Technical Release Bulletin QwikCheck™ Beads Open Vial Shelf Life Issue date: March 26, 2019

Background:

QwikCheck[™] Beads (Medical Electronic Systems) have an open and a closed vial shelf life. This labeling insures accurate results that could be compromised due to bead evaporation over time which can be related to high ambient laboratory temperature and/or infrequent use of the beads.

Storage conditions:

The stability of the QwikCheck[™] Beads control material is highly dependent on maintaining an intact matrix volume. Therefore, storage conditions and timeframes for use after opening are recommended as follows:

- 1. Each kit contains two known concentrations of **QwikCheck[™] Beads** in two 5 ml aliquots and one 5 ml negative concentration and motility control.
- 2. Store unopened bead kits @ 15-30°C (60-86°F).
- 3. After opening for the first time, store @ 15-30°C (60-86°F) for 90 days.
- 4. NO need to refrigerate the material.
- 5. The labeled storage expiration date assumes that **QwikCheck[™] Beads** are stored in their original containers and are tightly capped to prevent evaporation.
- QwikCheck[™] beads are stable and show no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20°C to +37°C (-4°F to +99°F).

Compliance Date: Effective March 26, 2019. Authority: Marina Friling, Clinical Director Distribution: ALL QwikCheck Bead users

