Medical Electronic Systems
A-Tech (a division of M.E.S.)
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SQA-VISION vs. SQA-V
California Pacific Medical Center, U.S.

Overview:

The new SQA-Vision system from Medical Electronic Systems (MES) was compared to the SQA-V sperm quality analyzer (MES) at California Pacific Medical Center (CPMC). Over one hundred (100) human semen samples were run in parallel on the two systems according to the manufacturer's guidelines. The following fresh semen parameters were compared: Concentration, Total Motility, Progressive Motility and Morphology.

Results

Sperm Concentration

Sperm Concentration run on the SQA-Vision and the SQA-V were statistically compared as shown in Table 1:

Table 1: SQA-Vision Sperm Concentration

TP	TN	FP	FN	Sensitivity[1,2] (%)	Specificity[1,2] (%)	Correlation (r)
4	97	0	0	100.0	100.0	0.99

[1]Sperm Concentration reference value used for calculation sensitivity and specificity per WHO 5th ed. manual is 15 M/ml
[2]Sensitivity = TP / (TP + FN) * 100; Specificity = TN / (TN + FP) * 100

Notes:

TP - True Positive (correctly classified as positive - presence of disease)
TN - True Negative (correctly classified as negative - absence of disease)
FP - False Positive (not correctly classified as positive - absence of disease)
FN - False Negative (not correctly classified as negative - presence of disease)

The correlation coefficient of Sperm Concentration results run on the SQA-Vision vs. the SQA-V is high (0.99), demonstrating strong agreement between the two methods. The SQA-Vision Sperm Concentration Sensitivity and Specificity (100% each) exceeds the acceptance cutoffs of ≥ 90% and 85% respectively. The tight relationship between Sperm Concentration results run on the two systems is demonstrated graphically in Figure 1:

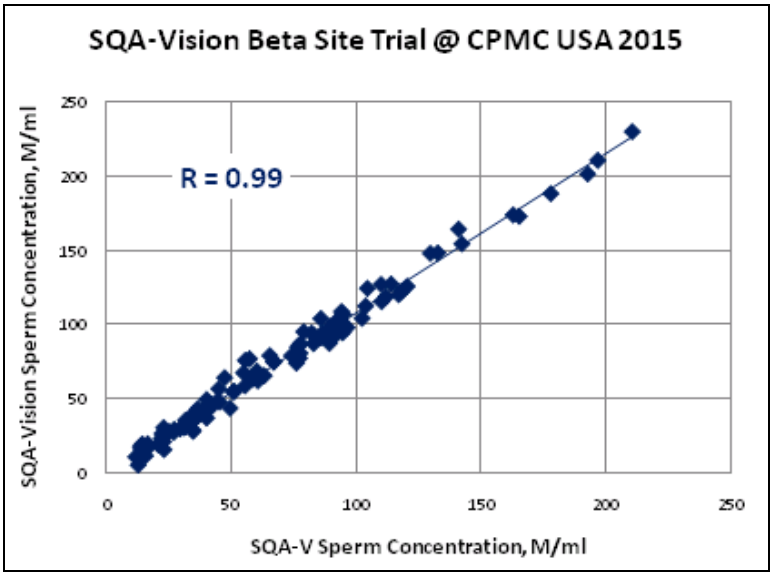

Figure 1. SQA-Vision vs. SQA-V Sperm Concentration

Total Motility (PR + NP)

Total Motility run on the SQA-Vision and the SQA-V were statistically compared as shown in Table 2:

Table 2: SQA-Vision Total Motility						
TP	TN	FP	FN	Sensitivity[1,2] (%)	Specificity[1,2] (%)	Correlation (r)
17	75	8	1	94.4	90.4	0.92

[1]Total Motility reference value used for calculation sensitivity and specificity per WHO 5th ed. manual is 40%
[2]Sensitivity = TP / (TP + FN) * 100; Specificity = TN / (TN + FP) * 100

Notes:
TP - True Positive (correctly classified as positive - presence of disease)
TN - True Negative (correctly classified as negative - absence of disease)
FP - False Positive (not correctly classified as positive - absence of disease)
FN - False Negative (not correctly classified as negative - presence of disease)

The correlation coefficient of the Total Motility results run on the SQA-Vision vs. the SQA-V is high (0.92) demonstrating strong agreement between the two methods. The SQA-Vision Total Motility Sensitivity and Specificity are high and exceed the acceptance cutoff. This tight relationship between Total Motility reported by the SQA-Vision and the SQA-V is demonstrated graphically in Figure 2:

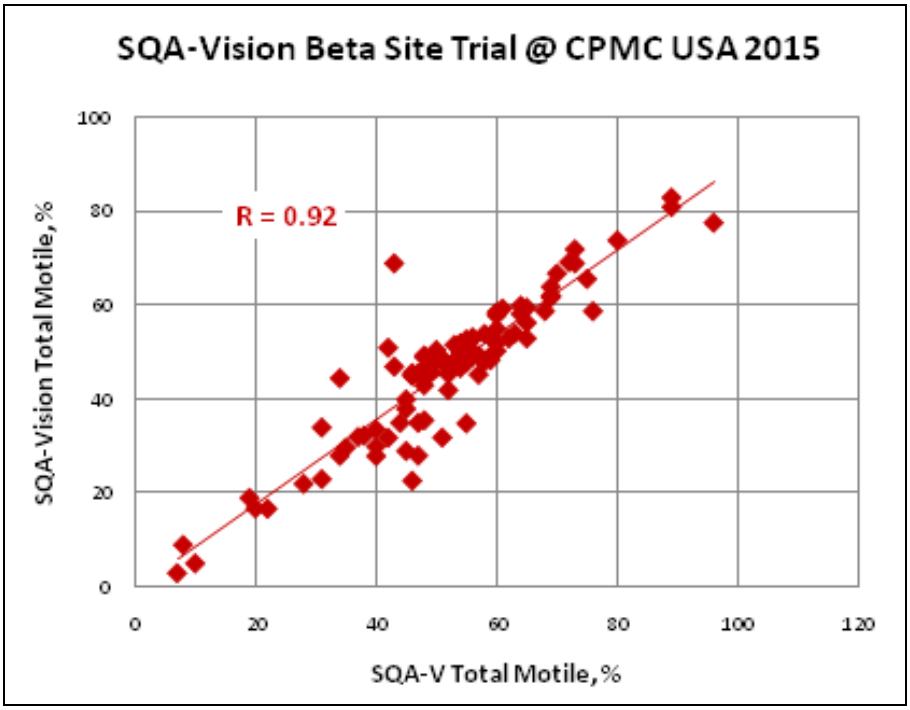

Figure 2. SQA-Vision vs. SQA-V Total Motility

Progressive Motility (PR)

Progressive Motility run on the SQA-Vision vs. the SQA-V were statistically compared. The results are summarized in Table 3:

Table 3: SQA-Vision Progressive Motility						
TP	TN	FP	FN	Sensitivity[1,2] (%)	Specificity[1,2] (%)	Correlation (r)
28	69	2	2	93.3	97.2	0.94

[1]Progressive Motility reference value used for calculation sensitivity and specificity per WHO 5th ed. manual is 32%
[2]Sensitivity = TP / (TP + FN) * 100; Specificity = TN / (TN + FP) * 100

Notes:
TP - True Positive (correctly classified as positive - presence of disease)
TN - True Negative (correctly classified as negative - absence of disease)
FP - False Positive (not correctly classified as positive - absence of disease)
FN - False Negative (not correctly classified as negative - presence of disease)

The correlation coefficient of the SQA-Vision Progressive Motility results vs. the SQA-V is high (0.94) and exceeds the acceptance criteria. The SQA-Vision Progressive Motility Sensitivity and Specificity are high and exceed the acceptance cutoff. The data shows that only a few samples were categorized as FP or FN between the two systems. The high correlation shows strong agreement between the methods. This tight relationship between Progressive Motility reported by the SQA-Vision and the SQA-V is demonstrated graphically in Figure 3:

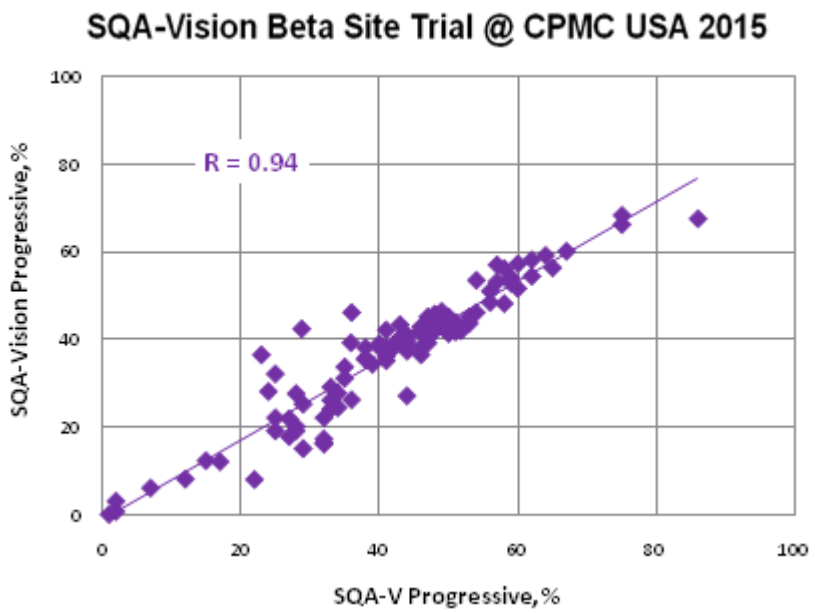

Figure 3. SQA-Vision vs. SQA-V Progressive Motility

Morphology

Summarized in Table 4 below are the results of Morphologically Normal Forms obtained by:

- SQA-Vision automatically
- SQA-V automatically

Table 4: Normal Forms (Morphology)						
TP	TN	FP	FN	Sensitivity[1,2] (%)	Specificity[1,2] (%)	Correlation (r)
10	91	0	0	100.0	100.0	0.93

[1]Normal Forms (Morphology) reference value per WHO 5th ed. manual is 4%.
[2]Sensitivity = TP / (TP + FN) * 100; Specificity = TN / (TN + FP) * 100

Notes:
TP - True Positive (correctly classified as positive - presence of disease)
TN - True Negative (correctly classified as negative - absence of disease)
FP - False Positive (not correctly classified as positive - absence of disease)
FN - False Negative (not correctly classified as negative - presence of disease)

The sensitivity and specificity of the SQA-Vision normal morphology assessed automatically vs. the SQA-V are both 100.0% which exceeds the acceptance cutoffs. The correlation coefficient of the SQA-Vision Normal Morphology results vs. the SQA-V is high (0.93) and exceeds the acceptance criteria. The high correlation demonstrates strong agreement between two methods. This tight relationship between Normal Morphology reported by the SQA-Vision and the SQA-V is demonstrated graphically in Figure 4:

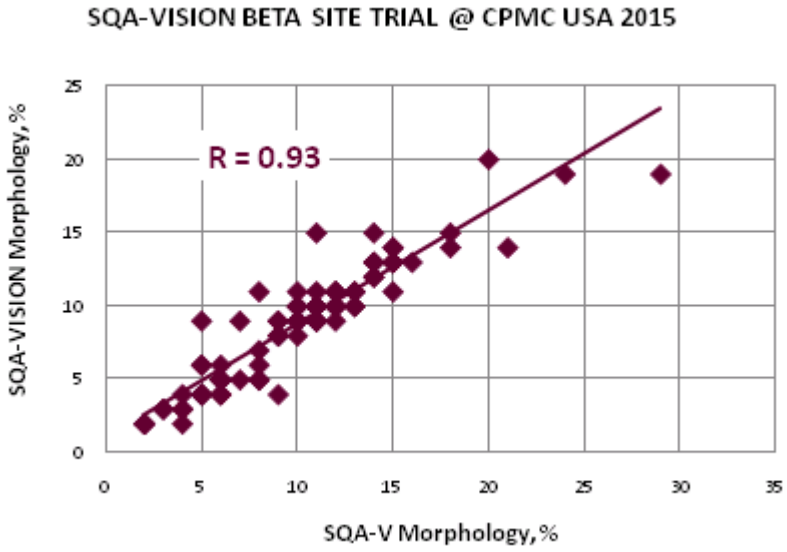

Figure 4. SQA-Vision vs. SQA-V Normal Morphology

Conclusions

- Based on results of the SQA-Vision CPMC trial, the system demonstrated that all assessed parameters passed the acceptance criteria and the results of the two systems (SQA-Vision and SQA-V) are in good alignment.
- A high level of correlation between the SQA-Vision and SQA-V automated results demonstrated a tight agreement between these methods.
- The Sensitivity and Specificity levels for all assessed parameters are higher than the acceptance criteria.
- The overall conclusion is that the SQA-Vision system shows substantial equivalence to the SQA-V system.

References

1. WHO laboratory manual for the examination and processing of human semen - 5th ed., World Health Organization 2010.
2. Agarwal A, Sharma RK (2007). Automation is the key to standardized semen analysis using the automated SQA-V sperm quality analyzer. Fertility and Sterility, 87(1):156-162.
3. J. Lammers J, Splingart C, Barrière P, Jean M, Fréour T (2014). Double-blind prospective study comparing two automated sperm analyzers versus manual semen assessment. Journal of Assisted Reproduction and Genetics, 31(1):35-43.