



Technical Release Bulletin for QwikCheck™ beads

Issue date: January 31, 2013

Subject: QwikCheck™ beads compliance

Background

QwikCheck™ beads are an in-vitro use only external quality control material for automated and manual sperm counting systems. The beads are used as a tool to assess the accuracy and precision of the laboratory's sperm counting methods by providing a known target value and +/- range. The beads were developed for use on the SQA-V semen analyzer however, they are also labeled for manual proficiency testing and calibration on hemacytometers such as Neubauer counting chambers, Makler chambers and conventional fixed coverslip chambers.

QwikCheck™ beads are supplied in a kit containing known concentrations of 4-micron latex beads suspended in an aqueous solvent and negative concentration/motility control. According to the CLIA '88 regulations, "...for most moderately complex tests, the general requirement is to analyze two levels of QC materials on each day of testing." It is recommended that QwikCheck™ beads be run on the SQA-V automated and visualization systems prior to each day of semen analysis testing.

QwikCheck™ beads Compliance

QwikCheck™ beads comply with the WHO 3rd, 4th, 5th edition manuals and ASCP recommendations as an external quality control material. Accordingly, the WHO recommends the use of QC samples and procedures for semen analysis as follows:

- **Manufactured QC samples:** Commercially available samples, manufactured and analyzed (assayed) according to manufacturing guidelines.
- **Internal quality control:** Quality tests measuring the variability in a procedure that exists within a laboratory. Such tests evaluate the precision of day-to-day operations. Useful for detecting random variation (assessing precision).
- **In control:** A process is in control when all values are within expected control limits.
- **Out of control:** process is out of control when a measured value exceeds expected control limits, or is within control limits but shows a significant trend in values. A process that is out of control must be evaluated.

Compliance Date: Effective February 1, 2013

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Distribution: All distributors and QwikCheck™ beads users