MEDICAL ELECTRONIC SYSTEMS
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"Remember, it ALL Started with a Sperm!"
www.mes-global.com

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