Technical Release Bulletin QwikCheck Beads – Level 2 Low Readings

Issue date: Monday, August 4, 2008

Subject: QwikCheck Beads Lower Level – Batch # 010408003 Expiration date 4/2009

Update:

It appears that some Level 2 QwikCheck Beads are reading lower than the acceptable range: 23 +/- 3.2 (19.8 to 26.2). The manufacturer is investigating this problem to determine what caused the problem. It appears that the beads are reading approximately 15% lower than the labeled range.

If this problem should occur please do the following:

- Allow 23 +/- 5.75 (17.25-28.75) for the acceptable range for Level 2 (Lower Controls) for batch # 010408003.
- Review the following sample handling issues:
 - o Do not re-use testing capillaries
 - \circ Mix controls thoroughly by rotating the bottle, without using a vortex or introducing bubbles into the solution
 - o Right after mixing, withdraw a sample into the testing capillary
 - Do not use the same capillary for testing different levels of beads
 - Do not mix the beads or pour previously opened beads from another bottle into a new bottle of beads.

Please contact your distributor if you have this problem and they will quickly check the SQA-V calibration parameters to insure that the system is within acceptable limits.

Compliance Date: Effective August 4, 2008 Authority: Lev Rabinovich, PhD CTO levr@mes-ltd.com Distribution: Distributors and customers



www.mes-Itd.com Tel: 972-4-637-3981 Fax: 972-4-637-3984 Technical Release SQA-V