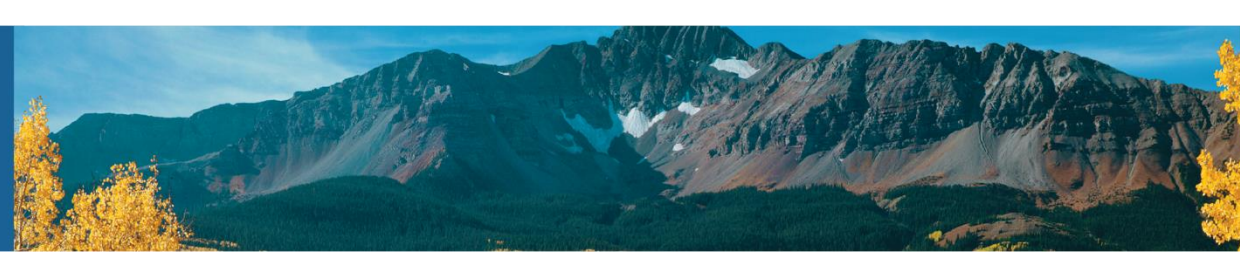




**ASRM 2024**  
*Equity, Access, and Innovation*



# 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
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# Background



- Updates to Male Infertility: AUA / ASRM Guideline (2024)<sup>1</sup>
  - 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

# 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.”***

# Amateur vs Professional Users of the YO Home Sperm Test: An Assessment of Usability<sup>1</sup>

- 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%**

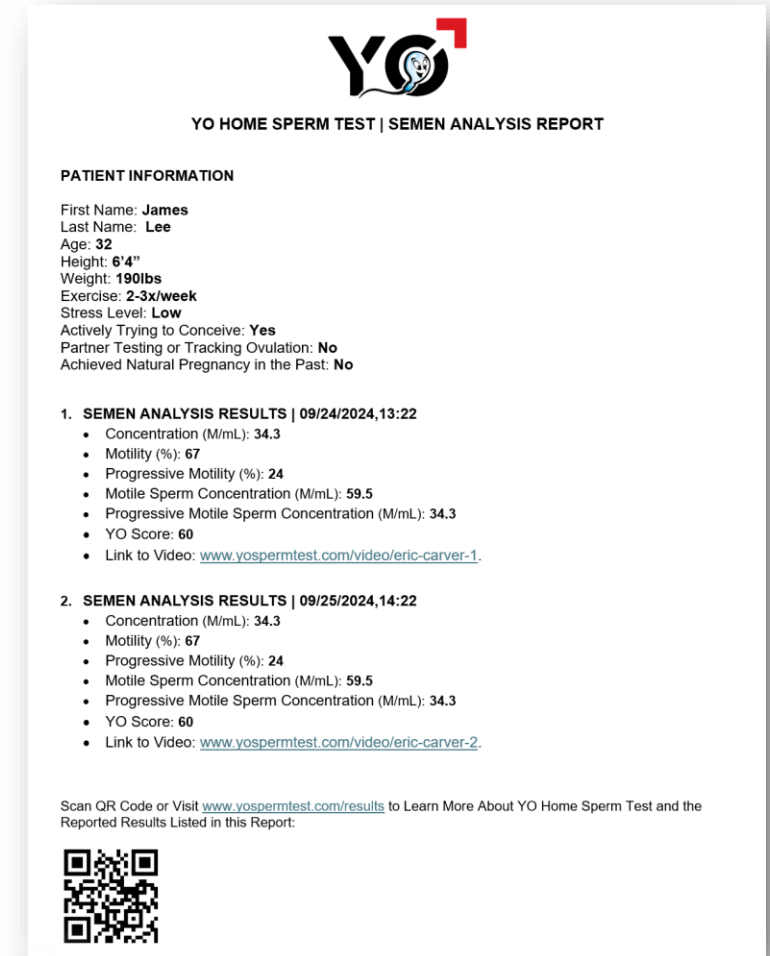
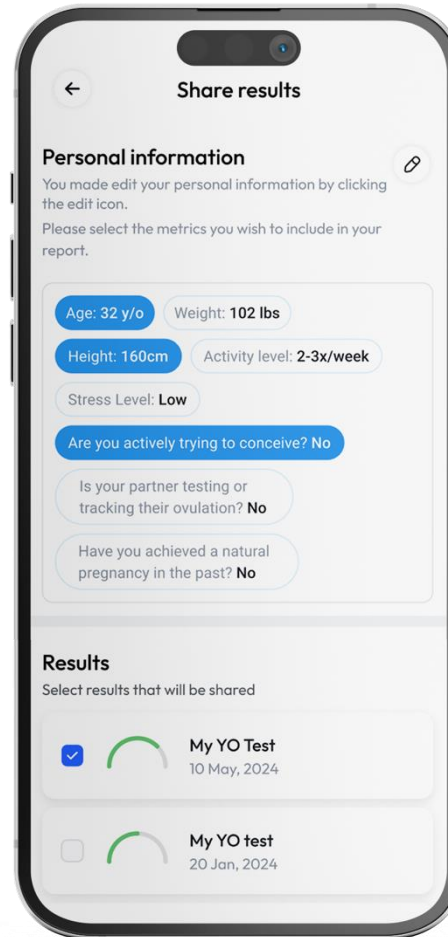
# YO (3.0) Additional Sperm Parameters



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

# 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 (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



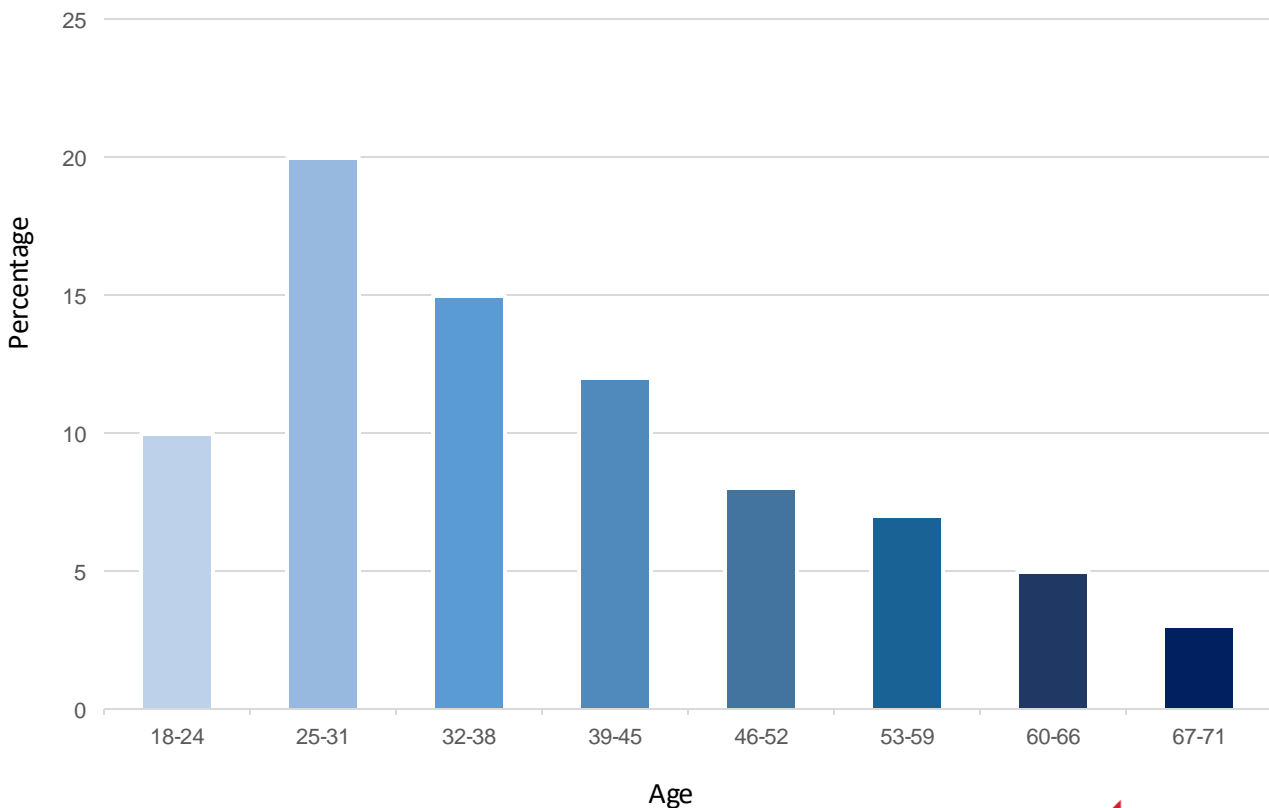
# Materials and Methods



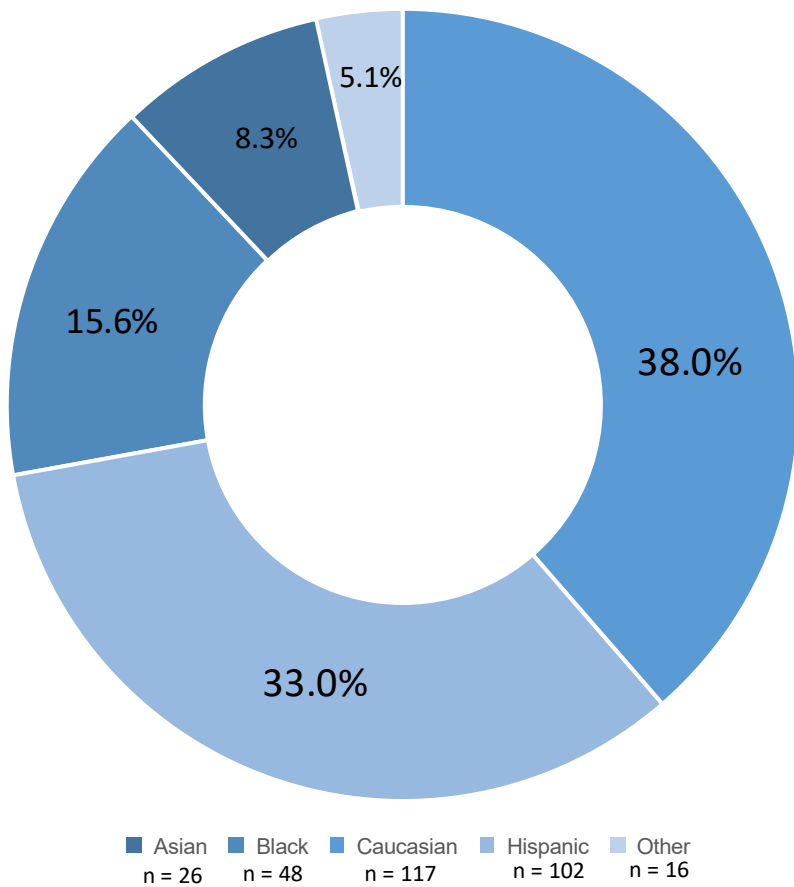
- This double-blind prospective study was conducted at three study sites, with a total of 309 lay users using only the instructions provided in the YO Home Sperm Test Kit and the Smartphone App
- Concurrently, blinded testing was performed on the same semen sample by professionally trained technicians 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

**Age Range**  
Mean: 28 ± 7.4 Years



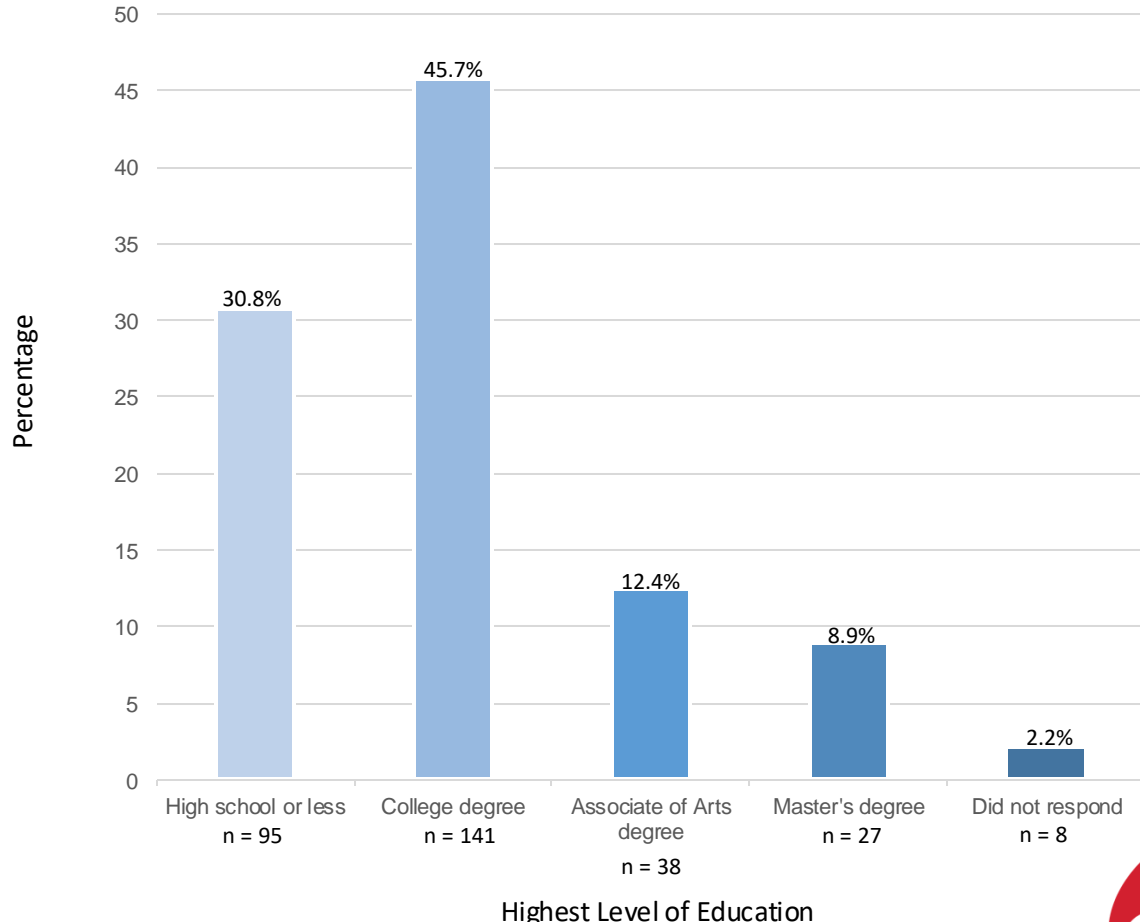
**Ethnicities**



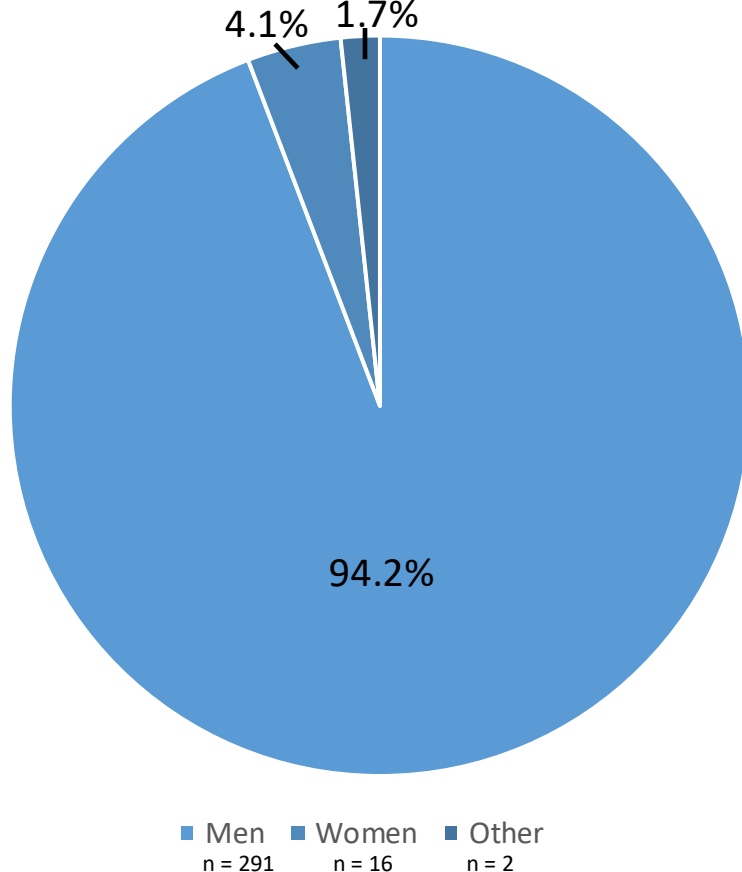


# Demographics | Lay User (n=309) Education & Gender

### Education



### Gender



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



A correlation of  $\geq 90\%$  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	<b>0.93</b>
Motility (%)	0.00	1.05	<b>0.90</b>
Progressive Motility (%)	-0.47	1.24	<b>0.88</b>
Motile Sperm Concentration (M/mL)	1.84	0.92	<b>0.94</b>
Progressive Motile Sperm Concentration (M/ml)	-0.04	1.03	<b>0.94</b>



# 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	<b>92.38</b>	6.9	0.63	0.00	0.00
Instructions for use	<b>91.11</b>	6.0	2.0	0.00	0.00
App Instructions	<b>94.92</b>	5.08	0.00	0.00	0.00
Video for preparing the YO Slide	<b>95.87</b>	5.08	0.00	0.00	0.00
Instructions for Slide Insertion	<b>93.67</b>	4.76	0.95	0.32	0.00
Overall YO (3.0) Semen Test	<b>93.65</b>	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
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# Thank You!

