Technical Release Bulletin

Subject: QwikCheck™ Beads assayed control for the SQA-V; Spermalite: SQA-V GOLD

Background:

Most medical devices require that an external control with a known target value be routinely run on the system for the following reasons:

- **To check the accuracy of the method for reporting test results**
- **To proactively determine if the device has a problem prior to running real samples**
- **To test operator efficiency and accuracy against a known standard**

It is imperative that the operator run a control that is specifically assayed for the device OR to correctly assay a compatible control before testing it on the device for the following reasons:

- **To have confidence that the target values and +/- ranges are correct for the device**
- **To correctly assess the accuracy of the system**
- **To measure Inter and intra operator or device variability**

Overview:

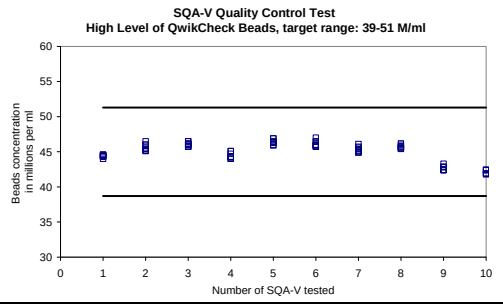
It is recommended by the manufacturer to run QwikCheck™Beads assayed control on the SQA-V for all ROUTINE control testing. The reason for this is that QwikCheck™Beads:

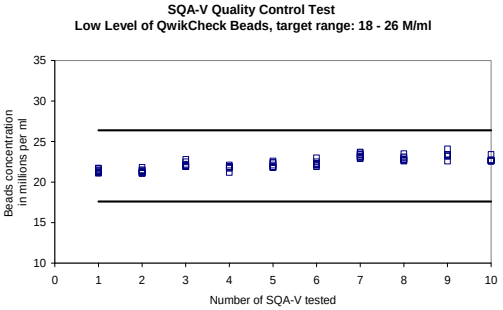
- **Are assayed for the SQA-V and thereby promote operator confidence and accuracy for testing the SQA-V without requiring any additional assaying or risk**
- **Are FDA approved**
- **Will correctly indicate a problem with the SQA-V that can be supported and resolved by the local distributor**
- **Contain a negative, low and high range series of controls that cover the dynamic range of the SQA-V for complete testing**

Testing the SQA-V with QwikCheck™Beads

The tables below demonstrate accuracy and intra/inter device variability of the SQA-V using QwikCheck™Beads:

ACCURACY: HIGH AND LOW LEVEL





PRECISION

SQA-V	QwikCheck Beads	CV, %
Intra-device Variability	High 47± 7.0 M/ml	≤ 1.0
	Low 24 ± 3.4 M/ml	≤ 1.0
	Negative Control	0.0
Inter-device Variability	High 47± 7.0 M/ml	≤ 2.0
	Low 24 ± 3.4 M/ml	≤ 2.0
	Negative Control	0.0