

Technical Release Bulletin
QwikCheck™ Beads Open Vial Shelf Life
Issue date: May 4th 2017

Background:

QwikCheck™ Beads (Medical Electronic Systems) have both an open and a closed vial shelf life. It was found that over time, evaporation of the beads occurs in labs that do not run QC daily after opening a bottle of QwikCheck™ Beads and also in laboratories where the ambient storage temperature is high.

Storage conditions:

The stability of the QwikCheck™ Beads control material is highly dependent on maintaining an intact matrix volume. Therefore, special 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, open vial shelf-life is 90 days @ 2-8°C (36-46°F).
4. Bring vial contents to room temperature before use.
5. The labeled storage expiration date assumes that **QwikCheck™ Beads** are stored in their original containers and tightly capped to prevent evaporation.
6. 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 May 4th, 2017. **Authority:** Dr. Lev Rabinovitch, CTO
Distribution: SQA-Vision, SQA-V, QwikCheck GOLD and QwikCheck™ Beads users.



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