Linearity Testing Using the QwikCheck™ Validation and Training Kit

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Overview:

The QwikCheck Validation and Training Kit contains QwikCheck Beads in a variety of concentrations along with instructions for how to run Precision, Accuracy and a Linearity Test on the SQA. Some customers have requested further explanation concerning the methodology of the Linearity Test.

Methodological principles:

The QwikCheck Validation and Training Kit's intended use is to both validate the performance of the SQA device and to train lab operators to accurately prepare and run samples that are sequentially diluted in order to plot a "dilution curve" to establish linearity. When running the QwikCheck Validation and Training kit linearity test on the SQA, with beads (and not with semen), the following methodological points should be taken into consideration:

- The test needs to be run with strict adherence to the product insert instructions and the dilution table provided in the kit.
- The beads should be mixed exactly as specified in the product insert.
- ALL sample dilutions should be made using a high-quality calibrated pipette with new tips for each dilution.
- After filling the capillary with beads, it should be checked for an absence of air bubbles.
- The expiration date of the kit should be followed – do not run the tests if the kit has expired because the sample solutions may evaporate, and the kit may not report proper results.
- If, after running, some bead material is left in the containers, it cannot be reused for re-running tests.

Kit performance/bead technology:

The SQA technology for assessing concentration is not based on counting cells visually. It is based on the principle of light absorption and proprietary algorithms, which provides very accurate results when used with the SQA testing capillary and SQA device. However, please note that each type of sample will absorb light differently.

The Beads used in the Validation and Training Kit may deviate along the trendline differently than live human sperm. This is expected. Other things that may influence the results along the trend line are sample handling (bead mixing, dilution errors, re-use of testing capillaries, and non-calibrated pipettes).

MES uses beads in the QwikCheck Validation and Training Kit to make it easier to run the difficult tests included in the kit, at a reasonable price point, without using donor semen samples

The Linearity Test will demonstrate:

- Dynamic range of the SQA device: 2-400 M/ml
- Regression coefficient of the dilution curve (R)
- Average coefficient of variation (CV) vs. expected results

In addition, the QwikCheck Validation and Training kit follows the U.S. CLIA regulation that requires a certified lab to validate the SQA based on the manufacturer's requirements. The PASS/FAIL criteria for the linearity test is based on the following requirements:

- CV <= 20%
- R >= 0.9

Irrespective of the individual data point positions vs. the best fit linearity trendline, the SQA validation is categorized as PASS if the CV <= 20% and the R >= 0.9.

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Distribution: All SQA-V and SQA-Vision users upon request