

FIRST THINGS FIRST

Why do you recommend FSH Testing?

In a typical natural cycle, one of the ovaries releases a mature egg. The role of FSH is to stimulate the growth of the dominant follicle that will release that mature egg. As your ovarian reserve diminishes, more FSH (Follicle Stimulating Hormone) is needed to help recruit and grow the dominant follicle every month. Elevated FSH levels can help you understand your ovarian reserve status and plan accordingly.

Testing FSH can help you know if your symptoms, such as inability to conceive, irregular periods, hot flashes, vaginal dryness, or sleep problems, might be in part due to a low ovarian reserve.

How Proov Tests Work

You must use the Proov brand tests included in this kit and the Proov Insight app together for accurate results.

Proov urine tests measure the concentration of hormones in your first morning urine. This concentration is reflected in the intensity of the red line that appears on the test strip after the 10-minute developing period. Each test strip will also display a control line that indicates the test is working properly.

Once you scan your test strip into the Proov Insight app, the app will read and interpret the color to provide numerical insight about your hormones. We calibrate the levels in the app by comparing the color intensity of your test strip to the color intensity of test strips dipped in urine samples of known hormone values.

Inside this kit You'll also need

- FSH test strips
- Urine Collection Cup
- Smartphone
- Internet Connection
- Free Proov Insight App download here* →



*Proov Insight App requires iPhone 6 or above or Android equivalent.

1 GETTING STARTED + TESTING BEST PRACTICES

This kit measures Follicle Stimulating Hormone (FSH) in your first morning urine. FSH is a hormone produced by the pituitary gland in your brain. FSH levels increase temporarily each month to stimulate your ovaries to produce eggs. When your ovarian reserve is low, FSH levels will increase.

Before Testing:

Download the free Proov Insight app at the QR code above. Create an account and input some basic cycle data to get started. You must use the Proov Insight app to read Proov Reserve test strips.

When to Test:

After you have created your free Proov Insight app account and added your cycle data, the app will seamlessly walk you through your test days. The first day of your period is cycle day 1 (CD1). FSH testing should start on cycle day 5. Since FSH levels can fluctuate, we recommend testing on cycle days 5, 7, and 9. If 2 or more tests are high, please follow up with your clinician to determine if your ovaries might not be working as well.

2 HOW TO TAKE PROOV FSH TESTS

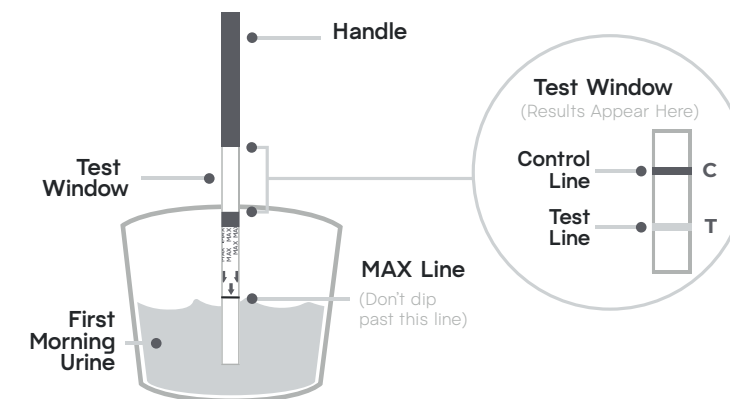
1: Pee. Collect your first morning urine in a clean, dry cup (not provided). **REMINDER:** Retain your urine sample until you've finished using your test strip and have scanned your results. That way, in the event of an error, you can easily test again with the same first morning urine.

2: Dip. Without going past the MAX line, dip the white end of the strip into the urine sample until you start to see urine going up the test window (about 10 seconds).

3: Wait 10 minutes. Set the strip aside on a flat, nonporous surface and wait 10 minutes for the test to develop. Reading the test before or after the 10-minute mark will produce inaccurate results.

4: Results. Place the developed test strip inside the gray box on the small card provided in your kit and follow the in-app directions to scan your test to determine and record your results. Then discard your strip and your urine sample.

Invalid results: FSH tests are invalid and will not be scanned by the Proov Insight app if zero lines or no Control Line is visible. Please contact us if your test fails.



Questions & Answers

1. What does "diminished ovarian reserve" (DOR) mean?

As a general rule, the fewer the eggs you have left, the higher your FSH levels are. DOR means you have less eggs left. This does not mean you will not be able to conceive, it just means you might have less time left to conceive. The amount of time you have left varies from woman to woman so if your FSH levels are high and you are having trouble conceiving, please reach out to your clinician so they can properly treat you.

2. What happens if my current cycle day is past the FSH testing start date?

We recommend starting your testing on cycle day 5 (CD5). If you are past CD5, then you'll need to wait until the next cycle. The good news is you'll know exactly what to plan for next time!

3. Does high FSH mean I am in menopause?

Levels of FSH consistently above 25 mIU/ml may indicate you are close to menopause. However, menopause is defined as not having a period for 12 consecutive months.

4. How accurate are Proov FSH Tests?

A laboratory study has shown these tests to be over 99% accurate in detecting FSH in urine.

5. Do I need to use first morning urine?

For best results we recommend you use first morning urine to test for FSH.

6. I have taken Proov FSH Tests as directed and am not getting high FSH results, does this mean my ovaries are working okay?

Proov Tests do not replace medical advice. If you're not getting high FSH results, but have symptoms of poor ovarian function, consult your clinician and tell them about this information so they can properly advise you.

7. Can I use my Proov FSH Test result to understand my overall fertility status?

No, Proov Reserve FSH tests do not determine if you are fertile or can become pregnant.

Got Questions?

WE'RE HERE FOR YOU!

Visit our website: proovtest.com
Send us an email: info@proovtest.com
Call us toll-free: 1-833-PROOV-IT (833-776-6848)
Monday-Friday 9am – 5pm
Mountain Time

Intended Use

The Proov Reserve Test is intended to measure follicle stimulating hormone (FSH) to assess ovarian status or ovarian reserve. Paired with the Proov App Test System, numerical tracking of FSH can be achieved.

Expected FSH Values for Women

According to the ACOG (American College of Obstetricians and Gynecologists), levels of FSH that are consistently greater than 25 mIU/ml are consistent with menopause. Although there are no definitive criteria for diminished ovarian reserve, FSH values above 10 mIU/ml may be considered consistent with diminished ovarian reserve.

During a natural ovulation cycle, hormones measured in this kit will fall within the following ranges:
0.1-45 mIU/ml.

Storage and Stability

1. Store tests at room temperature (36-86°F/2-30°C) in the sealed pouch.
2. Keep away from direct sunlight, moisture, and heat.
3. Do not freeze.
4. Use immediately after opening the pouch.
5. Pouch contains a test strip and a desiccant. Desiccant is for storage purposes only.
6. Do not use the test after the expiration date printed on the pouch, as the test may provide invalid or inaccurate results.

Precautions & Test Limitations

1. Tests are for in vitro diagnostic and external use only. Do not swallow.
2. Discard after use. Test strip cannot be used more than once.
3. Do not use strips if pouch is not sealed properly.
4. Keep out of reach of children.
5. Read all instructions prior to use. Improper usage may lead to invalid or inaccurate results.
6. This product is not for contraceptive use.
7. The test results will not be affected by pain relievers, antibiotics or other common drugs. However, results will be affected by certain fertility medications (i.e. Clomiphene, Letrozole, etc.).
8. Usage of pill or patch that contains hCG or LH may affect test results and should not be taken before using this test kit.
9. Test strips should only be used with the Proov Insight app. Similarly, the Proov Insight app should only be used with Proov's family of test strips.

proof
reserve

Check your
 ovarian
 reserve.

The Self-Testing FSH Test to Understand
 Ovarian Reserve.

instructions for use:

1. When to test
2. How to test
3. How to get results

PRINCIPLE OF THE PROCEDURE

The test device is a two site sandwich immunoassay. The membrane is pre-coated with anti- α -FSH capture antibody on the Test line region and goat anti-mouse antibody on the Control line region. The test device is an immunoassay containing mouse monoclonal anti- β -FSH antibody conjugated to colloidal gold and monoclonal anti- α -FSH as a capture antibody on the Test line region of nitrocellulose membrane. During testing, the urine specimen reacts with a colored conjugate (anti- β -FSH monoclonal antibody-colloidal gold conjugate) that is pre-dried on the test strip. As the test specimen flows through the membrane assembly of the device, the highly specific monoclonal anti- β -FSH antibody-colloidal gold conjugate complexes with the FSH in the specimen and travels on the membrane due to capillary action along. This complex moves further on the membrane to the test region (T) where it is immobilized by anti- α -FSH antibody coated on the membrane, leading to formation of a colored band. The unbound complex, if any, move further on the membrane and are subsequently immobilized by the goat anti-mouse antibodies coated on the membrane at the control region (C), forming a colored band.

PERFORMANCE CHARACTERISTICS

1. Sensitivity: This sensitivity level has been confirmed with FSH standards in urine. The results demonstrated that the cut-off of the test is 25 mIU/ml. The test has been standardized to the World Health Organization (WHO) Second International Reference Preparation (IRP 78/549).

2. Specificity: The test was determined from cross reaction studies with known amounts of human Chorionic Gonadotropin (hCG), human Luteinizing Hormone (LH) and human Thyroid Stimulating Hormone (TSH). The addition of 200 mIU/ml LH, 1000 mIU/ml hCG and 200 μ IU/mL TSH to hCG negative and positive specimens showed no cross-reactivity.

REFERENCES










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2. Pike J, Ellis J, Johnson S, Shaw R, Parkinson P, Perry P. Accuracy of new Clearblue Digital Pregnancy Test with Conception Indicator. *Hum Reprod* 2010; 25(suppl1):i169-170
3. Johnson S et al. Agreement between the Clearblue Digital Pregnancy Test Conception Indicator and standard-of-care ultrasound dating in the assessment of pregnancy duration. *Curr Med Res Opin* 2011. In Press


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Interpretation of Symbols

	Storage temperature	LOT	Lot Number
	In vitro diagnostic device		Expiry date
	Read instructions before use		Manufacturer
	Do not reuse		Sufficient for 1 test
EC REP	Authorized Representative		Device for self-testing
			Distributed By

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