

Clinical Evaluation of the Spermalite™/SQA-V

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INTRODUCTION:

The purpose of this study is to evaluate the performance, reliability, repeatability and accuracy of the new automated sperm quality analyzer, SPERMALITE™ (SQA-V). The SQA-V is a fully automated device that analyzes semen parameters via electro-optical technology, signal conversion and application of proprietary algorithms. The device has a built in video visualization system. The results are compared with conventional microscopic semen examination.

MATERIALS AND METHODS:

The study was conducted at Tel Hashomer (TH) and Ramat-Marpe (RM) Medical Centers in Israel as well as in the laboratories of Medical Electronic Systems, Ltd (MES). 145 samples of all types: Fresh, Washed and Frozen were analyzed after liquefaction. The SQA-V measurement capillary was filled with sample and inserted into the electro-optical measurement chamber of the device. In this electro-optical system, light beams are transmitted through the samples to photo-detectors that translate the information (based on light interruption and absorption) into electrical signals. These electrical signals are detected, digitized and sent to an internal computer that analyzes the data and applies proprietary algorithms, generating test results. Semen samples were concurrently tested microscopically using calibrated Makler chambers according to the WHO 2000 guidelines.

Repeatability was measured on 111 samples by running tests on the same specimen in the SQA-V capillary twice. The double blind study focused on spermatozoa concentration and motility. The High Sensitivity mode of the SQA-V was tested for accuracy reading "absence of motile sperm" vs "presence of motile sperm" (seminal plasma was used to test "absence"). The SQA-V visualization system was compared with the microscope. Raw data and regression/correlation analysis was utilized for statistical evaluation.

RESULTS:

Pearson correlation coefficients for the SQA-V vs. manual TSC, Motility and MSC semen parameters were high. Refer to the table below for the details of the study results by specimen type:

SAMPLE TYPE		SPECIMEN TYPE		
		Fresh	Washed	Frozen
TSC	R =	.93	.95	NA
Motility %	R =	.87	.70	NA
MSC	R =	.98	.93	.79

High Sensitivity Test: Presence or absence of motile sperm cells detected by the SQA-V was compared to visual data. No false positive or false negative results were detected. The high predictive value of this test was demonstrated.

Repeatability: The repeatability of the SQA-V was 93.4% for motility and 97.5% for total sperm concentration.

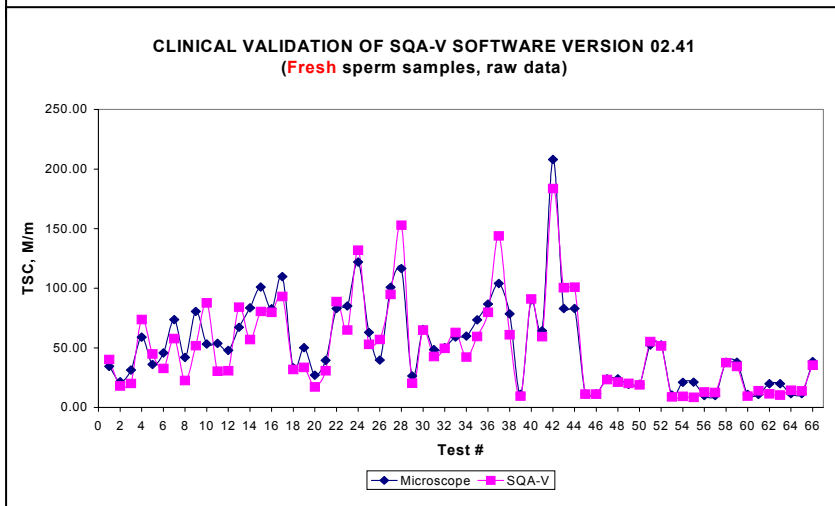
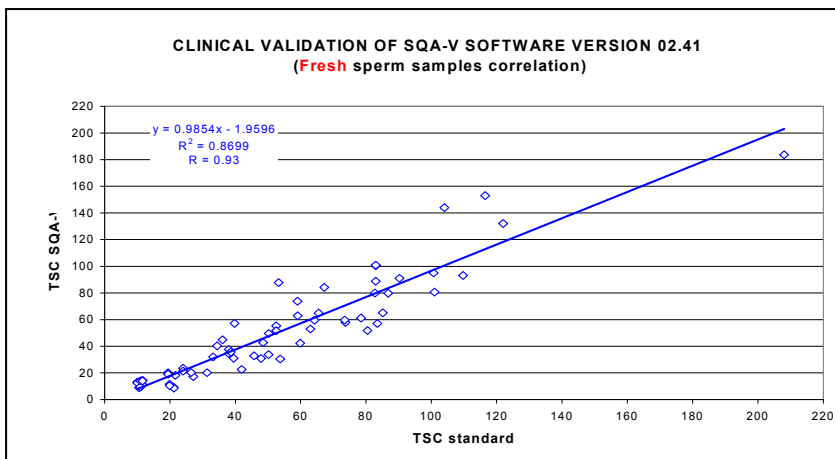
SQA Visualization System: The Pearson correlation coefficient between the SQA-V visualization system and microscope was: TSC R=.88 and motility R=.89. The performance of this system compares very favorably to the microscope.

CONCLUSION:

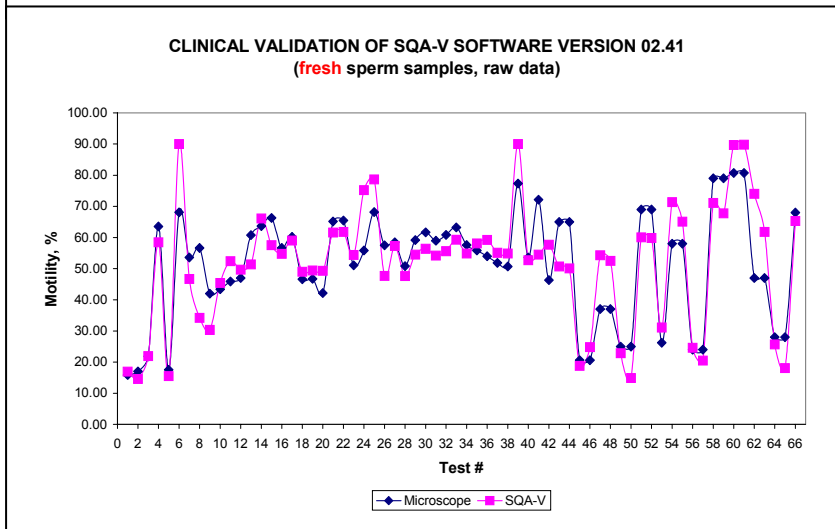
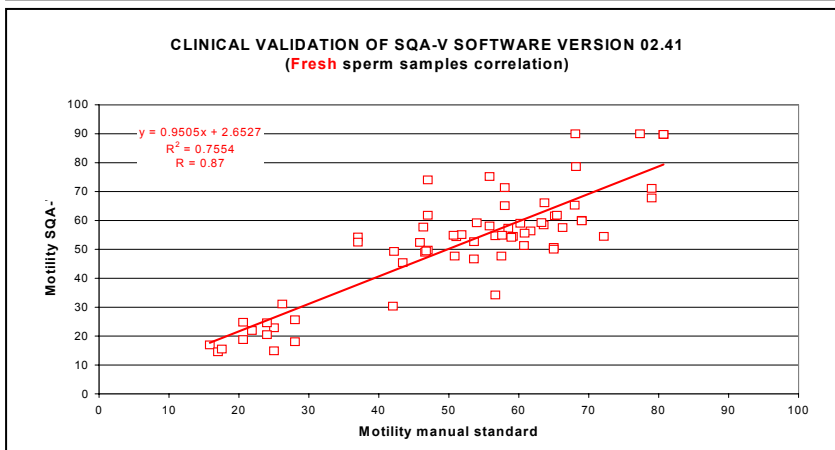
The SPERMALITE™ / SQA-V demonstrated consistent, reliable, accurate and repeatable performance when compared to standard microscopic evaluation methods for all types of specimens. The built-in video system of the device allows smooth variations of optical magnification between x300 and x500 and serves as a useful supplementary tool for visual microscopic evaluation.

GRAPHS: Specimen Type - FRESH

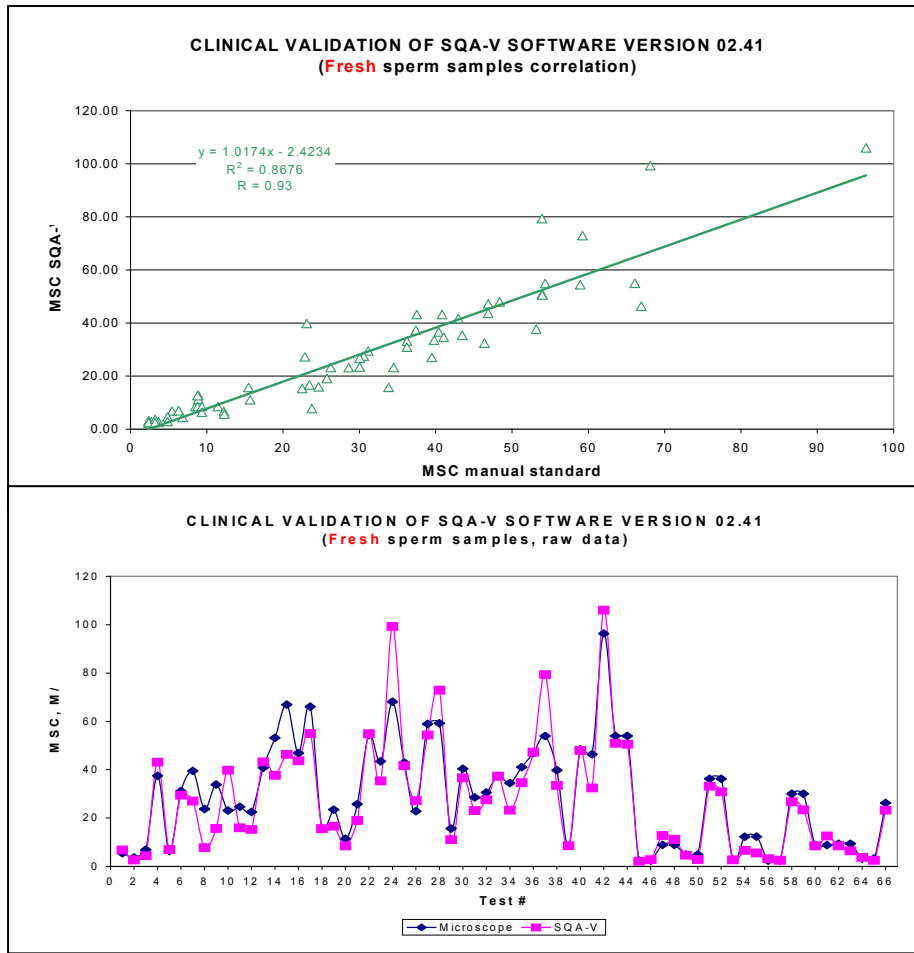
TSC



MOTILITY

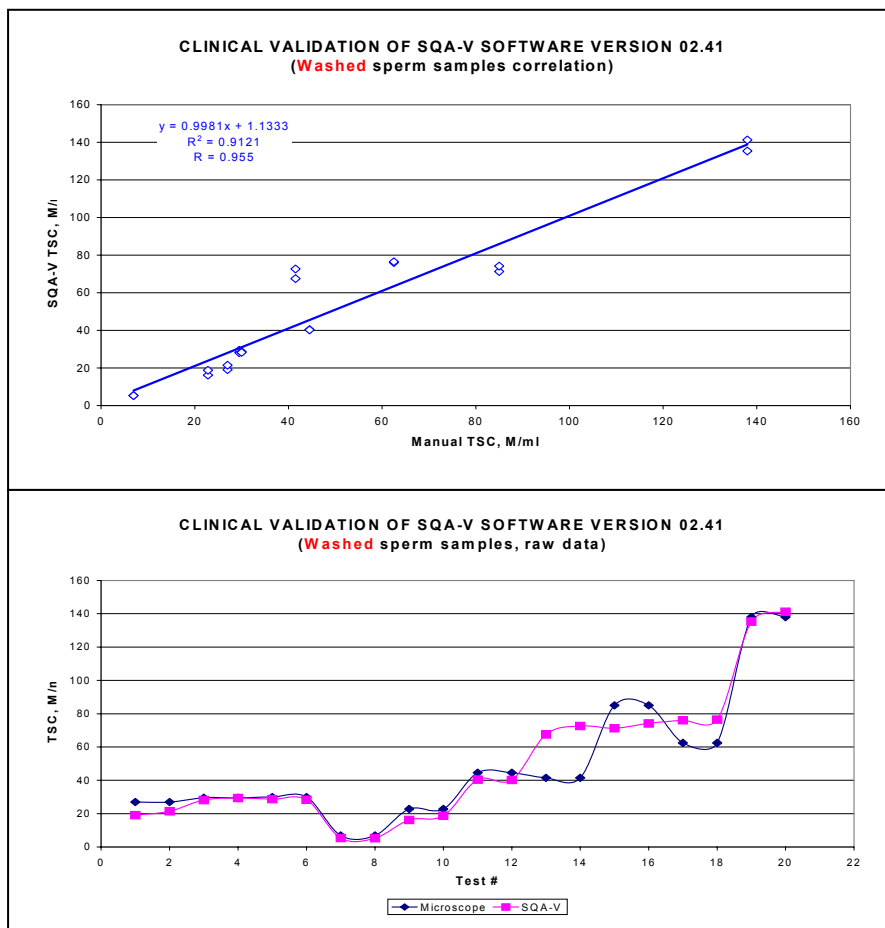


MSC

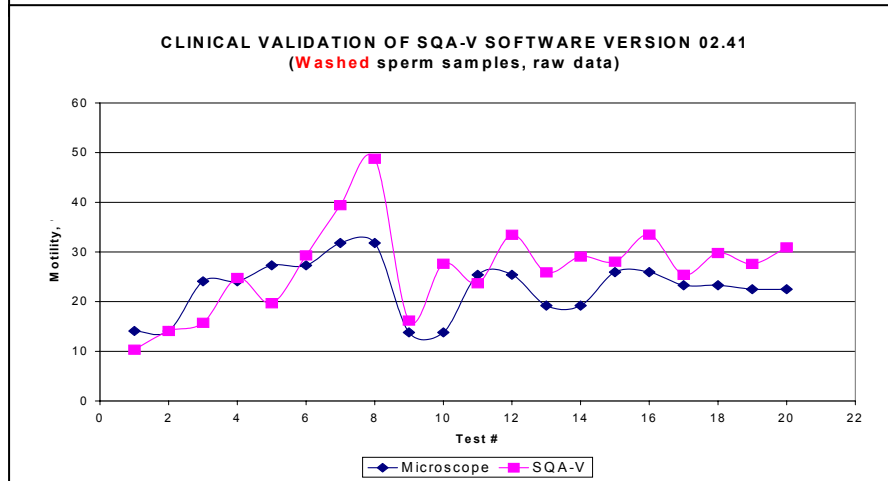
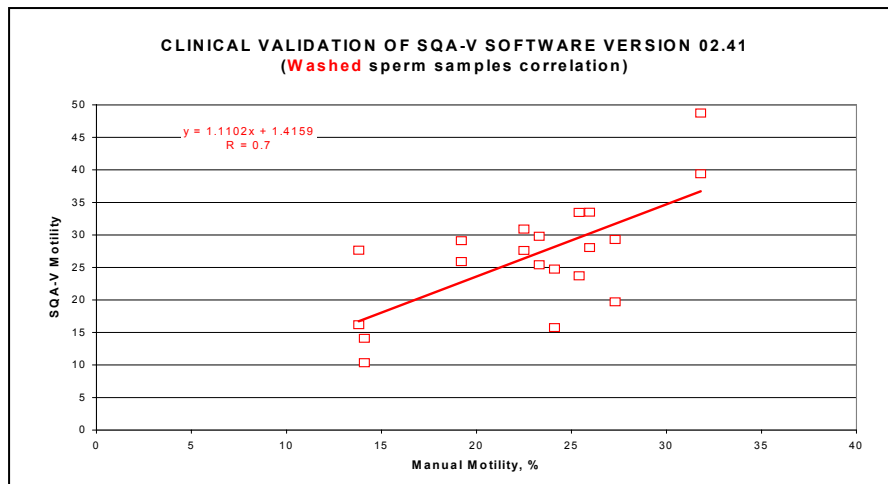


GRAPH: Specimen Type - WASHED

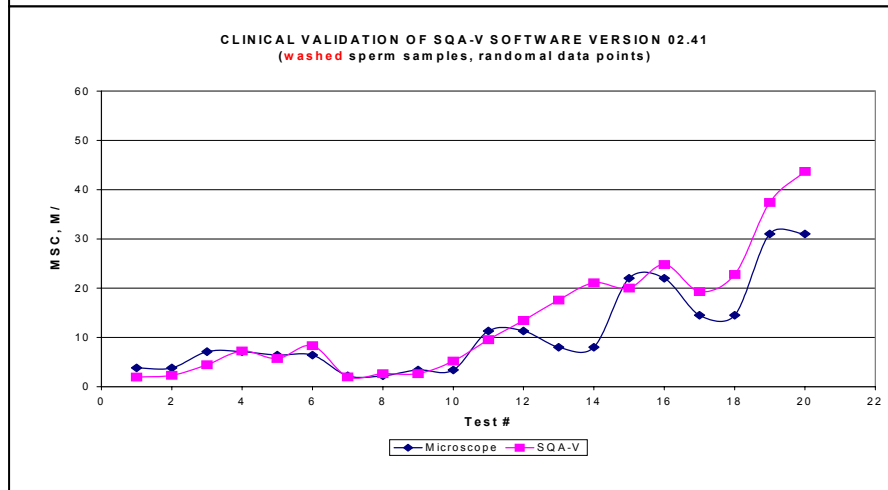
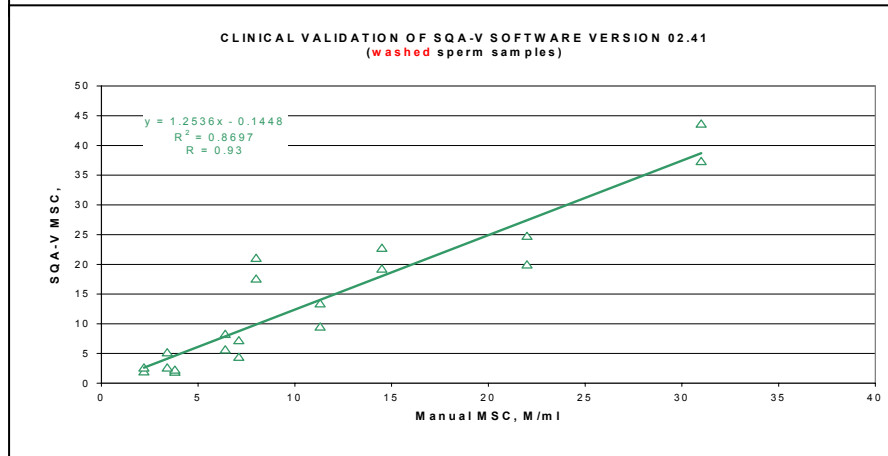
TSC



MOTILITY

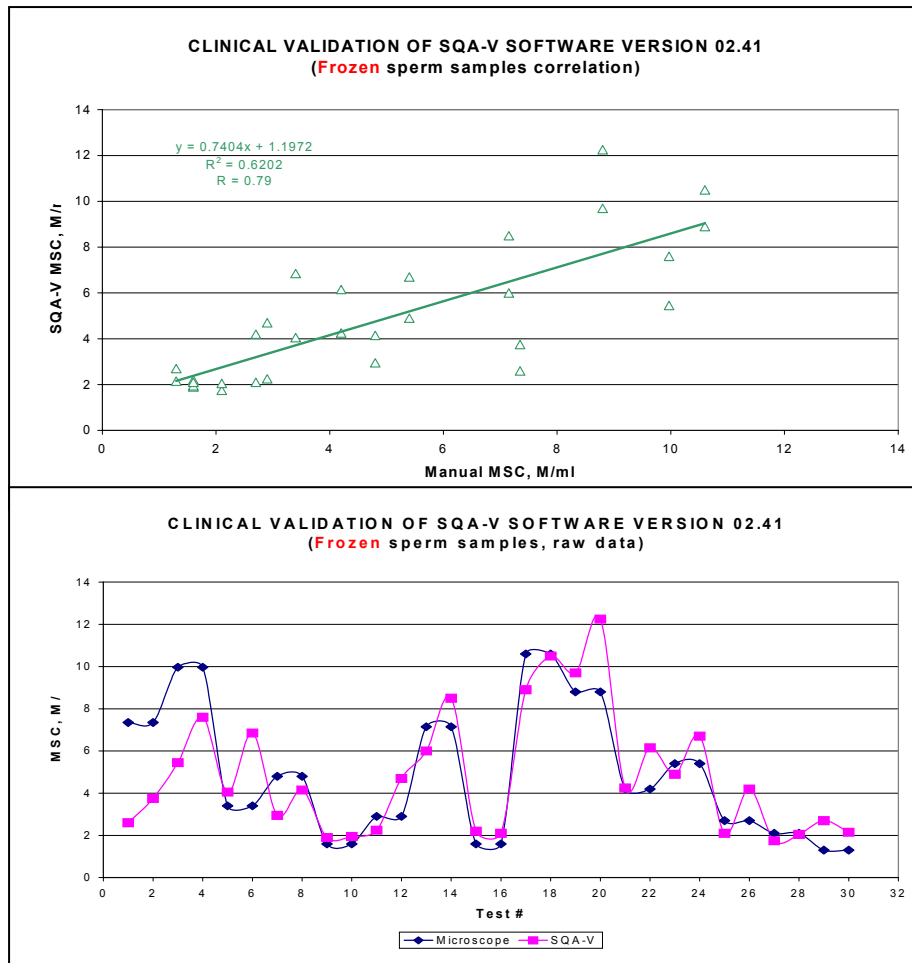


MSC

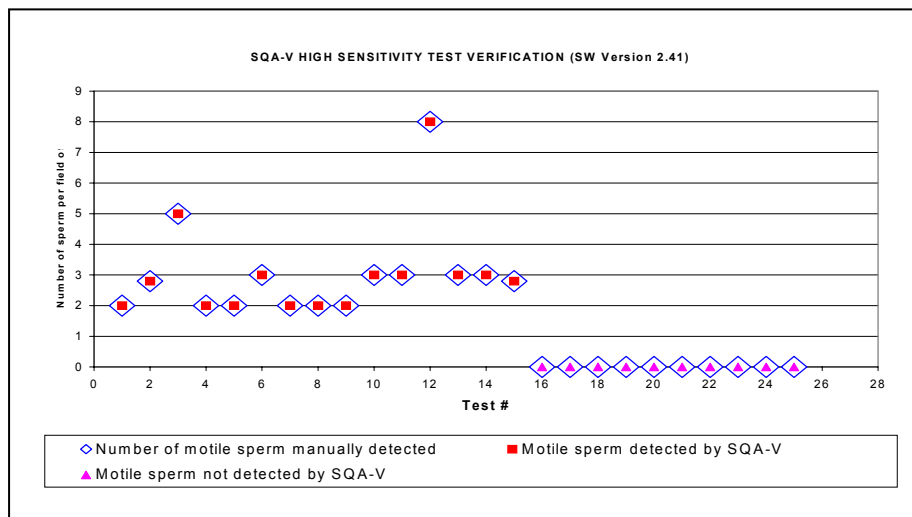


GRAPH: Specimen Type - FROZEN

MSC

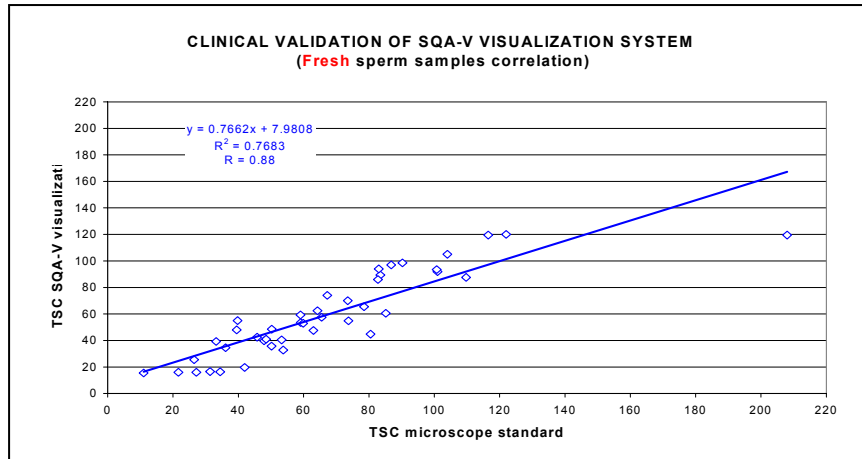


GRAPH: High Sensitivity

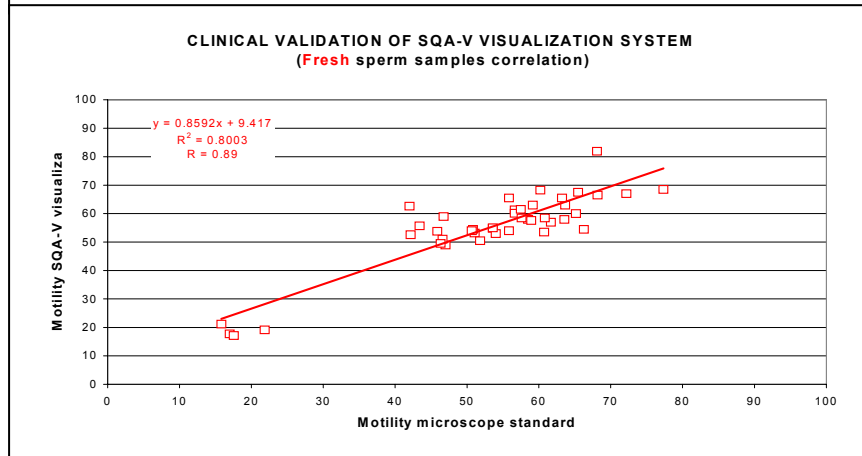


GRAPH: SQA-V Visualization System

TSC

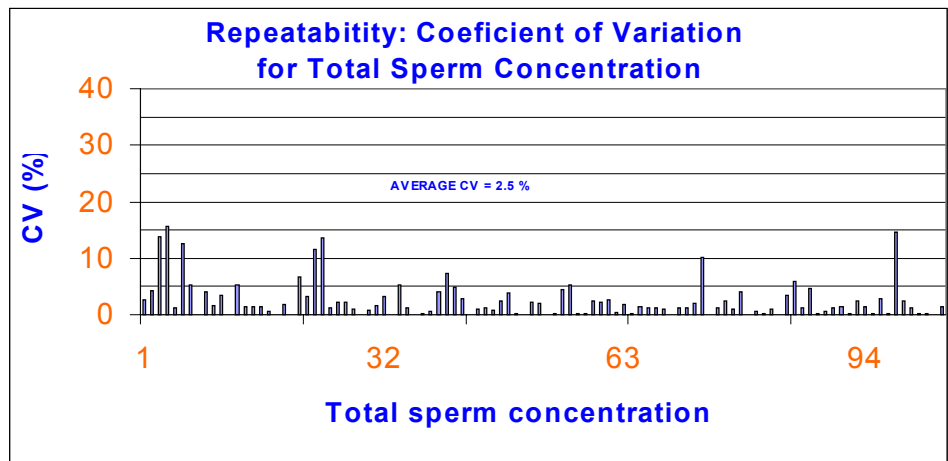


MOTILITY

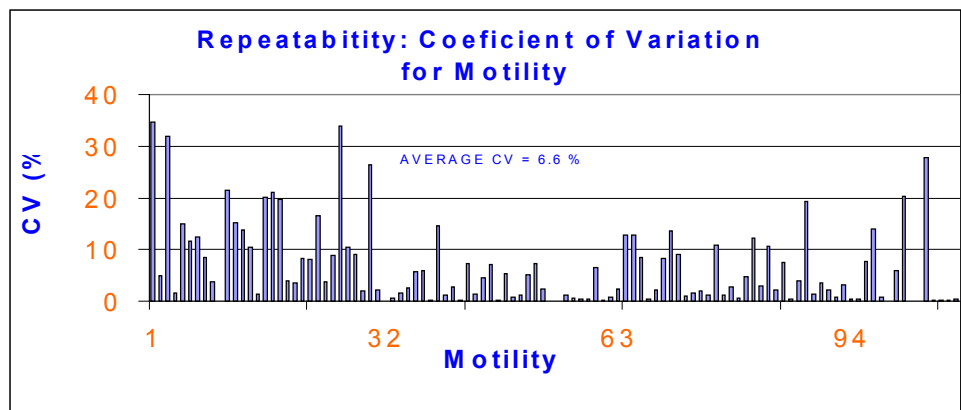


Graph: Repeatability of Test Results

TSC
97.5%
Repeatability*



Motility
93.4%
Repeatability*



*Running the same test twice on the SQA-V