Technical Release Bulletin: SQA Calibration, Maintenance and Controls

Issue Date: December 30, 2019

BACKGROUND

Before each automated test, the SQA runs three internal calibration verifications to ensure that the device is within acceptable manufacturer calibration ranges. If they are not, the system will not allow a test to be run.

- **Stabilization** – Measures the motility channel signal to verify that it reaches the reference value and is stable at that that value.
- **Autocalibration** – Tests the emission and reception of light that is used in the device to measure the motility and concentration reference values.
- **Self-test** – Checks to see if the Motility and Concentration signals as well as all of the device parameters are within the allowed ranges.

CAUSES of FAILURES

If the internal calibration results do not pass verification, an error message will be displayed on-screen, and the test cannot be run. A failure is generally caused by one of the following:

- The light emission intensity is not within the acceptable range resulting in a deficiency of light absorption by the detectors.
- A faulty detector is not absorbing sufficient light.
- Dirt, debris or dust particles are obstructing the optical channel.

MANUFACTURER'S RECOMMENDATIONS

If a failure occurs in one of the processes defined above, an error message will be displayed on the device and the test cannot be run until the values are brought back to the acceptable range. To bring the calibration parameters back to acceptable range, the following steps can be taken:

1. **Clean the device** (removing dirt, debris, dust particles) following the instructions in the SQA cleaning kit or user manual. Routine cleaning should be implemented after completing the daily testing or before beginning daily testing. Use the manufacturer supplied cleaning kit and clean according to the enclosed cleaning instructions.

   Important note: Cleaning / maintenance does not affect the test results.

2. **Run controls** daily before the daily testing run with QwikCheck Beads, the manufacture's controls for the SQA devices. Running controls before daily testing is sufficient to verify that the SQA is calibrated because the autocalibration processes are automatically run PRIOR to each test and will not allow testing if calibration parameters are out of range.

3. **If the device still fails** internal calibration verification, call for support.

Compliance Date: Effective December 30th 2019 **Authority**: Marcia Deutsch, CEO
Distribution: All SQA users