INSTRUCTIONS FOR USE

EXSEED HEALTH

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Congratulations on your ExSeed device!

About ExSeed

ExSeed is a self-test IVD Medical Device. The ExSeed system consists of a self-test kit that includes:

1. **ExSeed analysis device**
2. **Collection cups and lids**
3. **Sample slides**
4. **Wipes**
5. **Instructions for Use**

What is ExSeed used for?

ExSeed is a smartphone-based self-test for assessment of:

- Semen volume (ml)
- Sperm cell concentration (Million/ml)
- Sperm cell motility (%)
- Total Motile Sperm Cells (Million)

ExSeed enables a user to estimate the quality of his sperm sample. It also enables the user to monitor and track the progression of the sperm quality over time.

ExSeed does not provide a comprehensive evaluation of a male's fertility status and is intended for over-the counter, in vitro use only.
For a complete assessment of male reproductive health, the user should consult a medical professional.

Disclaimer: always seek the advice of a qualified medical professional before making any changes to your lifestyle (exercise, sleep, or nutrition), as doing so may cause harm.

THE EXSEED SYSTEM

How does the ExSeed system work?

The product works in the following way:

The user downloads the App and follows the guide for taking a semen analysis test. A semen sample is collected in the collection cup and left to liquefy for 15 minutes. A part of the sample is transferred to the sample slide with the pipette incorporated in the lid of the collection cup. Residual liquid is removed with the wipe and the sample slide is inserted into the ExSeed analysis device whereby a light in the device automatically turns on. The smartphone is then placed on top of the device and a video sequence of the sample is recorded via the ExSeed App and sent to the data analysis.

It takes around 1-3 minutes for the image analysis to be completed and the result to be shown in the ExSeed App. This will depend on the speed of the internet connection and the phone model that is used.

The image analysis consists of identifying 1) the number of sperm cells and 2) the number of motile sperm cells present in the sample.

What else will I need?

A smartphone model with:

- A camera with a maximum pixel size of 1.4 µm/pixel
- A camera with a minimum of 12 Megapixels
- An operating system of at least Android vers. 9.0 or iOS min vers. 12.0
- Internet connection (250 kbps or faster)
- ExSeed Application Version: 1.0.0 or above (see in App settings)

What sample may be tested?

The ExSeed system is designed to **only test human semen samples**. Use of any other sample will give an incorrect result.

For optimal results, do not ejaculate for 2-3 days before testing day and collect your sample by masturbation directly into the ExSeed collection cup. Don't use any lubricants.

How long does the kit last?

The ExSeed device has a battery life of 200 hours. The ExSeed collection cups, sample slides, and wipes have a shelf-life of 5 years. See expiration date on the kit box label and use these items within expiration date.

How long will my sample last?

Your sample should be tested within 60 minutes of ejaculation. A sample that has been kept longer than 60 minutes must be discarded, and a new sample provided for a new test. We recommend ejaculation abstinent of 2-3 days before testing.

TESTING INSTRUCTIONS

Step by step guide:

Before you take a semen analysis test, **download the ExSeed App, create a profile, and scan the QR code located in the ExSeed box.**

Make sure that:

- You have the latest updated version of the app
- Your phone has at least 20% battery
- You remember to password protect your phone to keep your information confidential

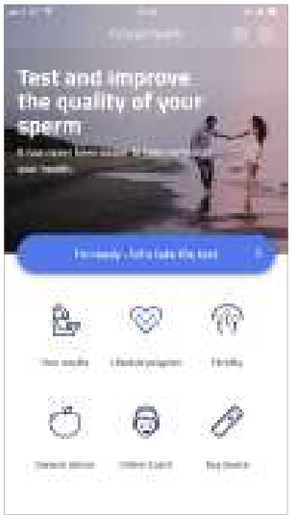
How to take a semen test

When you are on the App "home" screen, press the "I'm ready, let's take the test" button and follow the instructions for testing.

You will be guided by illustrations, text, and videos. We recommend you to start by seeing the full version of the **introduction video**.

Press this button to start a test:

I'm ready - let's take the test



Step 1

Unpack and get ready.

Step 2

Deliver the semen sample directly in the ExSeed cup.

Step 3

Leave the sample in the cup and let it rest for 15 minutes at normal room temperature.

Step 4

Mix the sample as instructed in the App.

Step 5

Use the scale on the ExSeed cup to evaluate the volume of the sample and insert it in the app.

Step 6

Transfer sample to the sample slide. Fill in both chambers as shown in the video.

Step 7

Remove residual semen from the sample slide using the wipe provided in the kit.

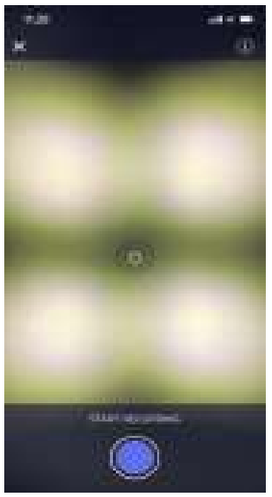
Step 8

Insert slide into the device.

Step 9

Press “I’M READY TO RECORD” and align the camera on the phone and the ExSeed device.

When 4 light cones appear as seen below, press "START RECORDING" to record the video.



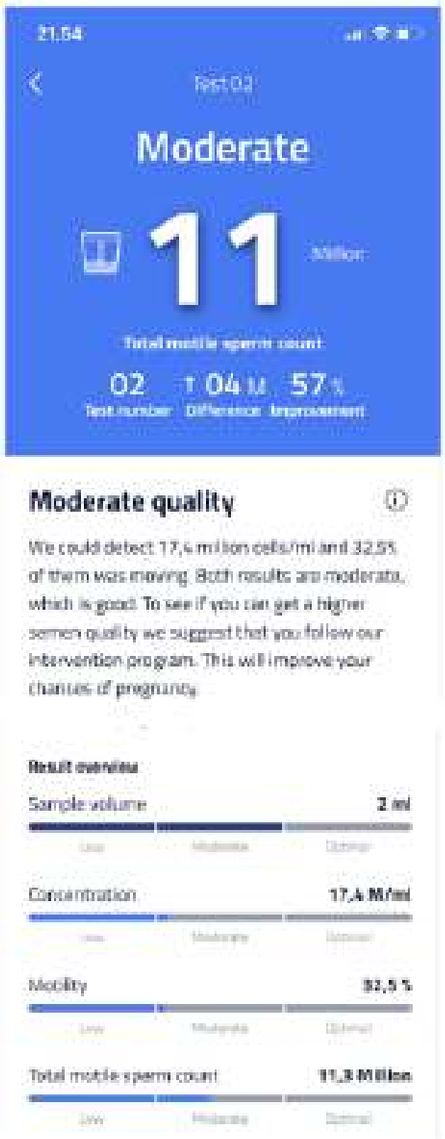
Step 10

When ExSeed has analysed your video, you will be presented with a result page like this:

Section 1

Section 2

Section 3



SEMEN QUALITY TEST RESULTS

What does it mean?

When completing a semen test you will see your result presented as in step 10.

In **section 1** you see if your sample is of **low, moderate,** or **optimal** quality based on the Total number of Motile Sperm Cells Count (TMSC).The main number is the TMSC and underneath you see test number, difference in TMSC since last the test in millions and in percentage.

In **section 2** your results are explained more thoroughly and when pressing the (i) you can read about how these results relate to pregnancy based on scientific literature.

In **section 3** you can view your results report in detail. Here you can see an assessment of each of your semen parameters.

How do I know the test has worked properly?

When you have a results view as shown in **step 10**, you have successfully completed a test. If it is the first time you use the device for semen quality testing, we advise you to take one more test within 10 days and compare the two results to be sure of the semen quality level.

Remember to have the same period of ejaculation abstinence (recommended 2-3 days) for both tests.

If the ExSeed system cannot capture sperm cells or the video is not of proper quality (e.g. because the 4 light cones are not visible), an error message will appear.

What might stop ExSeed giving me correct results?

The following circumstances may affect your semen quality result and should be considered before taking a test:

- If the full sample is not captured
- Irregular sleep for more than one week
- Use of medications affecting semen production
- Fever (above 38°C / 100.4°F) for more than 2 days
- If you have felt hungover from alcohol up to 4 days prior to testing

Wait until you feel completely healthy to do a test, otherwise contact your medical professional.

The following circumstances may affect results:

- Using the wrong semen sample
- Reusing a collection cup and lid
- Reusing a sample slide or using a slide that is not from ExSeed
- Filling the sample slide inappropriately

How accurate is the ExSeed system?

In a clinical study comparing the results of the ExSeed self-test to certified laboratory equipment, ExSeed correctly classified a low Total Motile Sperm Cell result in over 95% of cases.

Linearity for the sperm parameters has been tested in the concentration range of 5M/ml to 125M/ml. If the test repeatedly shows a concentration of less than 5M/ml, we recommend that you seek further medical consultation. If the test shows more than 125M/ml, it means that you are in the very high range. The test result in this range may be presented with less accuracy.

IMPORTANT NOTES AND WARNINGS

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

ExSeed 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.

- The ExSeed device is intended to be used by one person only. Do not share the device with anyone, including family members.
- Protective, powder free non-latex gloves are recommended for anyone helping you to test your semen sample.
- Semen collected during sexual intercourse is not recommended as test results may be adversely impacted due to the effect of vaginal mucous pH.

- Sample volume linearity has been tested between 1-3.5 mL. If your semen sample repeatedly is below 1 mL, we recommend that you seek further medical consultation. If your sample volume is above 3.5 mL it means that you are in the very high range, and we recommend that you estimate your volume and continue.
- Measurement precision has been tested with sample volumes between 1.5-3 mL. If sample volume is below 1.5 mL or above 3 mL, sperm parameters may be presented with less accuracy.

- If the full sample is not captured, discontinue and retest another day, since it may lead to inaccurate results.

- Please note that the presence of sexually transmitted diseases may negatively affect your sperm quality.

- Please note that the use of D-norgestrel (steroidal progestin) may negatively affect your sperm quality.

- Do not re-use any ExSeed sample slides or cups. For more sample slides or cups, order on: www.exseedhealth.com.

- Use only ExSeed cups within their expiration date. You can check the expiration date on the ExSeed box label.

- Be careful when handling the sample slide. There is a minimal possibility of cutting fingers if you break it by accident.

- The foil bag can be difficult to open. Please be careful when you rip it open and take out the sample slide.

- It may be difficult to take off the lid from the cup once it contains a sample. Please be careful so you don't spill any semen.

- The ExSeed home test should not be used for contraception purposes.

- Use the ExSeed device in a dry environment and do not test during shower or under other wet conditions.

- Perform ExSeed self-testing in an environmental temperature between 20-30°C (68-86°F). Do not heat or cool your semen sample.

AFTER USE

The sample slide and cup are for single-use only. Please dispose once used. Use a wet (alcohol based) wipe to clean the surface of the ExSeed device's surface.

Disposal

The ExSeed device incorporates batteries. Dispose device in accordance with local regulations.

After each semen test, the used cup with the lid should be closed, wrapped in a separate bag and disposed of normal household garbage. The sample slide is to be disposed of with other glass materials or in normal household garbage once inserted into the opened foil bag.

Storage

The ExSeed kit should be stored at normal room temperature (15-25°C / 59-77°F). We recommend that it is not exposed to temperatures below -20°C (-4°F) or above 40°C (104°F). The ExSeed Analysis Device should always be stored in the ExSeed Box when not in use.

HELP AND GUIDANCE

For technical help or other questions, you are always welcome to contact the ExSeed Team online via www.exseedhealth.com or request a technical call through the App in the "Online Coach" section.

ExSeed Health ApS
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Symbols used in the system

	Manufacturer information
	Instructions for Use
	CE mark, European Conformity
	In Vitro Diagnostic Device
	Expiration Date
	Manufacturer's Batch Code
	Manufacturer's article number
	Waste from Electrical and Electronic Equipment
	IMPORTANT: Read and understand user guide and all precautions before using
	Store at 15-25 degrees