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PRECISION AND ACCURACY OF THE SQA-IOW SPERM QUALITY ANALYZER IN THE HANDS OF CLIA WAIVED RN OPERATORS

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OBJECTIVE:

To demonstrate the precision and accuracy of the point-of-care SQA-iOw semen analyzer in the hands of non-professional waived Registered Nurse (RN) users.

MATERIALS AND METHODS:

The new SQA-iOw is a small-footprint, point-of-care automated medical device that performs a complete semen analysis in 75 seconds. It is designed for low- complexity Clinical Laboratory Improvement Amendments (CLIA) waived clinician offices that lack certified andrology labs or professional technicians. This study demonstrated the accuracy and precision of the Sperm Quality Analyzer (SQA-iOw) in the hands of CLIA-waived RN operators compared to the results generated by the FDA-cleared CLIA requiring SQA-V laboratory analyzer run by professional technicians.

An SQA-iOw accuracy trial was conducted at three study sites encompassing 398 donor semen samples run in singleton; once on the SQA-iOw, by nine waived RN operators, and then again on the FDA-cleared SQA-V, by professional operators. Correlations between these two groups were established for sperm concentration, motile sperm concentration (MSC), progressively motile sperm concentration (PMSC), motility, progressive motility, and sperm morphology using Passing-Bablok regression analysis. SQA-iOw precision trial was conducted at a single site to compare the results of three CLIA-waived SQA-iOw RN operators testing seven semen samples in duplicate, spanning low, middle, and high levels of four semen parameters on three SQA-iOw devices over 0, 20, 40, and 60-minute time intervals. This resulted in 168 replicate results for four semen parameters. Statistical evaluation included mean, standard deviation (SD), and coefficient of variation (CV, %).

RESULTS:

SQA-iOw accuracy of ≥ 96% was demonstrated for the 398 semen samples between the SQA-iOw CLIA waived RN user's and the SQA-V professional technician's results for sperm concentration, motile sperm concentration, progressively motile sperm concentration, sperm motility, progressive motility, and sperm morphology (Table 1). SQA-iOw precision was demonstrated by a <7.5% coefficient of variation CV for sperm concentration, MSC, PMSC, and morphology measured across the 168 replicates (Table 1.).

Table 1. SQA-iOw Versus SQA-V n=398

Sperm Parameters	Intercept	Slope	Correlation
Concentration M/ml	0.05	0.98	0.99
Motility %	1.94	0.94	0.96
Progressive Motility %	-0.26	0.94	0.98
Morphology %	-1.00	1.00	0.97
MSC M/ml	0.27	0.95	0.99
PMSC M/ml	-0.17	0.92	0.99

CONCLUSIONS:

The point-of-care SQA-iOw demonstrated a high level of accuracy and precision in the hands of CLIA-waived RN users.

IMPACT STATEMENT:

The accurate and precise SQA-iOw device offers a significant opportunity for point-of-care fertility practitioners to provide immediate, on-site, and reliable comprehensive semen analysis to their patients.