Technical Release Bulletin for SQA-V/SPERMALITE

(All software releases versions that run QwikCheck™Beads controls)

Issue date: August 17, 2011 Subject: QwikCheck[™]Beads open vial shelf life

Update:

The product insert for QwikCheck[™]Beads controls for the SQA-V and sperm counting chambers has been updated to include OPEN VIAL shelf-life information in compliance with CAP requests. For beads customers who do not yet have this new product insert, this technical bulletin contains the new information.

QwikCheck™Bead product insert revisions:

Section:

For in-vitro use only:

Each kit contains two known concentrations of $\mathbf{QwikCheck^{TM} beads}$ in two 5 ml aliquots and one 5 ml negative concentration and motility control. Store the beads at room temperature (20-25 °C or 65-77° F). The expiration date assumes that $\mathbf{QwikCheck^{TM} beads}$ are stored at room temperature in their original containers and tightly capped to prevent evaporation. Open vial shelf-life (tightly capped and stored in the original container at room temperature or refrigerated @ 5-15°C) is 90 days.

Compliance Date: Effective August 17, 2011 Authority: Marcia Deutsch CEO Distribution: All distributors