Technical Release Bulletin

SQA-V & QwikCheck Gold Sperm Analyzer Motility/Morphology Quality Control

(SQA-V software version 2.43 through 2.49; Gold QwikCheck Gold Sperm Analyzer software versions 1.00)

Re-Issue date: December 1st, 2011

Background: Organizations providing semen analysis proficiency testing/QC 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 cover sperm concentration but do not address motility or morphology due to natural limitations associated with shipping and testing live samples.

Response: In order to insure that the SQA-V is providing high quality and consistent test results and that the laboratory is maintaining appropriate proficiency, MES has established three independent motility/morphology quality control systems:

1. **Auto Calibration and Self-Test**
2. **QwikCheck Quality Control Material (zero level lower limit detection)**
3. **Annual Motility/Morphology user validation**

AUTO CALIBRATION AND SELF-TEST: An electronic testing process that is initiated each time the SQA-V is turned on and before each test:

- Modulated analog signals are generated by the SQA-V. These signals are similar to ones detected during a sample test when spermatozoa cross the SQA-V light beam in the thin section of the SQA-V capillary.
- The same motility and morphology algorithm used for converting electronic signals into clinical test results is used in this electronic simulation of motility and morphology.
- If the SQA-V Self-Test simulation reports a reading that exceeds the allowable range, the system will report FAILED SELF-TEST and will not allow a test to be run. Corrective action instructions are displayed on the SQA-V screen.
- When the system passes its Auto-Calibration and Self-Test a “Service Parameters” report can be printed automatically and kept on file to prove system preparedness and compliance.

EXTERNAL QUALITY CONTROL: QwikCheck™ Beads are an assayed external quality control for testing Concentration and zero level Motility (manufactured by Medical Electronic Systems – www.mes-global.com):

- The Negative Control level of the QwikCheck™ Bead kit provides verification that the SQA-V is not reporting false positive readings for both concentration and motility (MSC) when their level = 0.
- Running and printing out the control results show the motility lower limit detection accuracy and proficiency.
- In combination with the system Auto-Calibration and Self-Test from step one above, this lower level detection QC can be used to prove system accuracy and user proficiency in operation.

ROUTINE MINI-VALIDATION: Twice per year, MES recommends that all users run a motility and morphology “mini-validation” to confirm system precision and user proficiency (running the SQA-V and performing their manual backup method):

- Twice per year it is recommended that the user perform a detailed Precision test using live semen samples to ensure system accuracy and user proficiency.
- Please follow the instructions in document: “Motility/Morphology Precision Instructions” to complete this mini-validation.
- It is also suggested (optional) that the user compare at least 5 samples with their alternative method once per year as an additional step to validate the SQA-V Gold’s accuracy as compared to the backup method.

In conjunction with the Auto-Calibration, Self-Test, and External Daily QC this routine mini-validation proves system function, precision and user proficiency for routine Motility and Morphology on the SQA-V Gold.

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