDATION:

Clinical laboratories are air conditioned facilities. It is therefore recommended to maintain the room temperature of the lab in the range of 20 °C (68 °F or 293 K) to 25 °C (77 °F or 298 K). In addition Semen Samples should be at room temperature at the time of testing. Samples should not be pre-heated or incubated prior to testing on the SQA-V.

MEDICAL ELECTRONIC SYSTEMS
5757 W. Century Blvd. Suite 805
Los Angeles, CA. 90045
"Remember, it ALL Started with a Sperm!"

SQA-VISION Automated Parameter Reference Ranges (WHO 5th Edition)

SEMEN PARAMETER	SQA-V TEST NAME	REFERENCE RANGE*	SOURCE
Sperm Concentration (Count)	SPERM CONC.	≥15 M/ml	WHO 5th manual*
Total Motility (PR+NP)	TOTAL MOTILITY <PR+NP>	≥40 %	WHO 5th manual*
Progressive Motility (PR)	PROG. MOTILITY <PR>	≥32 %	WHO 5th manual*
Non-progressive Motility (NP)	NONPROG. MOTILITY <NP>	N/A	N/A
Immotility (IM)	IMMOTILITY <IM>	N/A	N/A
Sperm Morphology (normal forms, %)	MORPH. NORM FORMS, WHO 5th	≥4%	WHO 5th manual*
Motile Sperm Concentration	MSC	≥6 M/ml	MES*
Progressively Motile Sperm Concentration	PMSC	≥5 M/ml	MES*
Functional Sperm Concentration	FSC	N/A	N/A
Velocity (Average path velocity – VAP)	VELOCITY	≥5 mic./sec.	MES*
Sperm Motility Index	SMI	≥80	MES*
Total Sperm Number	SPERM #	≥39 M	WHO 5th manual*
Total Motile Sperm	MOT. SPERM	≥16 M	MES*
Total Progressively Motile Sperm	PROG. SPERM	≥12 M	MES*
Total Functional Sperm	FUNC. SPERM	N/A	N/A
Total Morphologically Normal Sperm	MORPH. NORM. SPERM	≥2 M	MES*

*** The ranges established above are based on WHO 5th reference values or MES (for proprietary semen parameters).**

MEDICAL ELECTRONIC SYSTEMS
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Los Angeles, CA. 90045
"Remember, it ALL Started with a Sperm!"

SQA-VISION Automated Results Defined (WHO 5th Edition)

SEMEN PARAMETER	SQA-V TEST NAME	DEFINITION
Sperm Concentration (Count)	SPERM CONC.	Total number for sperm cells per milliliter of sample – this includes live and dead cells.
Total Motility (PR+NP)	TOTAL MOTILITY <PR+NP>	The % of sperm moving in the sample. This includes progressive and non-progressive.
Progressive Motility (PR)	PROG. MOTILITY <PR>	The % of sperm that are moving in a "forwardly progressive" manner.
Non-progressive Motility (NP)	NONPROG. MOTILITY <NP>	The % of sperm that are moving without any forward progression or vigor.
Immotility (IM)	IMMOTILITY <IM>	The % of sperm that are not moving at all and appear completely still
Sperm Morphology (normal forms, %)	MORPH. NORM FORMS, WHO 5th	The % of normal sperm based on WHO 5th edition (Kruger Strict) criteria.
Motile Sperm Concentration	MSC	The total number of motile cells per milliliter of sample (MSC ÷ Count = % motile)
Progressively Motile Sperm Concentration	PMSC	The total number of progressively motile cells per milliliter of sample
Functional Sperm Concentration	FSC	The number of sperm that are progressively motile and morphologically normal ("champs")
Velocity (Average path velocity – VAP)	VELOCITY	Average speed of the progressively motile sperm – measured in microns per second.
Sperm Motility Index	SMI	A "quick reference" parameter developed by MES. Anything over 80 = a good sample.
Total Sperm Number	SPERM #	This is the total number of sperm in the sample (sperm concentration x volume)
Total Motile Sperm	MOT. SPERM	This is the total number of motile sperm in the sample (MSC x volume)
Total Progressively Motile Sperm	PROG. SPERM	This is the total number of progressive sperm in the sample (PMSC x volume)
Total Functional Sperm	FUNC. SPERM	This is the total number of functional sperm in the sample (FSC x volume)
Total Morphologically Normal Sperm	MORPH. NORM. SPERM	This is the total number of morphologically normal sperm in the sample.

SAFETY DATA SHEET

Section 1: Identification	
Product identifier	SQA-V, SQA-Vision and SQA II Cleaning Kit
Product number	0113; 0115; 0121; 0116; 0625; 0117; PEB-A-00597-00
Manufacturer/supplier	Medical Electronic Systems 5757 West Century Blvd. Suite #805, Los Angeles, CA 90045 Tel: 310 670-9066 Fax: 310 670-9069 Web: www.mes-global.com
Recommended use	The SQA-V, SQA-Vision and SQA II Cleaning Kits are intended for both routine and contamination cleaning of the labeled devices.
Section 2: Hazard(s) Identification	
Classification of the substance or mixture	**Classification according to Regulation (EC) No 1272/2008** Flammable liquids (Category 2), H225 **Classification according to EU Directives 67/548/EEC or 1999/45/EC** F, Highly flammable, R11
Label elements	**Labeling according Regulation (EC) No 1272/2008**  Pictogram Signal word: Danger **Hazard statement(s)** H225: Highly flammable liquid and vapor. **Precautionary statement(s)** P210: Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Supplemental Hazard Statements: none
Other hazards	None
Section 3: Composition/Information of Ingredients	
Mixtures	• Ethanol (CAS No.64-17-5) - 50% • Tween 20 (CAS No.9005-64-5) - 0.5%

Section 4: First-Aid Measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.
Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
Eyes: Rinse thoroughly with a copious amount of water for at least 15 minutes and consult a physician.
Skin: Wash off with soap and a copious amount of water. Consult a physician.
Ingestion: Do NOT induce vomiting. Rinse mouth with water – only if the person is conscious. Consult a physician.
Most important symptoms and effects, both acute and delayed: Refer to the labeling (see Section 2 and/or section 11).

Section 5: Fire-Fighting Measures

Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture: No data available.
Advice for firefighters: Wear self contained breathing apparatus for fire-fighting if necessary.
Further information: Use water spray to cool unopened containers.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas. For personal protection see section 8.
Environmental precautions: Do not let product enter drains.
Methods and materials for containment and cleaning up: Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations.

Section 7: Handling and Storage

Precautions for safe handling: Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Keep away from sources of ignition - No smoking. Take measures to prevent the build-up of electrostatic charge. For precautions see section 2.
Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place.

Section 8: Exposure Controls/Personal Protection

Exposure controls
General industrial hygiene practice.

Personal protective equipment
Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Body Protection: Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure: Do not let product enter drains.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties
a) Appearance Form: liquid, clear, colorless
b) Odor: no data available
c) Odor Threshold: no data available
d) pH: no data available
e) Melting point/freezing point: no data available
f) Initial boiling point and boiling range: no data available
g) Flash point: no data available
h) Evaporation rate: no data available
i) Flammability (solid, gas): no data available
j) Upper/lower flammability or explosive limits: no data available
k) Vapor pressure: no data available
l) Vapor density: no data available
m) Relative density: no data available
n) Water solubility: no data available
o) Partition coefficient: n-octanol/water: no data available
p) Auto-ignition temperature: no data available
q) Decomposition temperature: no data available
r) Viscosity: no data available
s) Explosive properties: no data available
t) Oxidizing properties: no data available

Other safety information: no data available

Section 10: Stability and Reactivity

Reactivity: no data available
Chemical stability: stable under recommended storage conditions.
Possibility of hazardous reactions: no data available
Conditions to avoid: Heat, flames and sparks. Extremes of temperature and direct sunlight.
Incompatible materials: Alkali metals, Oxidizing agents, Peroxides
Hazardous decomposition products: no data available
Other decomposition products: no data available
In the event of fire: see Section 5

Section 11: Toxicological Information

Information on toxicological effects
Acute toxicity LD50
Oral - Rat - 7.060 mg/kg
Remarks: Lungs, Thorax, or Respiration: Other changes.
LC50 Inhalation - Rat - 10 h - 20000 ppm
Skin corrosion/irritation
Skin - Rabbit
Result: No skin irritation - 24 h
(OECD Test Guideline 404)
Serious eye damage/eye irritation
Eyes - Rabbit
Result: Mild eye irritation - 24 h
(OECD Test Guideline 405)
Respiratory or skin sensitization: No data available
Germ cell mutagenicity: No data available
Carcinogenicity
Carcinogenicity - Mouse - Oral
Tumorigenic: Equivocal tumorigenic agent by RTECS criteria.
Liver: Tumors. Blood: Lymphomas including Hodgkin's disease.
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity
Reproductive toxicity - Human - female - Oral Effects on Newborn: Apgar score (human only).
Effects on Newborn: Other neonatal measures or effects.
Effects on Newborn: Drug dependence.
Specific target organ toxicity - single exposure: No data available
Specific target organ toxicity - repeated exposure: No data available
Aspiration hazard: No data available
Additional Information RTECS: KQ6300000
Central nervous system depression, narcosis, Damage to the heart.
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

All information presented above is correct to the best of our knowledge and Medical Electronic Systems does not claim that the information is all-inclusive but recommends that it should be used as a guide. Medical Electronic Systems shall not be held liable for any damage resulting from handling or from contact with the product.

MES Product (Articles) Exempt from SDS Requirements

Background:

Products that are manufactured or fabricated into an "article" typically are whole units that do not and cannot pose a risk in that they cannot be ingested, inhaled, or absorbed into the body through the skin, eyes, or mucous membranes under normal conditions of use. As such, these products are exempt from the SDS requirements.

According to 29 CFR 1910.1200 (c), the OSHA defines an article as "...a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

Exempt Articles:

The following products manufactured by Medical Electronic Systems (MES) are considered to be "articles" as specified by the Hazard Communication Standard and are therefore exempt from the requirements of the Standard according to the Occupational Safety and Health Administration (OSHA):

- SQA Vision
- SQA-V
- SQA-Vp
- SQA-Vb
- SQA-Vt
- SQA-Ve
- SQA IIC-P
- QwikCheck GOLD Sperm Analyzer
- QwikCheck GOLD Pig
- QwikCheck GOLD Bull
- QwikCheck GOLD Equine
- SQA-V capillaries
- SQA IIC-P capillaries
- SQA Vision Fixed Coverslip Slides

SAFETY DATA SHEET

Section 1: Identification

Product Identifier	QwikCheck™ beads
Product Number	0200
Manufacturer/supplier	Medical Electronic Systems 5757 West Century Blvd. Suite #805, Los Angeles, CA 90045 Tel: 310 670-9066 Fax: 310 670-9069 Web: www.mes-global.com
Recommended use	QwikCheck™ beads is an in-vitro use only external quality control material for automated and manual sperm counting systems. QwikCheck™ beads cannot be used to perform positive quality control for motility or correct for technician errors or faulty equipment.

Section 2: Hazard Identification

Classification of the substance or mixture

Contains highly diluted Sodium Azid.

Classification according to Regulation (EC) No 1272/2008
Acute toxicity, Oral (Category 4), H302
Chronic aquatic toxicity (Category 3), H412
For the full text of the H-Statements mentioned in this Section, see Section 12.

Classification according to EU Directives 67/548/EEC or 1999/45/EC
Xn Harmful R21/22
R52/53
For the full text of the R-phrases mentioned in this Section, see Section 12.

Label elements

Labeling according Regulation (EC) No 1272/2008

Pictogram: 
Signal word: Warning
Hazard statement(s):
H302: Harmful if swallowed.
H412: Harmful to aquatic life with long lasting effects.
Precautionary statement(s):
P273: Avoid release to the environment.
Supplemental Hazard Statements: none

According to European Directive 67/548/EEC as amended
Hazard symbol(s): Xn Harmful

R-phrase(s):
R21/22: Harmful in contact with skin and if swallowed.
R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S-phrase(s):
S36/37: Wear suitable protective clothing and gloves.
S61: Avoid release to the environment. Refer to special instructions/ Safety data sheets

Section 3: Composition/Information on Ingredients

Mixtures

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component	Classification	Concentration
Sodium Azide, CAS # 26628-22-8	Acute Tox. 2; Acute Tox. 1; Aquatic Acute 1; Aquatic Chronic 1; H300 + H310, H410, EUH032	<1%

Hazardous ingredients according to Directive 1999/45/EC

Component	Classification	Concentration
Sodium Azide, CAS # 26628-22-8	T+, N, R27 - R28 - R32 - R50/53	<1%

For the full text of the H-Statements and R-Phrases mentioned in this Section, see Section 12. The specific chemical identity of ingredients and/or exact percentage of composition is withheld as a trade secret.

Section 4: First-Aid Measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.
Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Consult a physician.
Eyes: In case of contact, flush eyes immediately with copious amounts of water. Seek medical attention if symptoms occur.
Skin: Wash with soap and water after each contact. Seek medical attention if symptoms occur.
Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Most important symptoms and effects, both acute and delayed: Described in the labeling (see Section 2) and/or in section 11.

Section 5: Fire-Fighting Measures

Extinguishing media: Suitable extinguishing media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture: No data available.
Advice for firefighters: Wear self contained breathing apparatus for fire-fighting if necessary.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. For personal protection see section 8.
Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Do not discharge into environment.
Methods and materials for containment and cleaning up: Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for safe handling: Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. For precautions see section 2.
Good laboratory practices should be followed, hand protection with gloves, clothing protection with laboratory coat - routine lab protection.
Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place.

Section 8: Exposure Controls/Personal Protection

Exposure controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment
Eye/face protection: Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Full contact Material: Nitrile rubber. Minimum layer thickness: 0,11 mm Break through time: 480 min Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)
Splash contact Material: Nitrile rubber. Minimum layer thickness: 0,11 mm. Break through time: 480 min. Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M). Data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374 If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.
Body Protection: Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure: If safe, prevent further leakage/spillage. Do not let product enter drains or be discharged into the environment.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

- Appearance Form: liquid
- Odor/Odor Threshold: no data available
- pH / Viscosity: no data available
- Melting point/freezing point / Initial boiling point and boiling range: no data available
- Flash point: no data available
- Evaporation rate: no data available
- Flammability (solid, gas)/Upper/lower flammability or explosive limits: no data available
- Vapor pressure/density: no data available
- Relative density: ~1,00 g/mL at 20 °C
- Water solubility / Partition coefficient: n-octanol/water: no data available
- Auto-ignition temperature: no data available
- Decomposition temperature: no data available
- Explosive/Oxidizing properties: no data available

Section 10: Stability and Reactivity

Reactivity: no data available
Chemical stability: Stable under recommended storage conditions.
Possibility of hazardous reactions: no data available
Conditions to avoid: no data available
Incompatible materials: Heavy metals may form extremely explosive azides.
Hazardous decomposition products: Hazardous decomposition products formed under fire conditions. Nature of decomposition products not known.
Other decomposition products: no data available
In the event of fire: see section 5

Section 11: Toxicological Information

Information on toxicological effects
Acute toxicity: no data available
Skin corrosion/irritation: no data available
Serious eye damage/eye irritation: no data available
Respiratory or skin sensitisation: no data available
Germ cell mutagenicity: no data available
Carcinogenicity IARC: No component of this product present at levels ≥1% is identified as probable, possible or a confirmed human carcinogen by IARC.
Reproductive toxicity: no data available
Specific target organ toxicity - single exposure: no data available
Specific target organ toxicity - repeated exposure: no data available
Aspiration hazard: no data available
Additional Information RTECS: Not available
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Section 12: Additional Comments

To prevent build-up of metal azids reagents should be discarded into appropriate sewage disposal containers/systems diluted with volumes of water.

Full text of H-Statements referred to under sections 2 and 3:
Acute Tox.: Acute toxicity
Aquatic Acute: Acute aquatic toxicity
Aquatic Chronic: Chronic aquatic toxicity
EUH032: Contact with acids liberates very toxic gas.
H300 + H310: Fatal if swallowed or in contact with skin
H302: Harmful if swallowed.
H410: Very toxic to aquatic life with long lasting effects.
H412: Harmful to aquatic life with long lasting effects.

Full text of R-phrases referred to under sections 2 and 3:
N: Dangerous for the environment
R21/22: Harmful in contact with skin and if swallowed.
R27: Very toxic in contact with skin.
R28: Very toxic if swallowed.
T+: Very toxic R32 Contact with acids liberates very toxic gas. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

All information presented above is correct to the best of our knowledge and Medical Electronic Systems does not claim that the information is all-inclusive but recommends that it should be used as a guide. Medical Electronic Systems shall not be held liable for any damage resulting from handling or from contact with the product.

Medical Electronic Systems
www.mes-global.com

SAFETY DATA SHEET

Section 1: Identification

Product identifier	QwikCheck™ Dilution Kit
Product number	0800
Manufacturer/supplier	Medical Electronic Systems 5757 West Century Blvd. Suite #805, Los Angeles, CA 90045 Tel: 310 670-9066 Fax: 310 670-9069 Web: www.mes-global.com
Recommended use	The QwikCheck™ Dilution kit is used to dilute semen prior to automated or manual semen testing, when indicated. It is also used for sample preparation. The dilution media is Earle's balanced salt solution which contains ingredients known to support sperm motility and viability. It is recommended by WHO for semen sample preparation (WHO 2010, 5th edition manual, page 163). The product is intended for in vitro use only.

Section 2: Hazard(s) Identification

Classification of the substance or mixture	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.
Label elements	**Labeling according Regulation (EC) No 1272/2008** Pictogram: none Signal word: none Hazard statement(s): none Precautionary statement(s): none Supplemental Hazard Statements: none Safety data sheet available on request. **According to European Directive 67/548/EEC as amended** Hazard symbol(s): none R-phrase(s): none S-phrase(s): none Safety data sheet available on request for professional users.
Other hazards	None

Section 3: Composition/Information of Ingredients

Mixtures

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component	Classification	Concentration
Calcium chloride dihydrate CAS-No. 10035-04-8	Skin Irrit. 2; Eye Irrit. 2; H315, H319	<10%

Hazardous ingredients according to Directive 1999/45/EC

Component	Classification	Concentration
Calcium chloride dihydrate CAS-No. 10035-04-8	Xi, R36	<10%

Section 4: First-Aid Measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.
Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Consult a physician.
Eyes: In case of contact, flush eyes immediately with copious amounts of water. Seek medical attention if symptoms occur.
Skin: Wash with soap and water after each contact. Seek medical attention if symptoms occur.
Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Most important symptoms and effects, both acute and delayed: Described in the labeling (see Section 2) and/or in section 11.

Section 5: Fire-Fighting Measures

Extinguishing media: Suitable extinguishing media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture: No data available.
Advice for firefighters: Wear self contained breathing apparatus for fire-fighting if necessary.
Further information: No data available.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Ensure adequate ventilation. For personal protection see section 8.
Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.
Methods and materials for containment and cleaning up: Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for safe handling: For precautions see section 2.

Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place. Stable and show no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20^{0}C to +37^{0}C.

Section 8: Exposure Controls/Personal Protection

Exposure controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment
Eye/face protection: Face shield and safety glasses.
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Body Protection: Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure: Do not let product enter drains. Discharge into the environment must be avoided.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

- Appearance Form: liquid
- Odor/Odor Threshold: no data available
- pH: no data available
- Melting point/freezing point: no data available
- Initial boiling point and boiling range: no data available
- Flash point: no data available
- Evaporation rate: no data available
- Flammability (solid, gas): no data available
- Upper/lower flammability or explosive limits: no data available
- Vapor pressure/density: no data available
- Relative density: no data available
- Water solubility: no data available
- Partition coefficient: n-octanol/water: no data available
- Auto-ignition temperature: no data available
- Decomposition temperature: no data available
- Viscosity: no data available
- Explosive/Oxidizing properties: no data available

Section 10: Stability and Reactivity

Reactivity: no data available
Chemical stability: stable under recommended storage conditions.
Possibility of hazardous reactions/conditions to avoid: no data available
Incompatible materials: strong oxidizing agents
Hazardous decomposition products: no data available
Other decomposition products: no data available
In the event of fire: see section 5

Section 11: Toxicological Information

Information on toxicological effects
Acute toxicity: no data available
Skin corrosion/irritation: no data available
Serious eye damage/eye irritation: no data available
Respiratory or skin sensitization: no data available
Germ cell mutagenicity: no data available
Carcinogenicity IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity: no data available
Specific target organ toxicity - single exposure: no data available
Specific target organ toxicity - repeated exposure: no data available
Aspiration hazard: no data available
Additional Information RTECS: not available
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Section 12: Additional Comments

Full text of H-Statements referred to under sections 2 and 3
Eye Irrit.: Eye irritation
H315: Causes skin irritation.
H319: Causes serious eye irritation.
Skin Irrit.: Skin irritation

Full text of R-phrases referred to under sections 2 and 3
Xi: Irritant
R36: Irritating to eyes

All information presented above is correct to the best of our knowledge and Medical Electronic Systems does not claim that the information is all-inclusive but recommends that it should be used as a guide. Medical Electronic Systems shall not be held liable for any damage resulting from handling or from contact with the product.

SAFETY DATA SHEET

Section 1: Identification

Product identifier	QwikCheck™ Liquefaction Kit
Product number	0900
Manufacturer/supplier	Medical Electronic Systems 5757 West Century Blvd. Suite #805, Los Angeles, CA 90045 Tel: 310 670-9066 Fax: 310 670-9069 E-mail: support @mes-ltd.com Web: www.mes-global.com
Recommended use	The QwikCheck™ Liquefaction Kit is used to accelerate the liquefaction of viscous semen samples in order to prepare them for automated or manual semen analysis. Samples that remain viscous 30 minutes or more after collection may not be accurately analyzed for sperm motility and concentration. For in-vitro use only.

Section 2: Hazard(s) Identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
Eye irritation: (Category 2), H319
Specific target organ toxicity - single exposure: (Category 3), H335
Skin irritation: (Category 2), H315
Respiratory sensitization: (Category 1), H334
For the full text of the H-Statements mentioned in this Section, see Section 12.

Classification according to EU Directives 67/548/EEC or 1999/45/EC
Xi, Irritant, R36/37/38, R42
For the full text of the R-phrases mentioned in this Section, see Section 12.

Label elements

Labeling according Regulation (EC) No 1272/2008

Pictogram 
Signal word: Danger

Hazard statement(s)
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.

Precautionary statement(s)
P261 Avoid breathing dust.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.
Supplemental Hazard Statements: none

Other hazards: None

Section 3: Composition/Information of Ingredients

Mixtures

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component	Classification	Concentration
Chymotrypsin CAS-No. 9004-07-3	Skin Irrit. 2; Eye Irrit. 2; Resp. Sens. 1; STOT SE 3; H315, H319, H334, H335	<=100%

Hazardous ingredients according to Directive 1999/45/EC

Component	Classification	Concentration
Chymotrypsin CAS-No. 9004-07-3	Xn, R36/37/38 - R42	<=100%

Section 4: First-Aid Measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.
Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Consult a physician.
Eyes: Flush eyes immediately with copious amounts of water. Seek medical attention if symptoms occur.
Skin: Wash with soap and water after each contact. Seek medical attention if symptoms occur.
Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Most important symptoms and effects, both acute and delayed: Described in the labeling (see Section 2) and/or in section 11.

Section 5: Fire-Fighting Measures

Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture: No data available.
Advice for firefighters: Wear self contained breathing apparatus for fire-fighting if necessary.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid breathing dust. Ensure adequate ventilation. For personal protection see section 8.
Environmental precautions: Use and dispose of without creating dust. Do not let product enter drains. Avoid discharging material into the environment.
Methods and materials for containment and cleaning up: Use and dispose of without creating dust. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for safe handling: Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.
Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place. Stable and show no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20^{0}C to +37^{0}C.

Section 8: Exposure Controls/Personal Protection

Exposure controls
Appropriate engineering controls. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment
Eye/face protection: Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Body Protection: Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure: Do not let product enter drains. Discharge into the environment must be avoided.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

- Appearance Form: powder, lyophilized
- Odor/Odor Threshold: no data available
- pH: no data available
- Melting point/freezing point: no data available
- Initial boiling point and boiling range: no data available
- Flash point: no data available
- Evaporation rate: no data available
- Flammability (solid, gas): no data available
- Upper/lower flammability or explosive limits: no data available
- Vapor pressure/density: no data available
- Relative density: no data available
- Water solubility: no data available
- Partition coefficient: n-octanol/water: no data available
- Auto-ignition temperature: no data available
- Decomposition temperature: no data available
- Viscosity: no data available
- Explosive properties: no data available
- Oxidizing properties: no data available

Section 10: Stability and Reactivity

Reactivity: no data available
Chemical stability: stable under recommended storage conditions.
Possibility of hazardous reactions: no data available
Conditions to avoid: no data available
Incompatible materials: strong oxidizing agents
Hazardous decomposition products: no data available
Other decomposition products: no data available
In the event of fire: see Section 5

Section 11: Toxicological Information

Information on toxicological effects
Acute toxicity: LD50
Oral - rat: > 4.000 mg/kg
Inhalation: no data available
Skin corrosion/irritation: no data available
Serious eye damage/eye irritation: no data available
Respiratory or skin sensitization: no data available
Germ cell mutagenicity: no data available
Carcinogenicity IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity: no data available
Specific target organ toxicity - single exposure: may cause respiratory irritation.
Specific target organ toxicity - repeated exposure: no data available
Aspiration hazard: no data available
Additional Information:
RTECS: GC3050000
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Section 12 Additional Comments

Full text of H-Statements referred to under sections 2 and 3
Eye Irrit.: Eye irritation
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335: May cause respiratory irritation.
Resp. Sens.: Respiratory sensitization
Skin Irrit.: Skin irritation
STOT SE: Specific target organ toxicity - single exposure

Full text of R-phrases referred to under sections 2 and 3
Xn: Harmful
R36/37/38: Irritating to eyes, respiratory system and skin
R42: May cause sensitization by inhalation.

All information presented above is correct to the best of our knowledge and Medical Electronic Systems does not claim that the information is all-inclusive but recommends that it should be used as a guide. Medical Electronic Systems shall not be held liable for any damage resulting from handling or from contact with the product.

SAFETY DATA SHEET

Section 1: Identification	
Product identifier	QwikCheck™ Test Strips
Product number	0700
Manufacturer/supplier	Medical Electronic Systems 5757 West Century Blvd. Suite #805, Los Angeles, CA 90045 Tel: 310 670-9066 Fax: 310 670-9069 Web: www.mes-global.com
Recommended use	QwikCheck™ Test Strips are for in vitro diagnostic use for the determination of pH and leukocytes (WBCs) in semen. The test is semi-quantitative.
Section 2: Hazard Identification	
Classification of the substance or mixture	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This product is not classified as dangerous according to Directive 67/548/EEC.
Label elements	The product does not need to be labeled in accordance with EC directives or respective national laws.
Other hazards	None
Section 3: Composition/Information on Ingredients	
Mixtures	Buffered salts, enzymes, pH indicators on plastic strips. Other components either non-hazardous or at concentrations below that requiring hazardous listing

Section 4: First-Aid Measures

Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration.
Eyes: Flush eyes with water as a precaution.
Skin: Wash with soap and water after each contact.
Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed:
The most important known symptoms and effects are described in the labeling (see Section 2) and/or in section 11.

Section 5: Fire-Fighting Measures

Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture: carbon oxides, hydrogen bromide gas.
Advice for firefighters: Wear self contained breathing apparatus for fire-fighting if necessary.
Further information: No data available.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. For personal protection see section 8.
Environmental precautions: Do not let product enter drains.
Methods and materials for containment and cleaning up: Pick up. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for safe handling: Normal measures for preventive fire protection. For precautions see section 2.
Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place. Stable and show no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20^{0}C to +37^{0}C.

Section 8: Exposure Controls/Personal Protection

Exposure controls: General industrial hygiene practice.

Personal protective equipment:
Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Body Protection: Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: Respiratory protection is not required.
Control of environmental exposure: Do not let product enter drains.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

- Appearance Form: solid
- Odor/Odor Threshold: no data available
- pH: no data available
- Melting point/freezing point: no data available
- Initial boiling point and boiling range: no data available
- Flash point: no data available
- Evaporation rate: no data available
- Flammability (solid, gas): no data available
- Upper/lower flammability or explosive limits: no data available
- Vapor pressure/density: no data available
- Relative density: no data available
- Water solubility: no data available
- Partition coefficient: n-octanol/water: no data available
- Auto-ignition temperature: no data available
- Decomposition temperature: no data available
- Viscosity: no data available
- Explosive properties: no data available
- Oxidizing properties: no data available

Section 10: Stability and Reactivity

Reactivity: no data available
Chemical stability: stable under recommended storage conditions.
Possibility of hazardous reactions: no data available
Conditions to avoid: no data available
Incompatible materials: strong oxidizing agents
Hazardous decomposition products: no data available
Other decomposition products: no data available
In the event of fire: see Section 5

Section 11: Toxicological Information

Information on toxicological effects
Acute toxicity: no data available
Skin corrosion/irritation: no data available
Serious eye damage/eye irritation: no data available
Respiratory or skin sensitisation: no data available
Germ cell mutagenicity: no data available
Carcinogenicity IARC: No component of this product present at levels ≥ 0.1% is identified as a probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity: no data available
Specific target organ toxicity - single exposure: no data available
Specific target organ toxicity - repeated exposure: no data available
Aspiration hazard: no data available
Additional Information: RTECS: LM5800000
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

All information presented above is correct to the best of our knowledge and Medical Electronic Systems does not claim that the information is all-inclusive but recommends that it should be used as a guide. Medical Electronic Systems shall not be held liable for any damage resulting from handling or from contact with the product.

SAFETY DATA SHEET

Section 1: Identification

Product Identifier	SQA-V Validation and Training Kit
Product Number	ACA-00691-00
Manufacturer/supplier	Medical Electronic Systems 5757 West Century Blvd. Suite #805, Los Angeles, CA 90045 Tel: 310 670-9066 Fax: 310 670-9069 Web: www.mes-global.com
Recommended use	The SQA Validation and Training Kit is an in-vitro use only material for SQA-V and SQA Vision validation and user training. The SQA-V Validation and Training Kit cannot be used to perform positive quality control for motility or correct for technician errors or faulty equipment.

Section 2: Hazard Identification

Classification of the substance or mixture

Contains highly diluted Sodium Azid.

Classification according to Regulation (EC) No 1272/2008
Acute toxicity, Oral (Category 4), H302
Chronic aquatic toxicity (Category 3), H412
For the full text of the H-Statements mentioned in this Section, see Section 12.

Classification according to EU Directives 67/548/EEC or 1999/45/EC
Xn Harmful R21/22
R52/53
For the full text of the R-phrases mentioned in this Section, see Section 12.

Label elements

Labeling according Regulation (EC) No 1272/2008

Pictogram: 
Signal word: Warning
Hazard statement(s):
H302: Harmful if swallowed.
H412: Harmful to aquatic life with long lasting effects.
Precautionary statement(s):
P273: Avoid release to the environment.
Supplemental Hazard Statements: none

According to European Directive 67/548/EEC as amended
Hazard symbol(s): Xn Harmful

R-phrase(s):
R21/22: Harmful in contact with skin and if swallowed.
R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S-phrase(s):
S36/37: Wear suitable protective clothing and gloves.
S61: Avoid release to the environment. Refer to special instructions/ Safety data sheets

Section 3: Composition/Information on Ingredients

Mixtures

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component	Classification	Concentration
Sodium Azide, CAS # 26628-22-8	Acute Tox. 2; Acute Tox. 1; Aquatic Acute 1; Aquatic Chronic 1; H300 + H310, H410, EUH032	<1%

Hazardous ingredients according to Directive 1999/45/EC

Component	Classification	Concentration
Sodium Azide, CAS # 26628-22-8	T+, N, R27 - R28 - R32 - R50/53	<1%

For the full text of the H-Statements and R-Phrases mentioned in this Section, see Section 12. The specific chemical identity of ingredients and/or exact percentage of composition is withheld as a trade secret.

Section 4: First-Aid Measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.
Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Consult a physician.
Eyes: In case of contact, flush eyes immediately with copious amounts of water. Seek medical attention if symptoms occur.
Skin: Wash with soap and water after each contact. Seek medical attention if symptoms occur.
Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Most important symptoms and effects, both acute and delayed: Described in the labeling (see Section 2) and/or in section 11.

Section 5: Fire-Fighting Measures

Extinguishing media: Suitable extinguishing media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture: No data available.
Advice for firefighters: Wear self contained breathing apparatus for fire-fighting if necessary.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. For personal protection see section 8.
Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Do not discharge into environment.
Methods and materials for containment and cleaning up: Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for safe handling: Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. For precautions see section 2.
Good laboratory practices should be followed, hand protection with gloves, clothing protection with laboratory coat - routine lab protection.
Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place.

Section 8: Exposure Controls/Personal Protection

Exposure controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment
Eye/face protection: Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Full contact Material: Nitrile rubber. Minimum layer thickness: 0,11 mm Break through time: 480 min Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)
Splash contact Material: Nitrile rubber. Minimum layer thickness: 0,11 mm. Break through time: 480 min. Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M). Data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374 If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.
Body Protection: Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure: If safe, prevent further leakage/spillage. Do not let product enter drains or be discharged into the environment.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

- Appearance Form: liquid
- Odor/Odor Threshold: no data available
- pH / Viscosity: no data available
- Melting point/freezing point / Initial boiling point and boiling range: no data available
- Flash point: no data available
- Evaporation rate: no data available
- Flammability (solid, gas)/Upper/lower flammability or explosive limits: no data available
- Vapor pressure/density: no data available
- Relative density: ~1,00 g/mL at 20 °C
- Water solubility / Partition coefficient: n-octanol/water: no data available
- Auto-ignition temperature: no data available
- Decomposition temperature: no data available
- Explosive/Oxidizing properties: no data available

Section 10: Stability and Reactivity

Reactivity: no data available
Chemical stability: Stable under recommended storage conditions.
Possibility of hazardous reactions: no data available
Conditions to avoid: no data available
Incompatible materials: Heavy metals may form extremely explosive azides.
Hazardous decomposition products: Hazardous decomposition products formed under fire conditions. Nature of decomposition products not known.
Other decomposition products: no data available
In the event of fire: see section 5

Section 11: Toxicological Information

Information on toxicological effects
Acute toxicity: no data available
Skin corrosion/irritation: no data available
Serious eye damage/eye irritation: no data available
Respiratory or skin sensitisation: no data available
Germ cell mutagenicity: no data available
Carcinogenicity IARC: No component of this product present at levels ≥1% is identified as probable, possible or a confirmed human carcinogen by IARC.
Reproductive toxicity: no data available
Specific target organ toxicity - single exposure: no data available
Specific target organ toxicity - repeated exposure: no data available
Aspiration hazard: no data available
Additional Information RTECS: Not available
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Section 12: Additional Comments

To prevent build-up of metal azids reagents should be discarded into appropriate sewage disposal containers/systems diluted with volumes of water.

Full text of H-Statements referred to under sections 2 and 3:
Acute Tox.: Acute toxicity
Aquatic Acute: Acute aquatic toxicity
Aquatic Chronic: Chronic aquatic toxicity
EUH032: Contact with acids liberates very toxic gas.
H300 + H310: Fatal if swallowed or in contact with skin
H302: Harmful if swallowed.
H410: Very toxic to aquatic life with long lasting effects.
H412: Harmful to aquatic life with long lasting effects.

Full text of R-phrases referred to under sections 2 and 3:
N: Dangerous for the environment
R21/22: Harmful in contact with skin and if swallowed.
R27: Very toxic in contact with skin.
R28: Very toxic if swallowed.
T+: Very toxic R32 Contact with acids liberates very toxic gas. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

All information presented above is correct to the best of our knowledge and Medical Electronic Systems does not claim that the information is all-inclusive but recommends that it should be used as a guide. Medical Electronic Systems shall not be held liable for any damage resulting from handling or from contact with the product.

SAFETY DATA SHEET

Section 1: Identification	
Product identifier	QwikCheck™ Vitality Kit
Product number	A-CA-01057-00
Manufacturer/supplier	Medical Electronic Systems 5757 West Century Blvd. Suite #805, Los Angeles, CA 90045 Tel: 310 670-9066 Fax: 310 670-9069 Web: www.mes-global.com
Recommended use	The QwikCheck™ Vitality kit is used to assess the percentage of live spermatozoa in a semen sample. The product is intended for in vitro use only. The kit does not assess sperm motility.
Section 2: Hazard Identification	
Classification of the substance or mixture	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This product is not classified as dangerous according to Directive 67/548/EEC.
Label elements	The product does not need to be labeled in accordance with EC directives or respective national laws.
Other hazards	None
Section 3: Composition/Information of Ingredients	
Mixtures	• Eosin Y (Sigma-Aldrich, catalog # 119830-25g, CAS # 17372-87-1) - 0.5% • NaCl (Sigma-Aldrich, catalog # S5886-500g, CAS # 7647-14-5) - 0.9%

Section 4: First-Aid Measures

Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration.
Eyes: Flush eyes with water as a precaution.
Skin: Wash with soap and water after each contact.
Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed:
The most important known symptoms and effects are described in the labeling (see Section 2) and/or in section 11.

Section 5: Fire-Fighting Measures

Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture: Carbon oxides, hydrogen bromide gas.
Advice for firefighters: Wear self contained breathing apparatus for fire-fighting if necessary.
Further information: No data available.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Avoid breathing vapours, mist or gas. For personal protection see section 8.
Environmental precautions: Do not let product enter drains.
Methods and materials for containment and cleaning up: Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for safe handling: Appropriate exhaust ventilation. Normal measures for preventive fire protection. For precautions see section 2.
Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place. Stable and show no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20^{0}C to +37^{0}C.

Section 8: Exposure Controls/Personal Protection

Exposure controls: General industrial hygiene practice.

Personal protective equipment
Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards (NIOSH (US) or EN 166(EU).
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Body Protection: Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: Respiratory protection is not required.
Control of environmental exposure: Do not let product enter drains.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

- Appearance Form: liquid
- Odor/Odor Threshold: no data available
- pH: no data available
- Melting point/freezing point: no data available
- Initial boiling point and boiling range: no data available
- Flash point: no data available
- Evaporation rate: no data available
- Flammability (solid, gas): no data available
- Upper/lower flammability or explosive limits: no data available
- Vapor pressure/density: no data available
- Relative density: no data available
- Water solubility: no data available
- Partition coefficient: n-octanol/water: no data available
- Auto-ignition temperature: no data available
- Decomposition temperature: no data available
- Viscosity: no data available
- Explosive properties: no data available
- Oxidizing properties: no data available

Section 10: Stability and Reactivity

Reactivity: no data available
Chemical stability: stable under recommended storage conditions.
Possibility of hazardous reactions: no data available
Conditions to avoid: no data available
Incompatible materials: strong oxidizing agents
Hazardous decomposition products: no data available
Other decomposition products: no data available
In the event of fire: see Section 5

Section 11: Toxicological Information

Information on toxicological effects
Acute toxicity: no data available
Skin corrosion/irritation: no data available
Serious eye damage/eye irritation: no data available
Respiratory or skin sensitisation: no data available
Germ cell mutagenicity: no data available
Carcinogenicity IARC: No component of this product present at levels ≥ 0.1% is identified as probable, possible or a confirmed human carcinogen by IARC.
Reproductive toxicity: no data available
Specific target organ toxicity - single exposure: no data available
Specific target organ toxicity - repeated exposure: no data available
Aspiration hazard: no data available
Additional Information: RTECS: LM5800000
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

All information presented above is correct to the best of our knowledge and Medical Electronic Systems does not claim that the information is all-inclusive but recommends that it should be used as a guide. Medical Electronic Systems shall not be held liable for any damage resulting from handling or from contact with the product.