Technical Release Bulletin
SQA-V/Vision & QwikCheck Gold Sperm Analyzer Quality Controls

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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 are for testing only sperm concentration. Motility and morphology challenges currently require a live semen sample which is too complex to deliver and the target values are not standardized between labs (Exception: IVF Australia Proficiency challenge).

Response: In order to ensure that the automated sperm analyzer is providing high quality and consistent test results and that the laboratory is maintaining appropriate proficiency, MES has established four independent concentration/motility/morphology quality control systems:

1. **Autocalibration and Self-Test**
2. **QwikCheck Quality Control Material (including zero level lower limit motility detection)**
3. **Calibration Parameter Confirmation**
4. **Routine Concentration, Motility and Morphology analyzer validation**

AUTOCALIBRATION AND SELF-TEST: An electronic testing process that is initiated each time the analyzer is activated.

- Modulated analog signals are generated by the system. These signals are similar to signals detected during actual semen testing (when spermatozoa cross the instrument light beam in the thin section of the SQA testing 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 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 screen.
- When the SQA passes Auto-Calibration and Self-Test, a “Service Parameters” report can be printed 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):

- Three concentration levels are provided in a kit.
- The Negative Control level of the QwikCheck™ Beads kit verifies that the SQA is not reporting false positive readings for both concentration and motility (MSC) at level = 0.
- A printed report of the control results will demonstrate the accuracy of the system and the operator’s proficiency

CALIBRATION PARAMETER CONFIRMATION

Once or twice per year, the Self-Test data of the SQA can be sent to MES for calibration verification. Based on a comparison of the initial analyzer calibration data maintained by the manufacturer (MES) and the current self-test data, the status of the SQA calibration can be evaluated.

CONCENTRATION, MOTILITY AND MORPHOLOGY VALIDATION ON THE SQA ANALYZER

Based on CLIA regulations and MES recommendation, it is advisable to run the **QwikCheck Beads Validation and Training kit** that verifies:

- Linearity and Reportable Range
- Precision – Replication & Detection Limit
- Accuracy

MES also recommends that the SQA is validated semi-annually using the **QwikCheck Beads Precision and Linearity kit** to verify:

- Linearity and Reportable Range
- Precision and Lower Limit Detection
- Concentration Accuracy

In addition and in coordination with the QwikCheck Beads kit testing, MES recommends assessing fresh semen concentration, motility and morphology to confirm the SQA accuracy and user proficiency. The following is a protocol for running the automated analyzer and comparing the results to manual analysis (back-up method):

- Run, in duplicate, 10 fresh semen samples on the SQA; 5 should be low motility (<40%) and 5 normal motility (>=40%) range.
- In parallel assess, in duplicate, the concentration, motility and morphology of the same samples under the microscope per WHO 5th edition manual guidelines.
- Run samples at room temperature within a 2 minute timeframe between the two methods (manual morphology can be assessed > 2 minutes following the laboratory protocol for manual morphology assessment).
- Compare the automated and manual results (Can be sent to MES for statistical evaluation).

In conjunction with the Auto-Calibration, Self-Test, External Daily QC, Calibration Parameter Confirmation and running Validation kits, this routine mini-validation proves system function, accuracy and user proficiency for Concentration, Motility and Morphology.

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