

YO⁷
Instructions

YO QUICK START GUIDE:

Welcome to YO home sperm testing! This Quick Start Guide summarizes ALL of the things you MUST KNOW before running your YO test. For greater detail, we recommend reading the full instructions in this booklet.

PHONE PREPARATION: Turn your phone into a sperm testing device

- Download the YO app for your phone by visiting the appropriate online store for iPhone or Galaxy or by going to the www.yospermtest.com website and tapping: DOWNLOAD APP.
- Password protect your phone for medical confidentiality.
- Place your phone on AIRPLANE MODE.
- Charge your phone to at least 80% to avoid warning messages.
- Insure that you have 500MB of memory for YO video storage.
- Remove your phone case. OK to leave the phone screen protector on.

COLLECT YOUR SAMPLE: RULES

- Collect your sample by masturbation directly into the sample container provided.
- Do not use condoms, lubricants or partners or this could affect results.
- At least ~1/8 teaspoon of semen is required for testing.
- Your sample can "sit" for up to one hour. Do not heat, do not cool and do not place your sample in the refrigerator - just let it rest.
- Start YO testing following the YO app instructions right after collecting your sample for best results. Your swimmers die over time.
- For optimal results, do not have any sexual intercourse 2-7 days before YO testing.
- Wash your hands after collecting your sample.

HOW LONG DOES THE TEST TAKE? ~ 25 minutes

- Sample Liquefaction (making your sample runny for testing): 10 minutes.
- Filling the YO Slide with your sample: ~ 3-5 minutes.
- Video capture, QC and analysis time: ~ 3-4 minutes.
- Phone cleaning: 5 minutes.
- Watching your YO video in awe: This could go on forever...

GETTING THE YO TESTING SUPPLIES READY

- Prepare a white surface for testing (a piece of paper will do).
- Grab the testing supplies marked "Supplies for one YO Test" and lay them out in front of you.

AFTER TESTING: CLEAN YOUR PHONE and YO CLIP

- Remove the YO® Clip from your phone.
- Grab one wipe from the YO kit:
 - Wipe your phone, front and back, lens and camera. Avoid saturating the port areas.
 - Using the same wipe, clean the YO Clip on all accessible surfaces.
- Let your phone/YO Clip air dry for 5 minutes (it will be decontaminated in 1 minute). Do not wipe with a dry cloth or tissue.
- Between tests, zip lock the YO® Clip in the bag provided in your YO kit.
- Throw away used wipes, collection cup, slide and pipette after each test.
- Wash your hands with soap and water after cleaning the phone and YO Clip.

YO PRODUCT INSTRUCTIONS

ABOUT YO

YO is the first FDA cleared, smartphone based sperm test that not only reports whether your MOTILE SPERM CONCENTRATION (MSC) is LOW or MODERATE/NORMAL but also shows you a live video of your sperm. In normal intercourse, only a motile sperm can reach an egg so it is important to test your “supply” of moving sperm. YO navigation is easy. 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 place the YO Clip on your phone and insert the slide. YO records a video of your sperm and then analyzes it to see if you have ≥ 6 million motile sperm or less. Before you start you can watch HOW YO WORKS or read the instructions provided.

Please note: YO is a smartphone based home sperm test that provides a qualitative assessment of motile sperm concentration (MSC) in human semen. MSC is one aspect of a male semen examination. The YO Home Sperm Test does not provide a comprehensive evaluation of a male's fertility status and is intended for over-the-counter, in vitro use only.

WHAT IS MOTILE SPERM CONCENTRATION?

MOTILE SPERM CONCENTRATION is the number of moving sperm cells in 1 milliliter of your semen. So, both sperm concentration and motility are considered. YO reports results as MODERATE/NORMAL MSC RANGE or LOW MSC RANGE based on a 6 million per milliliter threshold (cut-off). Results below 6 million will be reported as LOW MSC RANGE. Results equal to or greater than 6 million will be reported as MODERATE/NORMAL MSC RANGE. An explanation of your test results is displayed after your test is run. Please note: YO is not to be used to determine the success of a vasectomy.

WHAT IS INCLUDED IN THE YO KIT?

- (2) Plastic cups for collecting your semen sample
- (2) YO slides for sample testing
- (2) Vials of liquefaction powder (to make your samples 'runny')
- (2) Plastic pipettes for transferring the sample to the slide
- (1) YO Clip which attaches to your smartphone
- (1) Plastic zip-lock YO Clip storage bag
- (2) Cleaning wipes

HOW LONG DOES THE TEST TAKE?

Preparing your sample for testing takes the most time. In order 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. The actual analysis time is ~ 2 minutes. So, allow a minimum of 25 minutes of your time to run your test (not including the time you need to collect your sample).

CAN I USE MY PHONE DURING THE YO TEST?

Your phone needs to be on AIRPLANE MODE when running YO. When you see this icon  you can use your phone.

PHONE MEMORY AND CHARGING

Start with a fully charged phone before beginning a YO test. 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.

BEFORE YOU START TESTING

It's a great idea to prepare ahead, before you start the actual testing procedure. 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. Watch **HOW YO WORKS** in the YO app and/or read the step by step test instructions before you start.
- step 2:** **Prepare your phone before starting:** Password protect your phone and remove your phone case. Place your phone on AIRPLANE MODE; Charge your phone to at least 50% and make sure you have enough free memory to run the YO application (500MB 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 considered to be 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.**

If you have not collected your sample before starting the app, **YO will tell you when to collect your sample** (when you reach the START TESTING screen). **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 this instruction. A minimum of about 1/8 teaspoon of semen is required for testing. For best results, do not have any sexual intercourse 2-7 days before YO® testing.

step 5: Your sample can "sit" for up to one hour. Do not heat, 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, begin YO testing because your sample motility may decline after 1 hour. Once you place the liquefaction powder into your sample as directed in the application, wait 10 minutes before testing as instructed. Do not wait longer than 30 minutes after the powder is placed into the sample or your sperm motility may decline.



START YO

Click the YO icon  on your phone desktop. For step-by-step instructions, read HOW YO WORKS.

WHY TWO TESTS?

Your sperm values can change over time. A "low" result today could be "normal" in a month. It is important to run your test two times – especially if you receive a LOW MSC RANGE result the first time. Remember that it only takes ONE sperm to fertilize an egg so you may be fertile even with a low result.

PHONE and YO CLIP CLEANING AND STORAGE

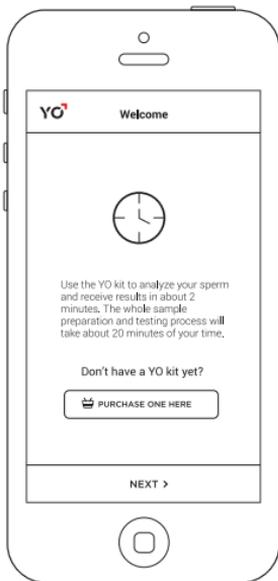
Use one of the cleaning wipes provided to clean your phone and YO Clip after testing. Save the second wipe for your second test. You will not be able to exit YO without confirming that you have completed the cleaning process. YO will advise you to clean your phone according to the instructions below.

- Remove the YO Clip from your phone. Using one cleaning wipe, clean the phone, front and back, all areas and let the solution air dry for 5 minutes. Although the wipes are compatible with all surfaces of your phone, avoid saturating the phone port areas as they will take longer to dry. Be sure to clean the phones' camera/lens. Your phone will be decontaminated in 1 minute and will air dry in 5 minutes. Do not wipe the phone or YO clip with a dry cloth or tissue.
- Using the same wipe, clean the YO Clip on all accessible surfaces following the SAME instructions for cleaning the phone.
- Between tests, zip lock the YO Clip into the bag provided in your YO kit.
- Throw away the used wipe, collection cup, slide, pipette and empty liquefaction vial after each test.
- Wash your hands with soap and water after cleaning the phone and the YO Clip.
- Failure to follow these cleaning instructions could result in the transmission of infectious diseases such as hepatitis or HIV to others.

HOW YO WORKS:

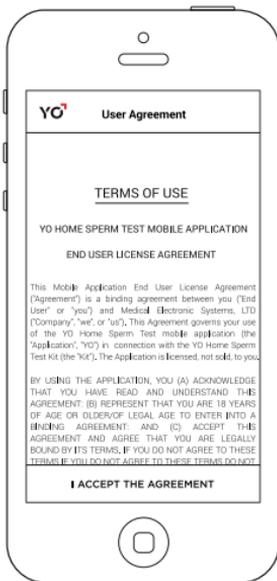
Step-by-Step Instructions for using the YO Application and Test Kit to run your semen sample

I. NAVIGATION AND PHONE PREPARATION



PHONE PREPARATION:

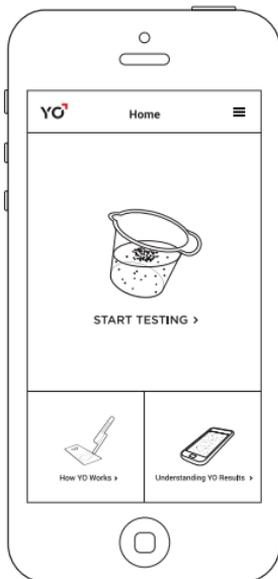
- Charge to 50%
- Place on airplane mode
- Password protect for medical confidentiality



USER AGREEMENT:

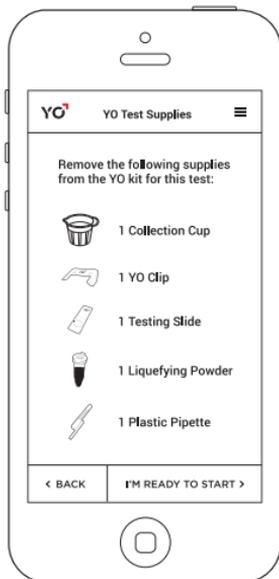
- Read and scroll to the bottom to accept

II. START TESTING: SUPPLIES AND SAMPLE COLLECTION



START TESTING:

- Tap START TESTING
- Tap HOW YO WORKS to see a short video
- Tap ABOUT YO RESULTS to understand the YO test



SUPPLIES FOR ONE TEST:

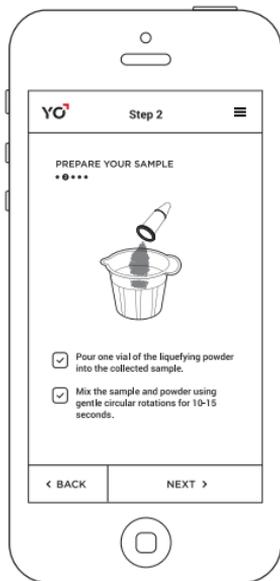
- Place these supplies in front of you
- Tap I'M READY TO START

II. START TESTING: SUPPLIES AND SAMPLE COLLECTION



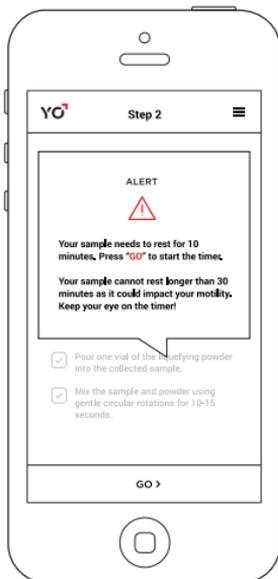
COLLECT YOUR SAMPLE:

- Read the Quick Start Guide
- Collect your sample and tap NEXT >



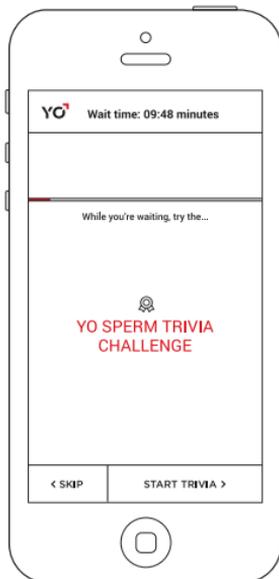
PREPARE YOUR SAMPLE:

- Pour in the powder
- Mix the sample - it will turn slightly pink
- Tap NEXT>



SAMPLE RESTING TIME:

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

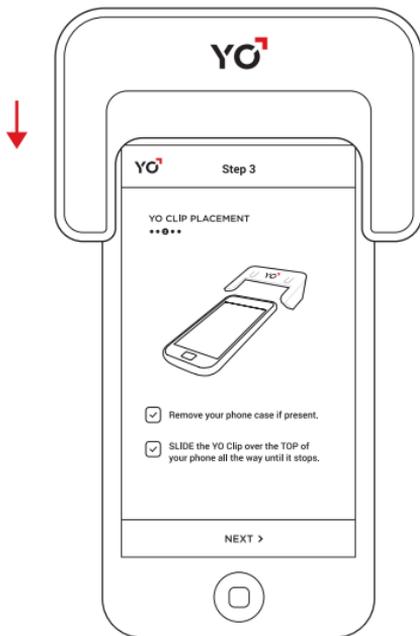


SPERM TRIVIA CHALLENGE:

- While waiting 10 minutes ...
- Tap START TRIVIA >

III. ATTACH THE YO CLIP TO YOUR PHONE

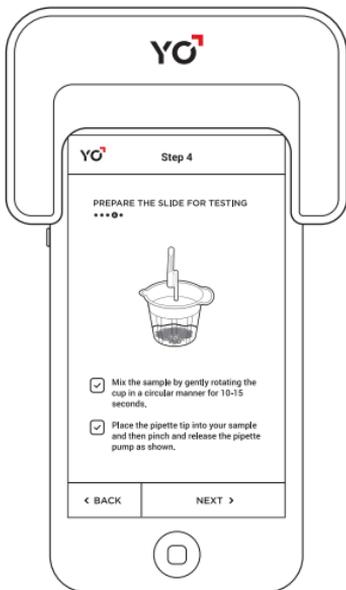
(Your YO Clip may look different than the one pictured)



YO CLIP PLACEMENT:

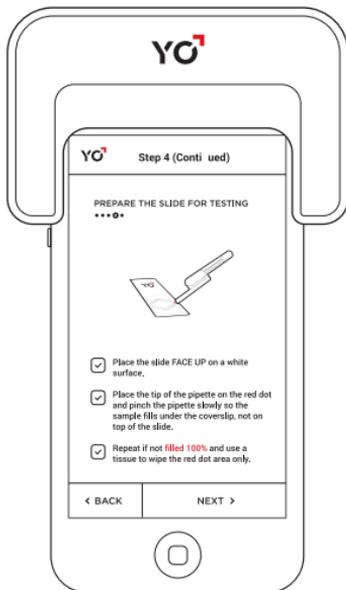
- Remove your phone case
- Slide the YO Clip over the TOP of your phone
- Tap NEXT >

IV. PREPARE THE YO SLIDE FOR TESTING



GRAB YOUR SAMPLE:

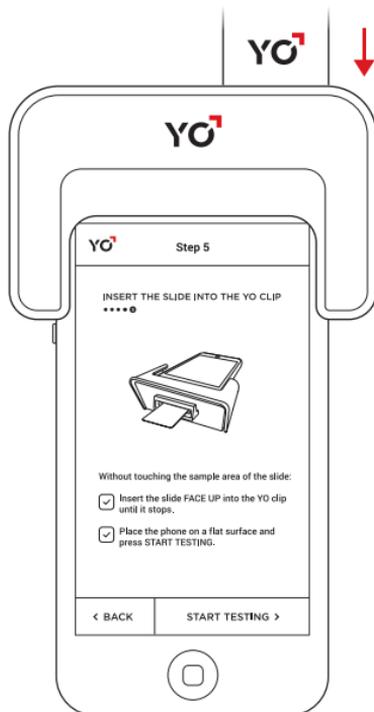
- Mix your sample
- Fill the pipette as shown
- Tap NEXT >



LOAD THE SLIDE:

- Find the red dot on the slide
- Put the tip of the pipette on the red dot and pinch
- Watch your sample fill the triangle well of the slide
- Wipe the slide gently with a Kleenex

IV. PREPARE THE YO SLIDE FOR TESTING



INSERT THE SLIDE:

- Insert the slide FACE UP into the YO Clip
- Tap: START TESTING>

V. TESTING PROCESS



VIDEO CAPTURE:

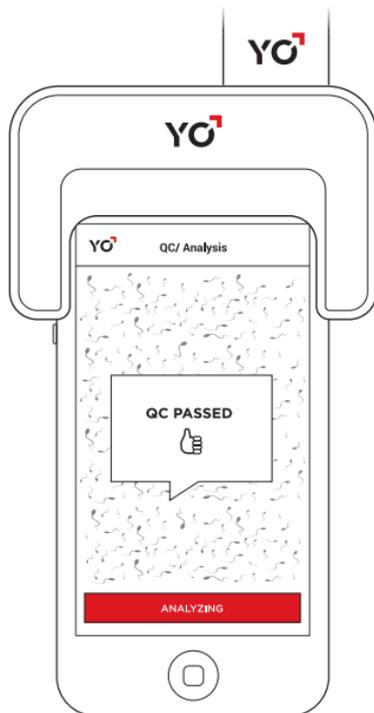
- YO captures a video of your sperm
- Do not touch your phone



CHECKING THE VIDEO:

- YO checks to see if everything is OK

V. TESTING PROCESS



QC:

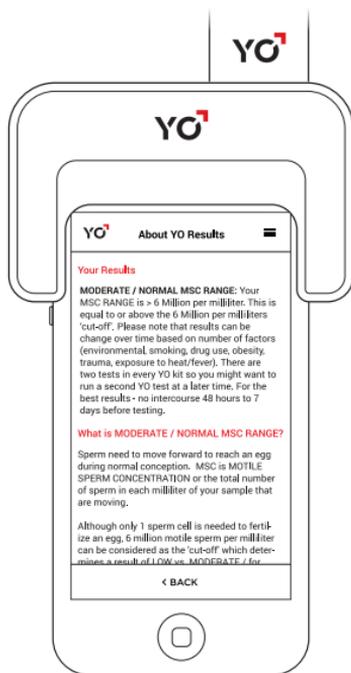
- Everything is OK so YO runs your test
- View your Swimmers in Action!

VI. YO RESULTS AND CLEANING



TEST RESULTS: MODERATE/NORMAL

- Tap WHAT DOES IT MEAN to learn about your results
- Minimize the screen to view your swimmers



YO RESULTS:

- Read about your test results

VI. YO RESULTS AND CLEANING

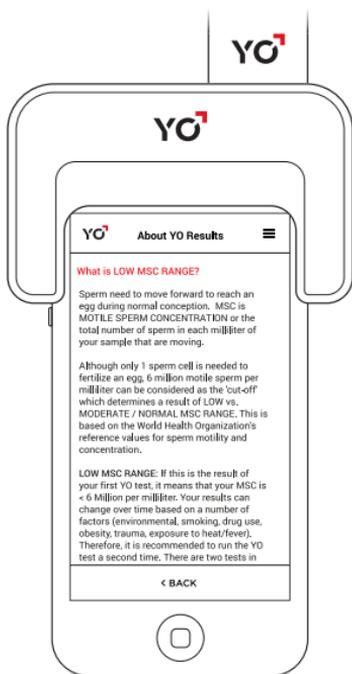


VIEW YOUR SWIMMERS

- See your swimmers full screen
- Stretch the screen to enlarge the image

TEST RESULTS: LOW

- Tap WHAT DOES IT MEAN to learn about your results
- Minimize the screen to view your swimmers



YO RESULTS:

- Read about your test results



CLEANING

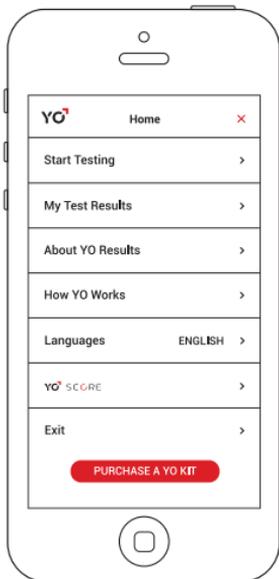
- Follow the instructions in the Quick Start Guide for cleaning your phone and YO Clip.

VII. EXITING YO AND NAVIGATION OPTIONS



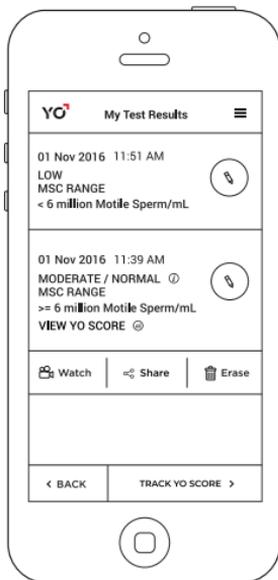
THANK YO:

- The end of the YO testing cycle.
- Wait 5 seconds and it will disappear



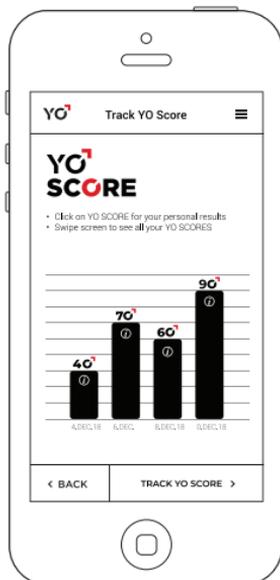
YO MENU:

- Select from this menu of choices



YO ARCHIVE:

- View/share your YO results
- View and track your YO Score if your results are MODERATE/ NORMAL



YO SCORE:

- Track your YO SCORE over time

PERFORMANCE CLAIMS:

In clinical studies conducted with 316 first-time users, the correct YO result, as compared to a laboratory instrumented method, was obtained 95% of the time. When conducted by professionals, correct results were obtained > 97% of the time.

Phone Type: Galaxy		SQA-V		
Galaxy		Low	M/N	Total
	Low	33	6	39
	M/N	1	96	97
	Total	34	102	136
PPA = 33/34 = 97.1%		95% CI: (84.7%; 99.9%)		
NPA = 96/102 = 94.1%		95% CI: (87.6%; 97.8%)		

Phone Type: iPhone		SQA-V		
iPhone		Low	M/N	Total
	Low	48	3	51
	M/N	3	126	129
	Total	51	129	180
PPA = 48/51 = 94.1%		95% CI: (83.8%; 98.8%)		
NPA = 126/129 = 97.7%		95% CI: (93.4%; 99.5%)		

IMPORTANT NOTES AND WARNINGS:

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

 YO home test kit components that come into contact with semen should be treated as bio-hazardous. Strictly follow the cleaning, storage and disposal instructions of this product insert : **PHONE and YO CLIP CLEANING AND STORAGE.**

- YO home test kit components are intended for use by one person. Don't share the kit contents with anyone, including family members.
- Protective, powder free non-latex 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.
- Please note that in the presence of STD causing bacteria and viruses: e.g., Neisseria gonorrhoea, cytomegalovirus (CMV), human papillomavirus (HPV), herpes simplex virus and Chlamydia trachomatis your potential sperm motility may be affected. YO may report results in LOW MSC RANGE in the presence of sexually transmitted diseases or infections but in the absence of such disease or infections your sperm could be in the MODERATE/ NORMAL MSC RANGE.
- Please note that the use of the drug D-norgestrel (steroidal progestin) may affect your sperm motility count by lowering the count.
- Filling the slide inappropriately by not following the screen instructions may impact test results.
- The YO home sperm test should not be used for contraception purposes.

- Perform YO home sperm 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 Home Sperm Test is intended for over the counter home 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.
- YO is not FDA cleared for use in evaluating the effectiveness of vasectomy surgery.

SUPPORT

YO support can be obtained by visiting our website: www.YOspermTEST.com or by emailing our support: Support@YOspermTEST.com

SYMBOLS USED IN THE SYSTEM

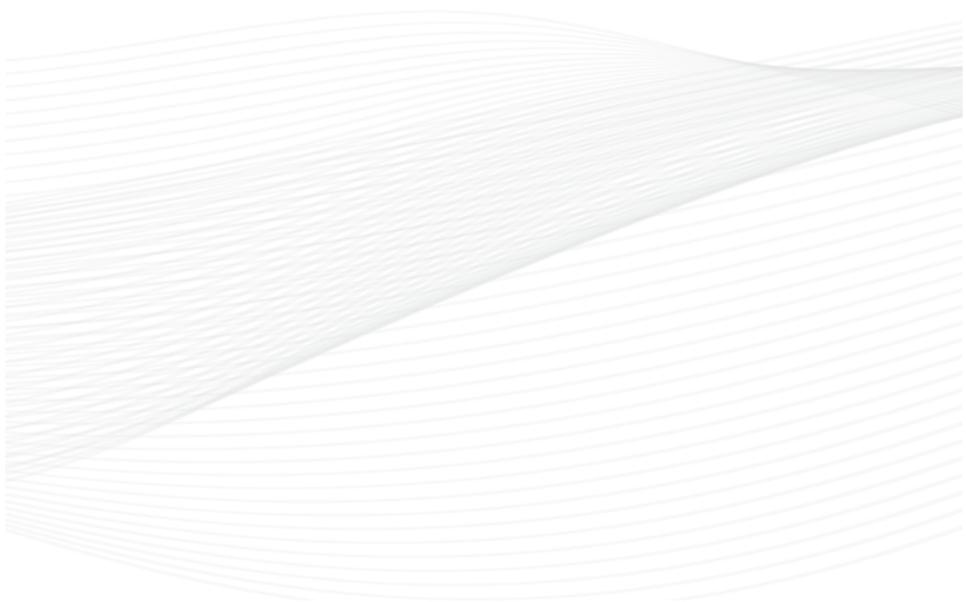
Symbol	Description
	CE mark. European Conformity
	Consult Instructions For Use
	IMPORTANT: Read and understand user guide and all precautions before using
	Manufacturer address
	Manufacturer's Batch Code
	Expiration Date
	In Vitro Diagnostic Device
FDA	FDA Cleared: U.S.



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