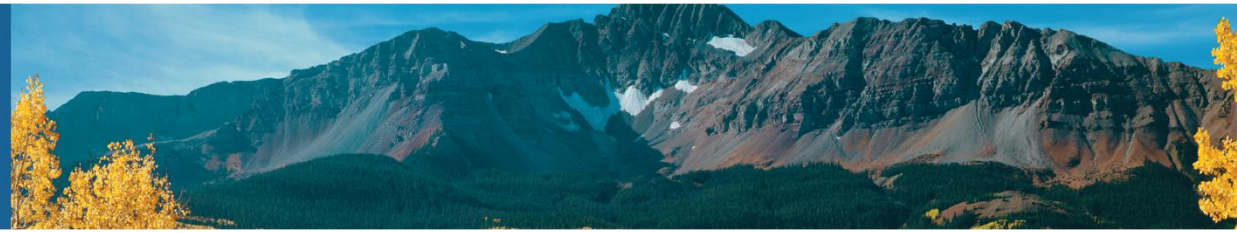

ACCURACY AND USABILITY OF THE YO (3.0) HOME SPERM TEST

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Disclosures & Acknowledgements

- Natan Bar-Chama is a Medical Advisor at Genentech / Roche Pharmaceuticals and at WINFertility
- Lev Rabinovitch is the Chief Technology Officer at Medical Electronic Systems
- This study was funded by Medical Electronic Systems (MES), Encino, California

Background

- Updates to Male Infertility: AUA / ASRM Guideline (2024)[1]
  - The male and female should be evaluated for infertility in parallel
  - The initial male evaluation is comprised of reproductive history and one or more semen analysis
  - Male reproductive experts should evaluate patients when indicated by one or more abnormal semen parameters or presumed male infertility.

- Barriers to Semen Analysis / Resulting in Delay in Diagnosis and Fertility Treatment
  - Access to care
  - Financial
  - Time off work
  - Psychological barriers

1 Brannigan et al The Journal of Urology Vol. 212, 1-11, December 2024

WHO 6th Edition Manual

The most recent 2021 World Health Organization laboratory manual for the examination and processing of human semen acknowledges At-Home Semen Analysis and notes that smartphone–based home sperm tests

"Could become a useful means for men to seek early proper medical advice, investigation, and causal treatment."

WHO 6th Edition Laboratory Manual for the Examination and Processing of Human Semen; World Health Organization, 2021.

Amateur vs Professional Users of the YO Home Sperm Test: An Assessment of Usability[1]

- The largest blinded, prospective study to date on a home sperm testing device
  - Accuracy of 316 amateur YO home sperm test results compared to a professional-grade SQA analyzer (>95.0%)
  - Accuracy of 316 amateur YO home sperm test results compared to 3 professionally trained YO test technicians (>97.0%)
- Established the YO Home Sperm Test as the first and only FDA-cleared device to assess motile sperm concentration (MSC) on a smartphone.

Agreement: YO Lay User vs SQA Professional User

YO by Lay User	SQA by Professional User		
	Positive	Negative	Total
Positive	81	9	90
Negative	4	222	226
Total	85	231	316

PPA % = 95.3% | NPA % = 96.1%

Agreement: YO Lay User vs YO Trained User

YO by Lay User	YO by Trained User		
	Positive	Negative	Total
Positive	87	3	90
Negative	3	223	226
Total	90	226	316

PPA % = 96.7% | NPA % = 98.7%

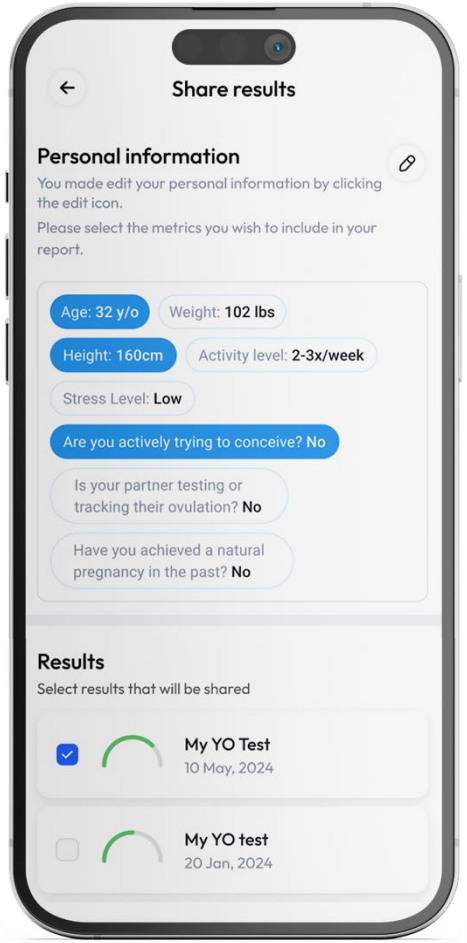
1. Bar-Chama et al. Urology Volume 190 p162 August 2024

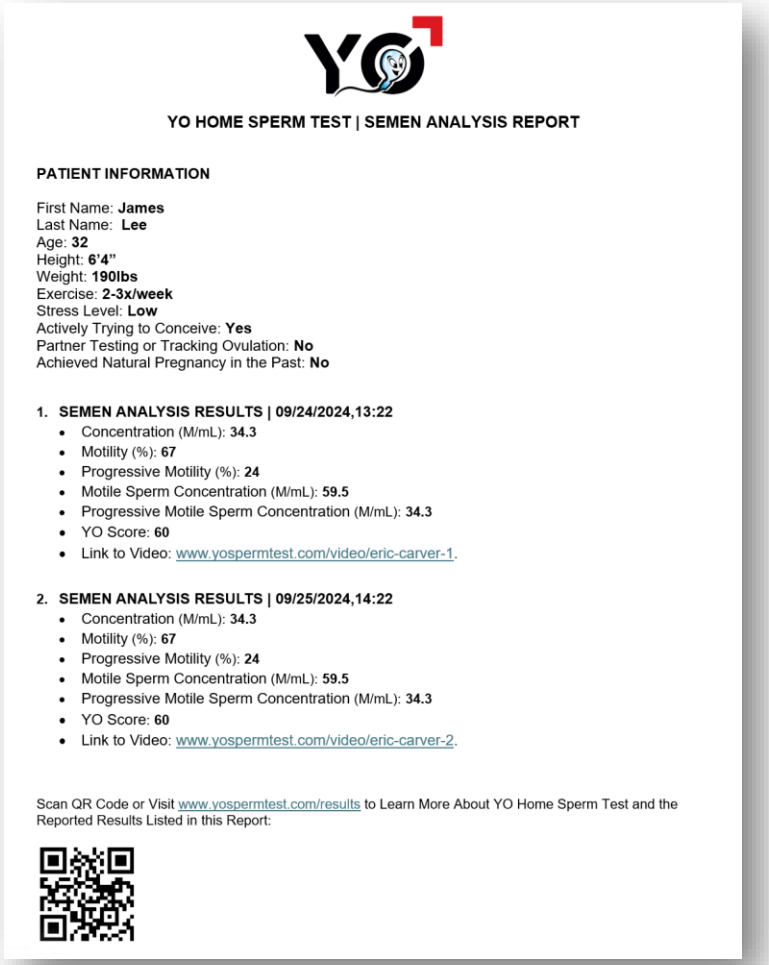
YO (3.0) Additional Sperm Parameters

Measured Parameter	Previous YO	New YO (3.0)
Motile Sperm Concentration (M/mL)	✓	✓
Sperm Concentration (M/mL)	X	✓
Motility (%)	X	✓
Progressive Motility (%)	X	✓
Progressive Motile Sperm Concentration (M/mL)	X	✓
Normal Morphology (%)	X	X
Volume (mL)	X	X

YO (3.0) Home Sperm Test

- Quantitative results for 5 sperm clinical parameters
  - Concentration (M/mL)
  - Motility (%)
  - Progressive Motility (%)
  - Motile Sperm Concentration (MSC) (M/mL)
  - Progressive MSC (M/mL)
- Video documentation of ejaculated sperm
- Comprehensive report and video that the patient can share with a medical professional
- Secure cloud storage of all results, videos, and reports





YO HOME SPERM TEST | SEMEN ANALYSIS REPORT

PATIENT INFORMATION

First Name: **James**
Last Name: **Lee**
Age: **32**
Height: **6'4"**
Weight: **190lbs**
Exercise: **2-3x/week**
Stress Level: **Low**
Actively Trying to Conceive: **Yes**
Partner Testing or Tracking Ovulation: **No**
Achieved Natural Pregnancy in the Past: **No**

1. **SEMEN ANALYSIS RESULTS | 09/24/2024,13:22**
   - Concentration (M/mL): **34.3**
   - Motility (%): **67**
   - Progressive Motility (%): **24**
   - Motile Sperm Concentration (M/mL): **59.5**
   - Progressive Motile Sperm Concentration (M/mL): **34.3**
   - YO Score: **60**
   - Link to Video: www.yospermtest.com/video/eric-carver-1.
2. **SEMEN ANALYSIS RESULTS | 09/25/2024,14:22**
   - Concentration (M/mL): **34.3**
   - Motility (%): **67**
   - Progressive Motility (%): **24**
   - Motile Sperm Concentration (M/mL): **59.5**
   - Progressive Motile Sperm Concentration (M/mL): **34.3**
   - YO Score: **60**
   - Link to Video: www.yospermtest.com/video/eric-carver-2.

Scan QR Code or Visit www.yospermtest.com/results to Learn More About YO Home Sperm Test and the Reported Results Listed in this Report:

YO (3.0) Home Sperm Test

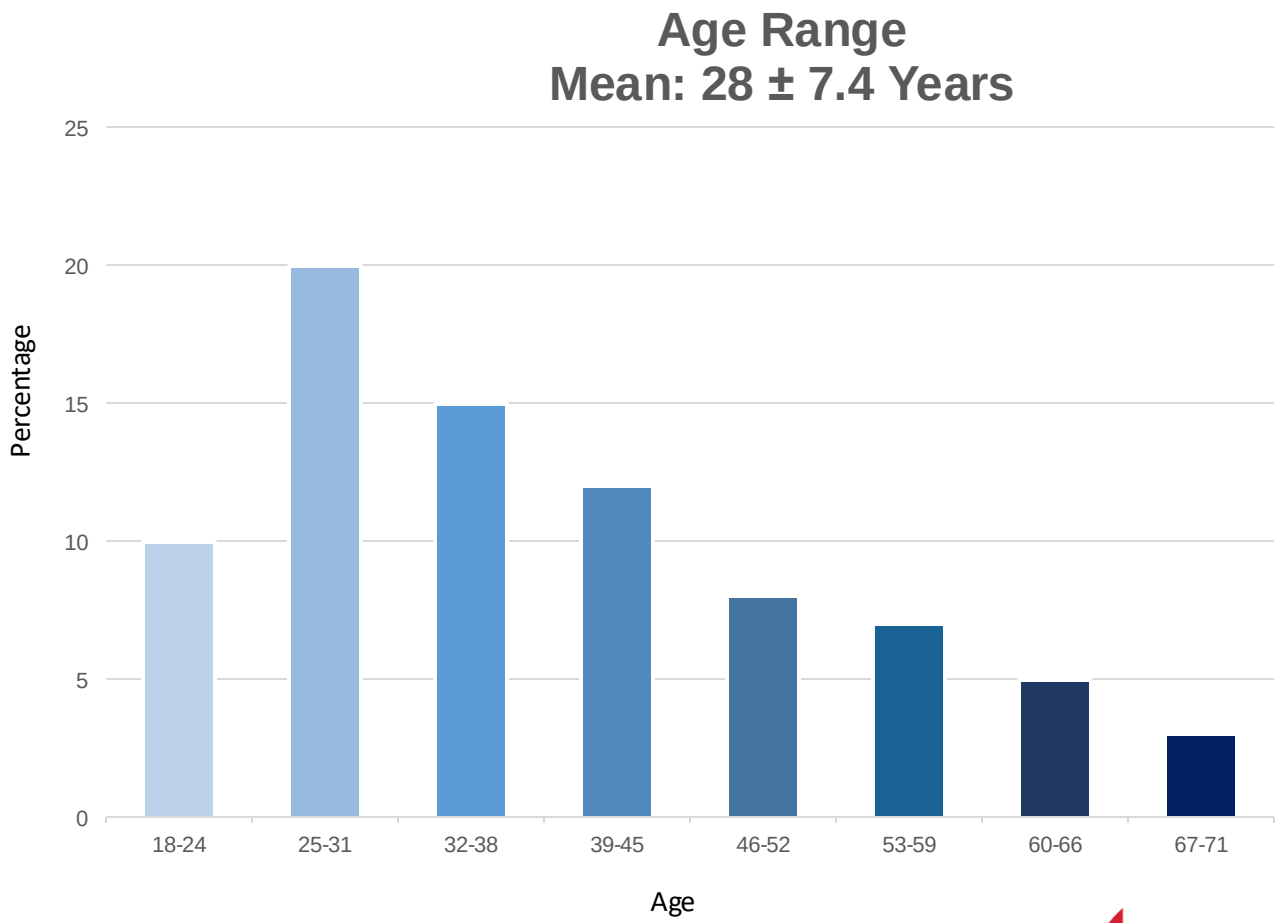
Study Objective

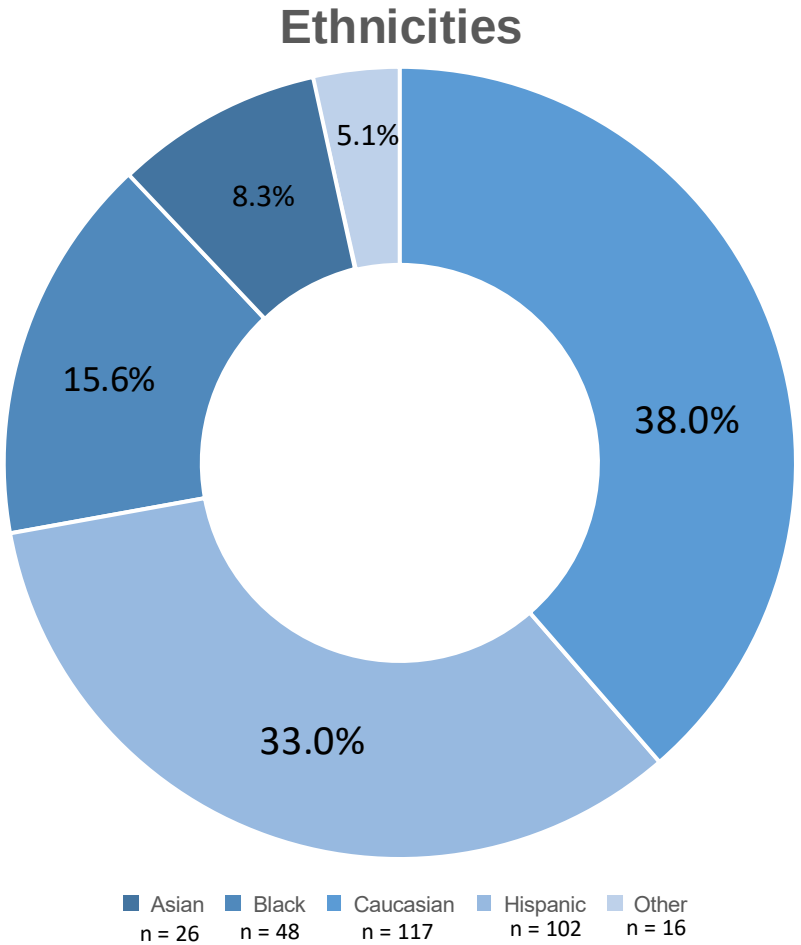
- To assess the accuracy of a quantitative semen analysis performed by lay users operating the YO (3.0) Home Sperm Test, compared to trained technicians using the laboratory-grade SQA Sperm Quality Analyzer
- User experience feedback

Materials and Methods

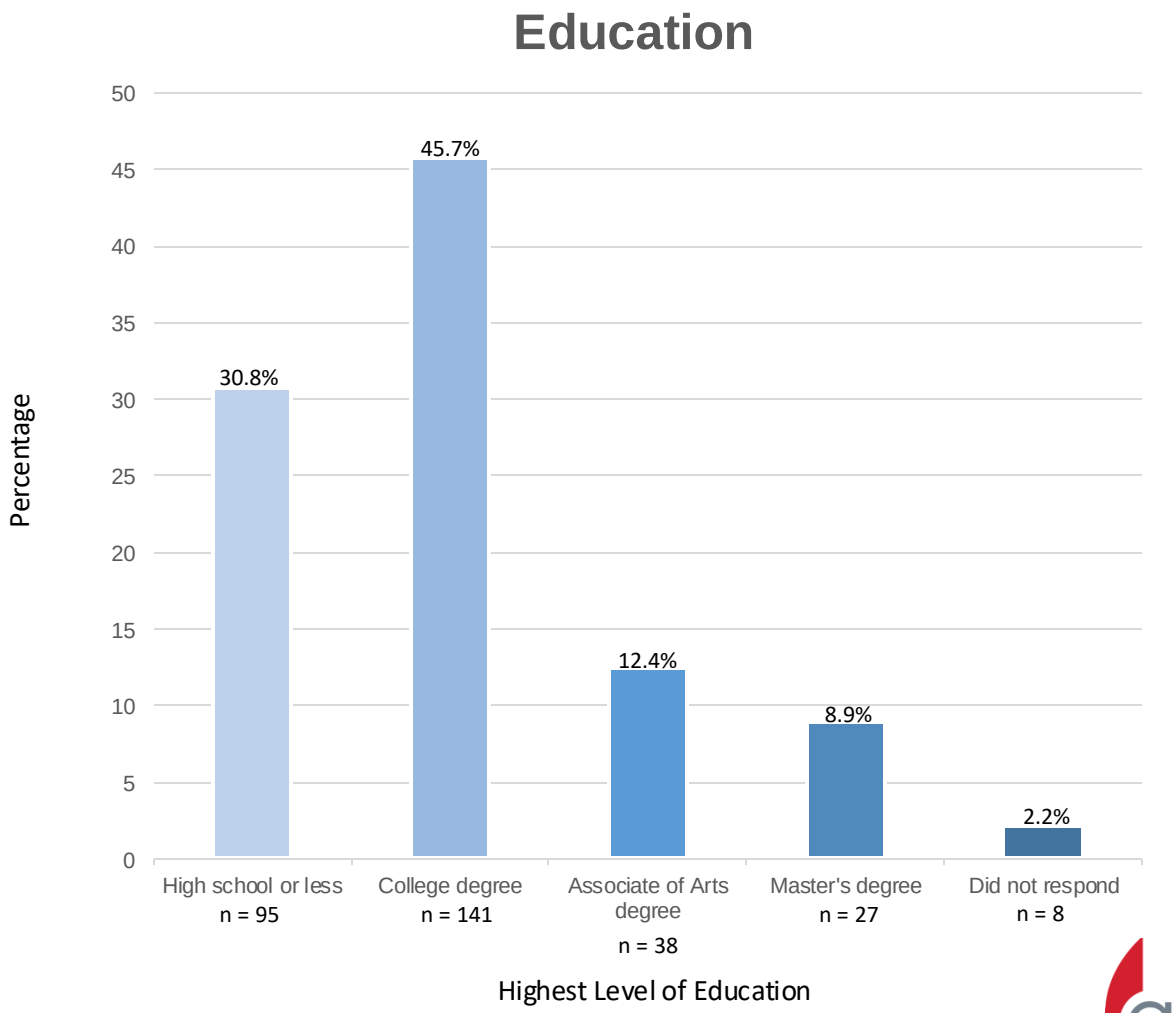
- This double-blind prospective study was conducted at three study sites, with a total of 309 lay users using only the instructions provided in the YO Home Sperm Test Kit and the Smartphone App
- Concurrently, blinded testing was performed on the same semen sample by professionally trained technicians using the FDA-cleared laboratory-grade SQA Automated Sperm Quality Analyzer
- Passing-Bablok regression analysis was conducted using MedCalc software.
- Additionally, lay users provided feedback on their experience performing the YO (3.0) Home Sperm Test

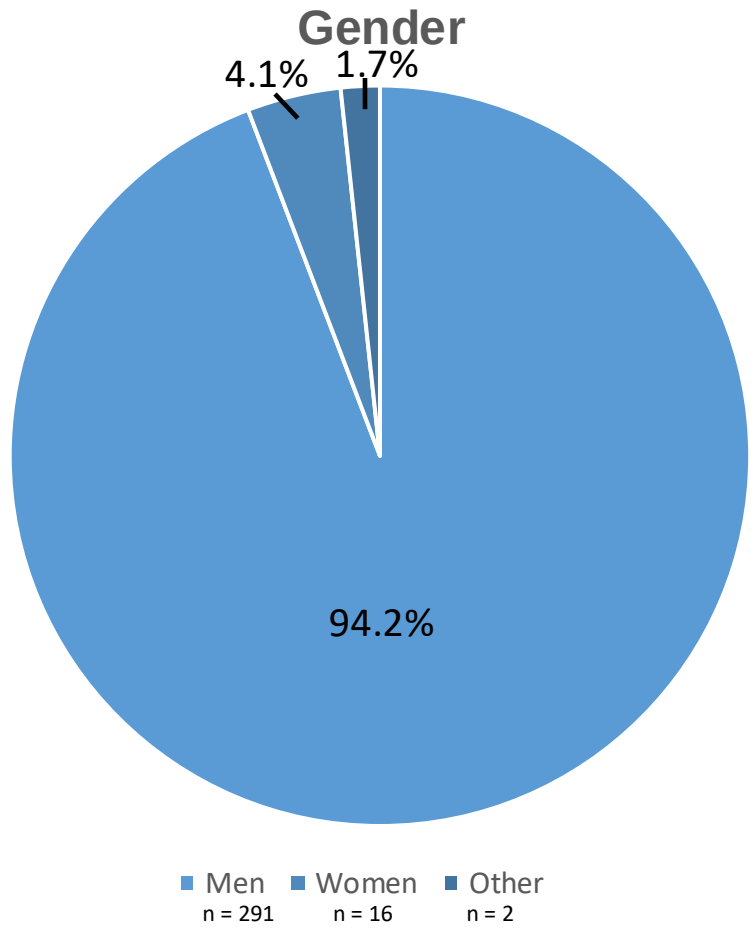
Demographics | Lay User (n=309) Age & Ethnicities





Demographics | Lay User (n=309) Education & Gender





Results: YO (3.0) Home Sperm Test Lay Users vs. Trained Technicians using the SQA Semen Analyzer

A correlation of ≥ 90% was noted for Sperm Concentration, Sperm Motility, Motile Sperm Concentration and Progressive Motile Sperm Concentration

YO (3.0) Home Sperm Test (Lay Users) vs. SQA Automated Semen Analyzer (Trained Technicians) n = 309			
Semen Parameters	**Intercept**	**Slope**	**Correlation**
Concentration (M/ml)	2.28	0.86	**0.93**
Motility (%)	0.00	1.05	**0.90**
Progressive Motility (%)	-0.47	1.24	**0.88**
Motile Sperm Concentration (M/mL)	1.84	0.92	**0.94**
Progressive Motile Sperm Concentration (M/ml)	-0.04	1.03	**0.94**

Results: YO (3.0) User Experience

> 90% of Lay Users described the YO (3.0) user experience as very clear and easy to follow

Category	Very Clear & Easy to Follow (%)	Somewhat Clear & Easy to Follow (%)	Neutral (%)	Somewhat Unclear but Can be Followed (%)	Unclear & Difficult to Follow (%)
YO Video	**92.38**	6.9	0.63	0.00	0.00
Instructions for use	**91.11**	6.0	2.0	0.00	0.00
App Instructions	**94.92**	5.08	0.00	0.00	0.00
Video for preparing the YO Slide	**95.87**	5.08	0.00	0.00	0.00
Instructions for Slide Insertion	**93.67**	4.76	0.95	0.32	0.00
Overall YO (3.0) Semen Test	**93.65**	5.31	0.78	0.06	0.00

Conclusions: YO (3.0) Home Sperm Test

- Using the YO (3.0) Home Sperm Test, lay users were able to accurately perform quantitative semen analysis for the following parameters:
  - Concentration (M/mL)
  - Motility (%)
  - Progressive Motility (%)
  - Motile Sperm Concentration (M/mL)
  - Progressive Motile Sperm Concentration (M/mL)
- The YO (3.0) is not intended to replace a comprehensive semen analysis performed in an andrology laboratory.
- The YO (3.0) Home Sperm Test has the potential to
  - Increase access to male fertility screening
  - Enable better adherence to the Male Infertility Practice Guidelines (2024)
  - Expedite the journey to parenthood and implementation ART recommendations
- The YO (3.0) continues to be the only FDA-cleared smartphone-based at-home sperm test with live video

References

- WHO laboratory manual for the examination and processing of human semen, Sixth Edition, World Health Organization 2021
- Agarwal et al. Home sperm testing device versus laboratory sperm quality analyzer: comparison of motile sperm concentration. Fertility and Sterility, Volume 110, No.7, Dec. 2018
- Bar-Chama et al. Amateur vs Professional Users of the YO Home Sperm Test: An Assessment of Usability. Urology Volume 190 p162-169 August 2024

Thank You!