

Technical Release Bulletin: Use of QwikCheck™-Beads SQA-V versions 2.43; 2.45; 2.46 and GOLD

Issue date: December 27, 2007

Subject: QwikCheck-Beads Reuse

Status/Description of failure:

QwikCheck-beads and/or SQA-V testing capillaries are being reused and, as a result, the SQA-V is not reading the beads accurately.

Troubleshooting:

QuickCheck-beads are produced under a strict protocol which insures that a specific concentration of 4 micron sized beads "float" in a suspension. Re-use of the beads or the testing capillaries is **not supported or authorized as an acceptable QC practice** by the manufacturer for the following reasons:

- The 4 micron sized beads adhere to the testing capillary – re-using a testing capillary with beads adhered will overstate the test results and could result in an "out of range" reading.
- A very exact amount of beads are contained in each level of the QwikCheck-beads. Because beads adhere to the plastic testing capillary, not all of the beads will be returned to the QwikCheck-beads bottle and test results may read "out of range" over time.
- Run QwikCheck-beads daily and dispose of both the beads and the testing capillary per laboratory protocol. Running the same beads and the same capillary over more than one day may result in an "out of range" reading because of fluid evaporation.
- According to laboratory practice, a quality control material is to be run in the same way a biological test is run. Re-running a biological sample over many days is not an acceptable practice.
- It may be assumed that the laboratory has a defective SQA-V if the results of the QwikCheck-beads are "out of range" when this is not the case at all.

Recommended Procedure:

- Precisely follow the QwikCheck-beads package insert, User Guide and on-screen instructions for running a QC material.
- Do not re-use QwikCheck-beads or the SQA-V testing capillaries.

Compliance Date: Effective Immediately (19_SEPT_2007)

Authority: Beni Cohen, R&D Director. beni@mes-ltd.com

Distribution: All distributors



www.mes-ltd.com Tel: 972-4-637-3981 Fax: 972-4-637-3984

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