# AUTOMATED SEMEN ANALYSIS

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## Abstract

Objective: To evaluate whether the automated SQA-V can replace manual semen analysis. Methodology: The study was conducted at Tel Hashomer and Ramat Marpe Hospitals in Israel. 539 semen samples were analyzed manually and then compared to the SQA-V. Additionally, 320 samples of commercially available latex bead controls (two levels of known concentrations) were run. Semen analysis was conducted according to WHO Manual, 4th edition guidelines. The SQA-V testing was performed according to the SQA-V User Manual instructions. Linearity: Initial semen and latex bead samples of known concentrations were sequentially diluted with commercial media and run on the SQA-V. Motile (sperm samples only) and total sperm concentration were measured for each dilution over the dynamic range of the SQA-V. Precision: Both semen and beads were run in duplicate to establish the coefficients of variation (%CV's). Analytical accuracy: Bland-Altman plots establish the method comparison. The SQA-V results were correlated to manual semen analysis. Analytical accuracy was also established by running two levels of beads on the SQA-V and comparing the results to the known bead concentration target +/- range. Clinical accuracy: Sensitivity and specificity were calculated based on the WHO Manual, 4th edition reference values for semen parameters. Conclusion: This study demonstrates that the SQA-V precisely and accurately measures semen and latex bead samples. Therefore, the SQA-V can reliably replace manual semen analysis for the semen parameters measured.

## Introduction

The need for objectivity, accuracy and standardized throughput are primary goals of laboratories today. To achieve these goals, laboratories utilize automated analyzers. One of the last bastions of manual processing is semen analysis. The SQA-V (Sperm Quality Analyzer) presents an automated alternative to manual analysis.

## Methods and Procedures

Manual and automated semen analysis were conducted in parallel at two hospitals in Israel. Specimens were run at room temperature. Manual semen analysis was conducted according to the guidelines in the WHO Manual, 4th edition and the SQA-V was run according to the user manual for the system. Analysis of the results was conducted according to standard analytical guidelines (see results in Table 1).

## Statistical Data

The Table 1: SQA-V Performance Characteristics, displays the statistical outcomes established in the trial.

## Results

The Table: SQA-V Performance Characteristics demonstrates that in the linearity experiments conducted using semen samples and beads, the slopes of the trend lines are close to 1.0 and regression coefficients are very high (R = 0.99). CVs characterizing precision of the SQA-V are below 7%. Concerning analytical accuracy, the semen parameters analyzed using the SQA-V demonstrate a high correlation to the manual methodology; The automated SQA-V results matched the target values for the quality control material (beads); Bland-Altman plot mean differences are very low. The SQA-V also demonstrated high clinical sensitivity and specificity when compared to manual analysis.

## Conclusions

This study demonstrates that the performance of the SQA-V is both precise and accurate when analyzing both semen and latex beads control material. Therefore, the automated SQA-V can reliably replace manual semen analysis.

## Table 1: SQA-V Performance Characteristics

| Parameter Definition | | Semen Parameters | | | | |
|---|---|---|---|---|---|---|
| | | Concentration | | Motility | Morphology | |
| | | | | | WHO 3rd | WHO 4th |
| Sample type | | Sperm | Beads | Sperm | Sperm | Sperm |
| Linearity | Slope | 1.00 | 0.98 | | | |
| | R | 0.99 | 0.99 | | | |
| | Deviation from Expected Values $10^6$/ml | 2.1 | 1.9 | | | |
| Precision: CV % | | 3.1 | < 0.01 | 5.1 | 4.6 | 6.6 |
| Analytical Accuracy | | 0.9* | 42.62 vs. 42.6+/-6.0 x $10^6$/ml*** | 0.85* | 0.66* | 0.49* |
| | | -2.8 x $10^6$/ml** | 20.76 vs. 20.8+/-2.9 x $10^6$/ml*** | -2.7%** | 5.2%** | 0.8%** |
| Clinical Accuracy | Sensitivity | 97% | | 92% | 94% | 69% |
| | Specificity | 93% | | 88% | 75% | 70% |

Notes: *Correlation to Manual Method; **Bland-Altman plot: SQA-V-manual MEAN difference; ***Result vs. target range.