



PLEASE NOTE:

These instructions are updated from time to time and there may be a more recent version on our website: www.yospermtest.com



YO OVERVIEW

Welcome to YO Home Sperm testing! This User Guide provides you with what you need to know before running your YO test. The YO app will take you through the entire sample preparation and testing process. The app is presented in a step-by-step manner with simple instructions to check-off before moving to the next screen.

SMARTPHONE PREPARATION

- · Password protect your phone for medical confidentiality
- Charge your phone to at least 50%
- Ensure that you have 100MB of memory for YO video storage
- You will receive a warning message if your phone is not charged to at least 50% or if there is not enough phone memory to run a YO test

CHECK THE YO KIT CONTENTS AND PREPARE AHEAD

- Prepare a white surface for testing (a piece of paper will do)
- Open your YO Test Kit and confirm you have all the supplies

WHAT IS INCLUDED IN THE YO KIT?

- · Plastic cups for collecting your semen sample
- · YO slides for sample testing
- Vials of liquefaction powder (to make your samples 'runny')
- Plastic pipettes for transferring the sample to the slide
- YO Device

WHY MORE THAN ONE TEST?

Your sperm values can change over time. A "low" result today could be "normal" in a month. It is important to run your test more than once, especially if you receive LOW result the first time.

HOW LONG DOES THE TEST TAKE?

Preparing your sample for testing takes the most time. To test your sample accurately, it needs to be runny (liquefied). The YO kit contains a powder that does this in 10 minutes. During the wait time, take the fun YO Sperm Trivia Challenge to learn some fun facts about sperm.

Next, a video of your sperm is captured and then analyzed, and this takes another 5-7 minutes. So, allow a minimum of 20 minutes of your time to run your test (not including the time you need to collect your sample).

YO PRODUCT INSTRUCTIONS

ABOUT YO

YO tests your sperm concentration, motility, progressive motility, motile sperm concentration, progressively motile sperm concentration and provides you with video of your sperm.

Simply follow the testing steps, checking off each step as you go and view the detailed animations. The test works by leading you through the process of preparing your sample and loading the YO slide. Then you will insert the slide into the YO device and YO will record a video of your sperm and analyze it.

INTENDED USE

The YO Home Sperm Test (YO 3.0) is a smartphone-based test for semen analysis performed by lay users.

The parameters reported by the YO Home Sperm Test are:

- 1. Total Sperm Concentration / Sperm Concentration, M/mL
- 2. Total Motile / Motility (PR + Non-Progressive [NP]), %
- 3. Progressive Motility (PR), % (Rapidly + Slowly Progressive, %)
- 4. Motile Sperm Concentration (MSC), M/mL
- Progressively Motile Sperm Concentration (PMSC), M/mL (Rapid and Slow Motile Sperm Concentration, M/mL)

The YO Home Sperm Test (YO 3.0) does not provide a comprehensive evaluation of a male's fertility status and is intended for in vitro, over the counter only.

YO TESTS

SPERM CONCENTRATION

SPERM CONCENTRATION is the total number of sperm in 1 milliliter of your semen.

% MOTILITY

SPERM MOTILITY is the % of your sperm that are moving. Your sperm may be moving forward, in circles or in place.

PROGRESSIVE MOTILITY

PROGRESSIVE MOTILITY is the % of your sperm that are moving forward.

MOTILE SPERM CONCENTRATION

MOTILE SPERM CONCENTRATION is the number of moving sperm in 1 milliliter of your semen.

PROGRESSIVELY MOTILE SPERM CONCENTRATION

PROGRESSIVELY MOTILE SPERM CONCENTRATION is the number of forward moving sperm in 1 milliliter of your semen.

YO TEST RESULTS

Some of your results may be NORMAL while others are LOW. In this case, you might consider seeking the opinion of a medical expert.



Follow these simple instructions and you will have great success testing your sample without interruption.

- Step 1: Download the YO™ software application from the Apple Store or Google Play based on the type of smartphone you have.
- Step 2: Prepare your phone before starting: Password protect your phone. Charge your phone to at least 50% and make sure you have enough free memory to run the YO program (100MB minimum). YO will warn you if you need to do these things but it's better to be prepared.
- **Step 3:** If you are running the test for someone else (it is not your sample), wear exam gloves because semen is a biologically hazardous material (exam gloves can be found online or at any pharmacy).

Step 4: Wash your hands with soap and water before and after handling your semen sample or test components.

When instructed by the YO app, collect your sample by masturbation directly into the sample container provided in the YO kit. Do not use condoms, lubricants, or partners. YO results may not be correct if you do not follow these instructions.

A minimum of about 1/8 teaspoon of semen (1/2 milliliter) is required for testing. For best results, do not have any sexual intercourse or masturbate 2-5 days before YO testing.

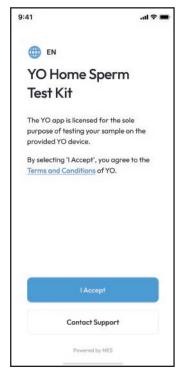
Step 5: Do not cool and do not place your sample in the refrigerator - just let it rest.

Sample testing and motility: Once you collect your sample, immediately follow the next steps in the YO App for testing.

Once you place the liquefaction powder into your sample as directed in the application, wait 10 minutes before testing as instructed.

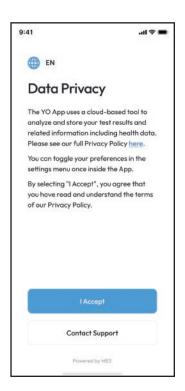
STEP-BY-STEP APP INSTRUCTIONS

1. INTRODUCTION



TERMS AND CONDITIONS

 Read the Terms and Conditions in the link provided and click I Accept.



DATA PRIVACY POLICY

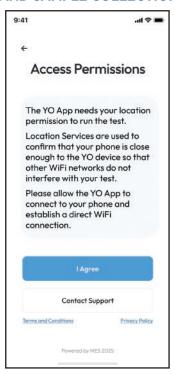
 Read the Privacy Policy in the link provided and click I Accept.

2. START TESTING: SUPPLIES AND SAMPLE COLLECTION





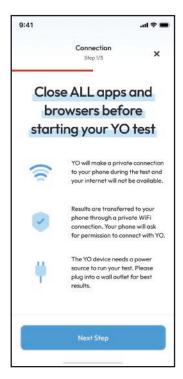
- Tap Start Testing! to run your YO Home Sperm Test.
- Optional: Tap How YO Works to watch a training video.
- Optional: Navigate through YO App Features in the bottom menu.



ACCESS PERMISSIONS

- YO connects to your device by secure Wi-Fi
- Allow YO to connect to your device by tapping I Agree.

3. CLOSE OPEN APPS AND PREPARE TO CONNECT YO



CLOSE ALL APPS

- Even those running in the background.
- · Tap Next Step to proceed.



REMOVE YO AND THE USB CABLE

· Tap Next Step to proceed.

4. CONNECT TO WI-FI & PREPARE TESTING SUPPLIES



CONNECT USB CABLE

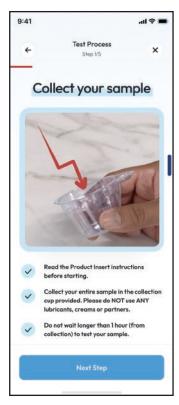
- Connect the USB power cable as shown.
- Tap Test Connection to confirm that YO is connected to your device.



REMOVE TESTING SUPPLIES

· Tap Next Step to proceed.

5. SAMPLE COLLECTION AND PREPARATION



COLLECT YOUR SAMPLE

 Collect your sample and tap Next Step.



PREPARE YOUR SAMPLE

- · Pour in one vial of the pink powder.
- · Swirl the sample to mix.
- · Tap Next Step to proceed.



SAMPLE LIQUEFACTION TIME

- Let your sample rest for 10 minutes.
- · Tap GO! to start the timer.



SPERM TRIVIA CHALLENGE

- Tap Start Trivia Challenge during the wait.
- Learn interesting facts about sperm and fertility.

6. PREPARE THE YO SLIDE FOR TESTING



LOAD THE TESTING PIPETTE

- · Mix your sample by swirling.
- · Fill the pipette as shown.
- · Tap Next Step to proceed.



FILL THE YO SLIDE

- · Find the red dot on the YO slide.
- Put the tip of the pipette on the red dot and pinch.
- Confirm that your sample fills the entire diamond area.

7. WIPE AND INSERT THE YO SLIDE



WIPE THE SLIDE

- Gently wipe the Red Dot on the YO slide filling area.
- Tap Next Step.



INSERT THE SLIDE

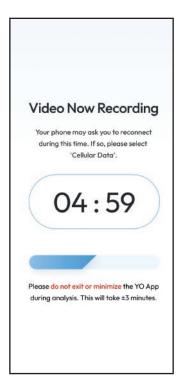
- Insert the slide Face Up all the way into the YO device.
- · Tap Next Step to proceed.

8. TESTING PROCESS & QC



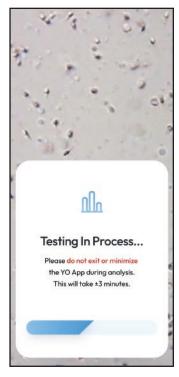
START TESTING

· Tap Next Step to proceed.



VIDEO CAPTURE

- YO will record a video of your sperm.
- Do not touch your phone during the analysis.



TESTING

- · YO will analyze your sperm video.
- Please do not operate your phone during the test.



QUALITY CONTROL (QC)

- YO will run QC before analyzing your result.
- You can now view a video of your sample.

9. YO HOME SPERM TEST RESULTS





YOUR RESULTS

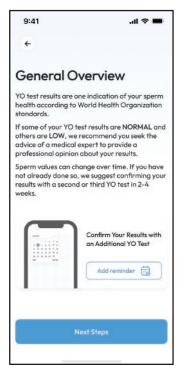
 YO reports Sperm Concentration, Motility, Progressive Motility, Motile Sperm Concentration and Progressive Motile Sperm Concentration, and provides a live video of your sperm. Tap on each parameter to learn more about your results.





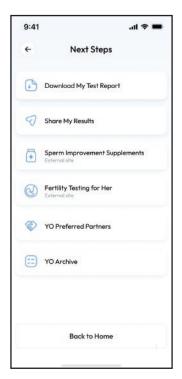
 Once you have reviewed your results and watched your video, tap General Overview for additional information.

10. RESULTS OVERVIEW, ARCHIVE AND NAVIGATION OPTIONS



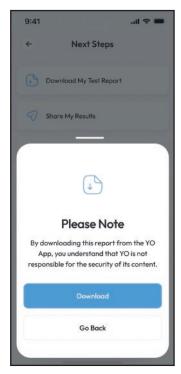
GENERAL OVERVIEW

- Review the recommendations after the test.
- Schedule a confirmation test reminder.
- · Tap Next Steps to proceed.



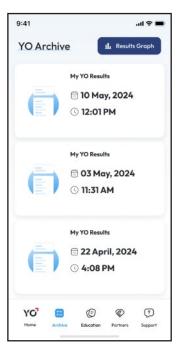
NEXT STEPS

 Download your Test Report, Share your Results, Improve your Sperm, and Explore Her Fertility.



REPORT DOWNLOAD

 Agree to the disclaimer before downloading your Test Report.



ARCHIVE

- · View your stored test results.
- Tap the YO Icon in the navigation menu to return to the home page at any time.

11. ACCOUNT SETTINGS AND SUPPORT



YO ACCOUNT OPTIONS

 Edit your personal information, manage security options, choose your language, and restore your results.



CHOOSE YOUR LANGUAGE

· Select your prefered language.



ACCOUNT SECURITY

- · Change your password.
- · Enable smart login.



CONTACT YO SUPPORT

 Reach out to YO Home Sperm Test if you have questions or problems.

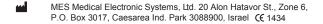
SUPPORT

Access YO support by visiting our website: www.yospermtest.com

Reach out by email: support@yospermtest.com

Give us a call (toll-free): 1-866-YOSPERM (866-967-7376).

Symbol	Description		
Œ	CE mark. European Conformity		
(i	Consult Instructions For Use		
\triangle	IMPORTANT: Read and understand user guide and all precautions before using		
<u></u>	Manufacturer address		
LOT	Manufacturer's Batch Code		
☒	Expiration Date		
IVD	In Vitro Diagnostic Device		
FDA	FDA Cleared: U.S.		
EC REP	European Authorized Representative		



Regulatory Supplement
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Tel: +49 69959325090

PERFORMANCE CLAIMS

In clinical studies, 309 first time YO users showed their results were in high agreement with laboratory results.

Semen Parameters	Correlation (Agreement)	Slope	Dynamic Range
Total Concentration, M/mL	0.93	0.93	2-150 M/mL
Motility, %	0.90	0.90	0-90%
Progressive Motility, %	0.88	0.88	0-85%
Motile Sperm Concentration, M/mL	0.94	0.94	2-80 M/mL
Progressive Motile Sperm Concentration, M/mL	0.94	0.94	0-75 M/mL

CYBERSECURITY CONTROLS

- Cybersecurity recommendations and instructions are available on the YO app during start-up and on the YO site: https://yospermtest.com/cybersecurity/
- · Operate the YO App in a private environment.
- · Keep the YO device in a secure location to prevent physical tampering.
- The USB port of the YO device is intended ONLY to connect the YO device to a power supply. Do not connect any USB devices such as a mouse or a keyboard to the USB port of the YO device.
- It is recommended to use a password to protect your phone for medical confidentiality.

IMPORTANT NOTES AND WARNINGS



According to the World Health Organization (WHO) semen is a biologically hazardous material which can potentially transmit hepatitis and HIV.



YO Home Sperm Test kit components that come into contact with semen should be treated as biohazardous.

YO Home Sperm Test kit components are intended for use by one person. Don't share the kit contents with anyone, including family members.

Protective, powder and latex-free gloves are recommended for anyone testing someone else's sperm. Gloves are not required to test your own sperm. (Example: Kimberly-Clark's sterling nitrile Xtra powder free exam gloves).

Condoms are not recommended for sample collection as they could impact the test results due to spermicidal agents that may be contained in the condoms. Samples collected during sexual intercourse are not recommended as test results may be adversely impacted due to the effect of vaginal mucous pH.

Filling the slide inappropriately by not following the screen instructions may impact test results. Wash your hands with soap and water before and after handling your semen sample or test components.

The YO Home Sperm Test should not be used for post vasectomy testing or contraception purposes.

Perform YO testing in an environmental temperature range of 60-85F. Avoid extreme cold and heat during testing. Do not heat or cool your semen sample.

The YO kit is intended for over-the-counter use. If used in a clinical laboratory or doctor's office, quality control testing should be performed according to federal, state and local requirements and regulations.

Revision Date: 23 DEC 2024

EMC (ELECTRO MAGNETIC COMPATABILITY) RELATED INFORMATION

Intended Use: the YO Home Sperm Test is designed and tested to comply with applicable Electromagnetic Compatibility (EMC) standards for use in the electromagnetic environment specified below.

EMC Compliance: the YO Home Sperm Test complies with the requirements of IEC 60601-1-2 general requirements for basic safety and essential performance related with electromagnetic compatibility of Medical Devices. Compliance has been verified through testing under specific conditions. To maintain compliance, follow the guidelines provided in this Instruction for Use.

No deviations were found from the reference standard or allowances during the YO Home Sperm Test EMC testing.

Use of Accessories: Only use accessories and cables provided or approved by the manufacturer. The use of unauthorized accessories may result in increased emissions or decreased immunity of the device. Specifications of the accessories required for the safe performance of the YO Home Sperm Test are included in the Instruction for Use.

Interference Caution and Reporting: The user should be aware that electromagnetic emissions from nearby equipment or devices may affect the proper operation of the YO device.

In case of EMC-related concerns or issues, users are encouraged to contact the manufacturer through CONTACT US

The YO device complies with both emission and immunity requirements.

The YO device communicates with the user's smartphone via a local Wi-Fi connection. The USB port is only intended to provide power to the YO device.

Maintenance instructions to ensure that the YO device remains safe and performs to EM disturbances as intended: Disconnect the device if not in use for an extended period.

To ensure the safe and effective operation of the YO device, please use a cell phone charger that meets the following specifications:

Charger Type: Standard USB-A/USB-C wall charger.

Input Voltage: 100-240V AC, 50-60 Hz.

Output Voltage: 5V DC, Output Current: Minimum 1.0A, Maximum 2.4A