Technical Release Bulletin
Stabilized Sperm Proficiency Challenge for LOW LEVEL Target Values
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Background: The need for external quality control schemes for confirming diagnostic procedures/equipment is of utmost importance. A number of multicentre studies on semen quality confirm this fact (1, 2). Quality control materials are best suited when they closely replicate the actual material being tested. However, due to the biological nature of semen, providing external quality control materials presents a challenge. Semen is motile for a relatively short period of time and the sample degenerates quickly. Semen samples prepared by proficiency/quality control organizations are based on adding a fixative media to the donor semen samples. As a result, the original nature of the fresh semen is distorted. In addition, there can be significant batch-to-batch variations in the proficiency challenge sample matrix. This causes problems running such samples in the SQA-V - especially at the low end of concentration.

Matrix and Spermatozoa Modification by Fixative Materials

Stabilized sperm is made from a fresh semen sample. This fixative process impacts the original semen sample as described below:

- The spermatozoa are shrunk because of fixation which causes a change to their size and shape.
- The seminal plasma is diluted with a fixative or completely replaced with a media causing a decrease in the sample viscosity. The SQA-V algorithm works based on the optical density of SEMINAL PLASMA (not the dilution media or modified "seminal plasma" used in stabilized sperm).
- A decrease in sample viscosity and density results in rapid cell sedimentation and uneven distribution of the cells throughout the volume of the sample. These factors may result in inconsistent concentration of cells in the samples received by the labs and in the aliquots taken for analysis. The sample tested may no longer reflect the target value established by the manufacturer.

All of these facts will adversely impact the accuracy of automated testing **especially in low concentration samples because the prepared quality control material is not the same as a normal semen sample**. The SQA-V is designed to run semen samples within one hour of collection and the concentration dynamic range of the SQA-V is 2 M/ml on the low end. Therefore, running a quality control sample of very low quality on the SQA-V, may result in a ZERO reading.

Running Low Level Stabilized Sperm Samples on the SQA-V GOLD System

If a stabilized sperm sample run on the SQA-V GOLD in the stabilized sperm Quality Control mode results in ZERO (beyond 2 M/ml dynamic range), re-run the sample in the **Fresh** mode as outlined below:

- Turn on the SQA-V GOLD system and wait until auto-calibration/self-testing is completed.
- Go to: MAIN MENU>TEST NEW PATIENT and enter:
  - PATIENT ID: **Sample #**
  - BIRTH DATE: **Test date**
- From the next screen select:
  - SAMPLE TYPE: **FRESH**
  - WBC CONC: **< 1 M/ml**
  - Select "**Yes**" when asked "**IS SAMPLE VOLUME SUFFICIENT FOR COMPLETE RESTING >= .5 ml?**"
- Vortex the stabilized sperm sample.
- Transfer the sample from the original vial to the 10-ml collection cup and mark it with the sample #.
- Mix the sample thoroughly and immediately fill the SQA-V capillary and run the test.

References

1. WHO laboratory manual for the examination and processing of human semen - 5th ed., *World Health Organization, 2010*.
2. Auger J. *et al.* Intra- and inter-individual variability in human sperm concentration, motility and vitality assessment during a workshop involving ten laboratories, *Human Reproduction, 2000, Vol. 15, Issue11, pp. 2360-2368.*

Dr. Lev Rabinovitch, CTO MEDICAL ELECTRONIC SYSTEMS

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