

Title: NEGATIVE CONTROL READING POSITIVE

Applies to the following: ALL SQA-V SYSTEMS SN# 850 OR LESS

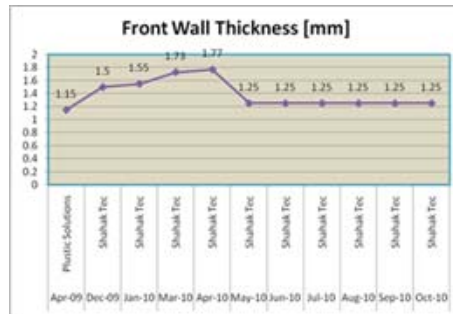
Issue date: December 16, 2010

Problem description:

The QwikCheck Beads NEGATIVE control is reading POSTIVE in SQA-V systems SN# 850 and less.

Explanation of the failure:

1. The problem is related to the FRONT WALL of testing capillaries that were produced by a new vendor in DECEMBER 2009 to MAY 2010 (see graph below concerning the variance. The front wall should be 1.25). The FRONT WALL was slightly thicker than seen on previous vendor capillaries and subsequent batches of new capillaries from the new vendor (after MAY 2010).



2. The FRONT WALL of the testing capillary was not thought to be a critical measurement initially as all capillary batches were tested on newer reference systems in the M.E.S. laboratories (SN# >850) and passed QC testing.
3. The reason for older systems showing problems with the negative control reading positive is that older systems have older optical blocks with slightly different tolerances than the newer system optical blocks. The older blocks are more sensitive to the FRONT WALL thickness.
4. The capillary batches that may have the FRONT WALL issues are described by production date and batch number in the table below.
5. Any remaining inventory of testing capillaries from these batches will be exchanged by M.E.S. at their expense.

Production Date	Batch No
December 2009	4021_081209
January 2010	4021_140110
March 2010	4021_010310 4021_210310
April 2010	4021_210410

Compliance Date: December 15, 2010

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Distribution: US; Europe



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