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ACCURACY AND USABILITY OF THE YO (3.0) HOME SPERM TEST

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OBJECTIVE:

To assess the accuracy of quantitative semen analysis (SA) performed by lay users operating the YO 3.0 Home Sperm Test, compared to trained technicians using the laboratory-grade computerized Sperm Quality Analyzer (SQA).

MATERIALS AND METHODS:

The YO 3.0 Home Sperm Test (YO 3.0) utilizes a standalone testing device that communicates via Wi-Fi to Smartphones. The YO 3.0 expands the capabilities of the previous version by reporting additional WHO 6 Edition-based quantitative semen analysis the variables such as sperm concentration (M/mL), motility (%), progressive motility (%), motile sperm concentration (M/mL), and progressively motile sperm concentration (M/mL). This double-blind prospective study was conducted at three study sites, with a total of 309 lay users. Using only the instructions provided in the YO kit and App, males testing their own samples comprised 94.2% of lay users, females, testing donor samples comprised 4.1%, and gender 'other' was 1.7%. The mean age of the lay users was 28+/-7.4 years. Concurrently, blinded testing was performed on the same semen sample by professionally trained technicians using the FDA-cleared laboratory-grade SQA Sperm Quality Analyzer. Passing-Bablok regression analysis was conducted using MedCalc software.

RESULTS:

Correlation coefficients ≥ 0.88 were obtained between lay users operating the YO 3.0 and trained technicians using the laboratory-grade computerized Sperm Quality Analyzer (SQA) for sperm concentration, sperm motility, progressive motility, motile sperm concentration, and progressively motile sperm concentration. (Table 1.).



Table 1

Comparison of the SQA-iOw (CLIA waived RN users) to the SQA-V (professional technicians) n= 398			
Parameters	Intercept	Slope	Correlation
Sperm CONCENTRATION, M/ml	0.05	0.98	0.99
Sperm MOTILITY, %	1.94	0.94	0.96
Sperm PROGRESSIVE MOTILITY, %	-0.26	0.94	0.98
Sperm MORPHOLOGY, %	-1.00	1.00	0.97
Motile Sperm Concentration, M/ml	0.27	0.95	0.99
Progressively Motile Sperm Concentration M/ml	-0.17	0.92	0.99

CONCLUSIONS:

Despite no prior training, lay users, performed accurate quantitative semen analysis on the YO 3.0 Home Sperm Test compared to trained technicians operating the laboratory-grade SQA Sperm Quality Analyzer.

IMPACT STATEMENT:

The YO 3.0 Home Sperm Test significantly expands the capabilities for accurate and user-friendly home-based quantitative semen analysis and has the potential to increase access to male fertility screening.