

FIRST THINGS FIRST

Why is fertility testing important?

The Proov 4 in 1 Fertility Test is the only at-home fertility test kit to track the full conception cycle - from ovarian reserve to ovulation to implantation window - to give you the most comprehensive view of your cycle and fertility status.

Here's what to expect:

In this kit you'll test FSH (follicle stimulating hormone) to gain insight into your ovarian reserve, LH (luteinizing hormone) to identify your 2 most fertile days or the best time to "try", PdG (a urine marker of the hormone progesterone) to confirm successful ovulation during the implantation window, and hCG (human chorionic gonadotropin) to check for pregnancy.

You'll need to test throughout one entire cycle - from the start of one period to the next - in order to gain full fertility insight from this kit. The good news is that the Proov Insight app will walk you through when & how to test, and will scan and your results, and help you understand what your results mean.

After a full testing cycle, you'll receive your Ovarian Reserve Status, an Ovulation Score, and a hormone trend chart of all your levels throughout your cycle.

Inside this kit

- FSH test strips
• LH test strips
• PdG test strips
• hCG test strips

You'll also need

- 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

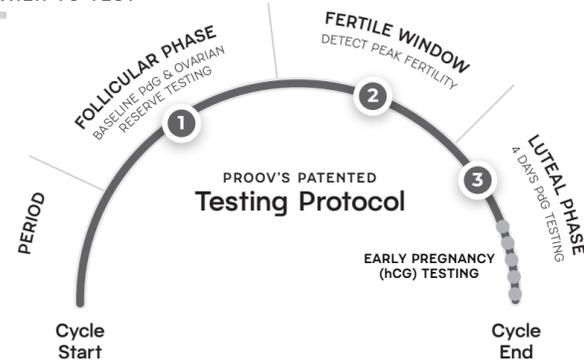
Download the Proov Insight app. Scan the QR code above and create an account to get started. Please note the app must be used to read Proov FSH tests, serves as an additional tool when using Proov LH and PdG tests, although Proov LH and PdG tests can be read by eye.

Consult the app first thing each morning (before you peel) to know if it is a testing day. You will not test on every day of the month, and your specific protocol for which tests to use when will depend on your particular hormonal profile.

You must begin testing on cycle day 5. Cycle day 1 refers to the first day of your period. Cycle day 5 testing is critical to getting your baseline hormone levels (which we use to determine whether or not you've ovulated successfully) and understanding your ovarian reserve, so you don't want to miss it.

Test using first morning urine, when applicable. Proov FSH and PdG tests must be used with first morning urine. Proov LH tests can be used with, but do not require first morning urine.

2 WHEN TO TEST



You'll take one FSH test (green pouch) on cycle day 5 (5 days from the start of your period) and one PdG test (purple pouch) on cycle day 5 or after your period ends. These tests are "really" important so please don't skip them!

You'll begin LH testing (blue pouch) to determine peak fertility 18 days before the expected start of your next period. Please use Chart A (right) to determine when you'll begin LH testing, or follow your in-app notifications.

Continue LH testing once or twice daily (we recommend testing once in the morning and once in the afternoon) until the Proov Insight app detects your LH surge or peak fertility. Once peak fertility has been detected, you may stop LH testing.

You'll then want to test PdG on days 7, 8, 9, and 10 past peak fertility (DPP) to confirm successful ovulation during the implantation window. The day of your first positive LH test is day 0 past peak fertility.

Lastly, you may test for pregnancy with Proov hCG tests (pink pouch) up to 5 days before an expected period, or after a missed period. If you choose to test early, please use the Chart A (right) to determine when you may begin testing based on your cycle length.

3 HOW TO TAKE PROOV TESTS

REMINDER: Proov FSH and PdG tests must be used with first morning urine. Proov LH tests can be used with, but do not require first morning urine. If testing with a Proov hCG test before an expected period, you must use first morning urine; after a missed period, testing with first morning urine is no longer required.

1: PEE

Collect your urine sample in a clean, dry cup (not provided). Please retain your urine sample until you've finished using your test strip and have either read or scanned your results. That way, in the event of an error, you can easily test again with the same first morning urine.

2: DIP

Dip the test strip up to the STOP/MAX arrows and hold it in place until you see the urine begin flowing up the strip (usually about 15 seconds).

3: WAIT

Set the strip aside on a flat, nonporous surface and wait for it to develop. Please use a timer and follow the wait times below. Reading your result by eye or scanning it into the app before or after the specified time below will yield inaccurate results.

FSH Tests: Wait 10 minutes. Reading your result before or after 10 minutes will yield inaccurate results.

LH Tests: Wait 5-10 minutes. Reading your result after 20 minutes will yield inaccurate results.

PdG Tests: Wait 5-10 minutes. Reading your result before 5 or after 10 minutes will yield inaccurate results.

hCG Tests: Wait 5-15 minutes. Reading your result before 5 or after 15 minutes will yield inaccurate results.

Note: If using the Proov app, you must scan your tests in at 10 minutes.

When scanning FSH, LH, and PdG tests into the Proov Insight app, the test strip should be placed in the designated box on the Proov App Card included with your kit. Failure to scan your test on the Proov App Card may yield inaccurate results.

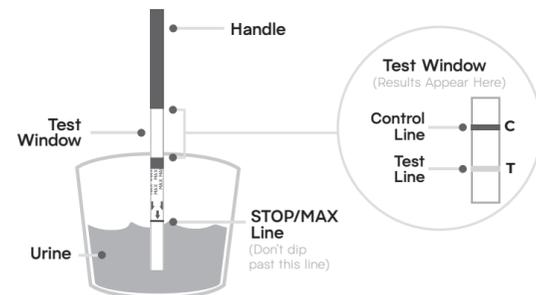


CHART A

Table with 3 rows: Cycle Length (# of days), Cycle Day to start testing LH, and Cycle Day to start testing hCG. Columns represent cycle lengths from 24 to 36 days.

4 HOW TO INTERPRET YOUR RESULTS

PROOV FSH TESTS (GREEN POUCH/TEAL HANDLE)

You must read Proov FSH tests using the Proov Insight app in order to obtain your results. Please follow the directions within the Proov Insight app to do so.

Note: 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 (see Chart B).

PROOV LH TESTS (BLUE POUCH/GREEN HANDLE)

You may choose to read your Proov LH tests using the Proov Insight app or you can read them by eye. Please follow the directions within the Proov Insight app to obtain your results via the app. Otherwise, please follow the below to interpret your results by eye:

POSITIVE LH RESULTS



Test line is as dark or darker than Control Line

LH levels are high, indicating your LH peak: the start of your two most fertile days this cycle. This is the time to "try."

NEGATIVE LH RESULTS



Test line not as dark as Control Line

Negative results mean: LH levels are low. Keep testing twice daily until you get a positive result. If you never get a positive result, mention it to your doctor and you can decide together what to do next.

At any time in your testing process, if no line shows at all, or if only a "test line" shows, your test did not function properly (see Chart B). Please contact us.

PROOV PDG TESTS (PURPLE POUCH/HANDLE)

Please follow the below instructions to interpret your PdG test results by eye.

You must complete a baseline plus all four days of testing as your levels can fluctuate day to day. In reading Proov Confirm results, it's important to take note of both the number of lines present (1 or 2), and the intensity of the test line's color, which can range from faint to dark.

POSITIVE PDG RESULTS



Control Line is present; no Test Line is present

If only a single line shows (the "control line"), your test is positive, indicating elevated PdG.

NEGATIVE PDG RESULTS



Both Control and Test lines are present, no matter how faint

When two lines appear, the result is negative, indicating PdG levels are not elevated enough for a positive result.

Note: A baseline reading will typically be negative, although the test line may be faint. If you receive an unexpected positive baseline reading, contact us.

CHART B

Diagram showing 'INVALID TEST' results: 'No control line or no lines at all after dip' and 'At any time in your testing process, if no line shows at all, or if only a "test line" shows, your test did not function properly. Please contact us.'

INTERPRETING PDG RESULTS:

Successful Ovulation

Positive results during testing window (sustained elevated PdG levels during the testing window) indicates a successful ovulation this cycle.

Successful ovulation is defined as sustained, elevated PdG levels during the 4-day testing window. Positive results during this testing window indicates a successful ovulation this cycle.

Unable to Confirm Successful Ovulation

Negative results during the testing window indicate PdG levels are not elevated high enough to indicate a successful ovulation this cycle. We recommend following up with your doctor if you get negative results.

You may have ovulated, but PdG levels were not elevated high enough or they did not remain positive for long enough to call it a "successful" ovulation this cycle. Proov PdG test results can be impacted by accuracy of ovulation prediction method used, fluctuations in individual PdG levels, and precision of Proov PdG test usage as indicated.

PROOV HCG TESTS (PINK POUCH/HANDLE)

POSITIVE



If two lines appear on the test, no matter how faint, your test is positive, indicating hCG is present.

A positive Proov hCG test most likely means you are pregnant. We recommend consulting your doctor to confirm that you are pregnant and discuss next steps. If you are unsure of your results, test again at least 48 hours after initially testing as hCG may need additional time to rise to produce a positive result.

NEGATIVE



If only one line appears, no matter how faint, your results are negative. If you test before your expected period and get a negative test result, there is still a chance you may be pregnant.

A negative Proov Check Early Pregnancy test could mean that you are not pregnant, or the level of hCG was not high enough yet to be detected, or you may have miscalculated your expected or missed period date.

If you are unsure of your results or still suspect you may be pregnant, test again at least 48 hours after initially testing as hCG may need additional time to rise to produce a positive result. If the test is still negative after a missed period, consult your doctor.

Note: At any time in your testing process, if no line shows at all, or if only a "test line" shows, your test did not function properly (see Chart B). Please contact us.

Have questions about your results? Simply snap a photo of your test strip after 10 minutes of processing and send it to us at info@proovtest.com. We're happy to help!

# (OUTSIDE)

## proof 4 in 1 Fertility Test

The Only Kit to Track the  
Implantation Window (with PdG)

### instructions for use:

1. When to test
2. How to test
3. How to read your results
4. What your results mean

### QUESTIONS & ANSWERS

#### 1. What is FSH and what does it tell me?

Tracking FSH levels over time can give you insight into your ovarian reserve (your remaining egg supply). FSH levels increase temporarily at the beginning of each cycle to stimulate your ovaries to produce eggs. When your ovarian reserve is lower, more FSH is required to stimulate them.

#### 2. What is LH and why is it important to track?

When trying to conceive, tracking LH helps to identify your two most fertile days in order to time intercourse just right. Peak fertility can be different from cycle to cycle, so it's informative to track it each cycle.

#### 3. What is PdG and why is it important to track?

PdG is the urine marker of progesterone, the hormone that rises after ovulation and prepares the uterus for implantation. By measuring PdG in daily urine on four consecutive days, Proov allows women to get a more complete picture of whether or not they have successfully ovulated.

#### 4. What is hCG and what does it tell me?

Human Chorionic Gonadotropin (hCG) is the hormone produced by your body when you are pregnant. The presence of hCG in your urine suggests that you are most likely pregnant.

#### 5. How accurate are these tests?

The Proov 4 in 1 Fertility Test is 99% accurate at detecting FSH, LH, PdG, and hCG in urine in lab studies.

#### 6. What happens if my current cycle day is past the 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!

#### 7. Do I need to use first morning urine?

Proov FSH and PdG tests must be used with first morning urine. Proov LH tests can be used with, but do not require first morning urine. If testing with a Proov hCG test before an expected period, you must use first morning urine; after a missed period, testing with first morning urine is no longer required.

#### 8. I have taken these tests as directed and my results indicate my hormone levels may be out of range – will I have trouble conceiving?

Proov tests do not replace medical advice. If your Proov results show potential hormone imbalances or out-of-range results, you should consult your physician and tell them about this information so they can properly diagnose you.

#### 9. I have taken Proov hCG tests as directed, and am not getting the result I wanted to see. What should I do?

If you are expecting a positive result and are testing before an expected period, continue testing until your period arrives or your test turns positive. If your test is still negative after a missed period we recommend consulting your doctor. If you are expecting a negative result and receive a positive, we recommend consulting your doctor to confirm pregnancy and discuss next steps.

#### 10. I have additional questions. What should I do?

Please visit the FAQ at our website [proovtest.com](https://www.proovtest.com) or contact us as directed to the right.

### PRECAUTIONS & TEST LIMITATIONS

1. Certain medical conditions such as pregnancy, menopause, Polycystic Ovarian Syndrome (PCOS), and medications that contain LH or hCG can affect LH Test results.
2. Some medications such as hormonal birth control (pills, patches, rings, etc.) and any medication containing natural or synthetic progesterone can affect your PdG results. Consult with your healthcare professional about how this may affect your test result. Proov PdG tests should only be taken 7-10 days after peak fertility is detected and should not be used beyond this time frame.
3. Some medications such as hormonal birth control (pills, patches, rings, etc.) and certain medications may affect your hCG results. Consult with your healthcare professional if your test is positive.
4. Tests are for in vitro diagnostic and external use only. Do not swallow.
5. Discard after use. Test strip cannot be used more than once.
6. Do not use strips if pouch is not sealed properly.
7. Keep out of reach of children.
8. Read all instructions prior to use. Improper usage may lead to invalid or inaccurate results.
9. This product is not for contraceptive use.
10. FSH 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.).
11. Usage of pill or patch that contains hCG or LH may affect FSH test results and should not be taken before using this test kit.
12. 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.
13. Do not use past the expiration date.
14. It is always best to consult a doctor prior to trying to conceive.

### INTENDED USE

To predict and confirm ovulation, to assess ovarian status or ovarian reserve, and to check for pregnancy.

### EXPECTED VALUES FOR WOMEN

#### FSH:

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

#### LH:

LH is normally detectable at low levels in urine or serum of health men (2-20 mIU/ml), or pre-menopausal women not during the LH surge. Prior to the test the following charts should be consulted.

LH Level:

Post-menopausal Women: 10-200 mIU/ml (a. baseline level 5-20 mIU/ml; b. surge level 40-200mIU/ml)

Men: 5-15 mIU/ml

#### HCG:

1. Negative results are expected in healthy non-pregnant women.
2. The amount of hCG will vary greatly with gestational age and between individuals.

#### PDG:

According to GLOWM (The Global Library of Women's Medicine), during a natural ovulation cycle, PdG measured in this kit will fall within the following range:  
PdG – 0.1 – 5 ug/ml

### STORAGE AND STABILITY

1. Store tests at room temperature (39.2-86°F / 4-30°C) in the sealed pouch.
2. Keep away from direct sunlight, moisture, and heat.
3. Do not freeze.
4. Use immediately after opening pouch.
5. Pouch contains a test strip and 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.

### CONTENTS & PRINCIPLES OF PROCEDURE

#### Proov LH Tests

Each kit contains one individually wrapped lateral flow chromatographic immunoassay in a foil pouch and a desiccant (for storage purposes only). The test utilizes a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH. The test strip includes: (1) a conjugate pad containing anti- $\alpha$ -LH antibody coupled to colloidal gold, and (2) nitrocellulose membrane containing a test line (T line) and a control line (C line). When the absorbent end is immersed into a sample, the sample is absorbed into the device by capillary action and mixes with the antibody dye conjugate. The complex migrates along the membrane to the mouse anti- $\alpha$ -LH antibody test region (T), and remains captured in the T line.

#### Proov FSH Tests

Each kit contains individually sealed two site sandwich immunoassay FSH strips and a desiccant (for storage purposes only). The membrane is pre-coated with anti- $\alpha$ -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- $\beta$ -FSH antibody conjugated to colloidal gold and monoclonal anti- $\alpha$ -FSH as a capture antibody on the Test line region of nitrocellulose membrane. During testing, the urine specimen reacts with a colored conjugate (anti- $\beta$ -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- $\beta$ -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- $\alpha$ -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.

#### Proov PdG Tests

Each pouch contains one immunochromatographic test individually sealed with a desiccant (for storage purposes only). Each test strip contains a membrane with anti-PdG antibodies and conjugates in a stabilizing matrix of proteins and sodium azide. The urine sample is applied to the strip by dipping. The sample moves by lateral flow into the test area, and then the control area. The test area has PdG-specific reagents impregnated on it to detect the presence of PdG in the urine. The control area has antibodies impregnated to be used as internal control for proper assay function. The test strip provides qualitative results with a single red line indicating a positive result for PdG and two red lines indicating a Negative result for PdG in urine.

#### Proov hCG Tests

Each test contains one rapid lateral flow immunochromatographic assay. Each test contains a combination of antibodies, including a monoclonal hCG antibody to selectively detect elevated levels of hCG. When the test is conducted by immersing the test strip in a urine specimen, the specimen migrates via capillary action to react with the colored conjugate. A colored line forms in the test region of the membrane when positive specimens react with the specific antibody-hCG-colored conjugate. Absence of a colored line suggests a negative result. A control line will always appear as a procedural control.

### PERFORMANCE CHARACTERISTICS

#### Proov LH Tests

1. Sensitivity: This sensitivity level has been confirmed with LH standards (0 mIU/ml, 10 mIU/ml, 15 mIU/mL, 20 mIU/ml, 50 mIU/ml, 100 mIU/ml) separately. The results demonstrated that the analytical sensitivity of the test (the lowest concentration that yields 100% positive results) is 20 mIU/mL. The test has been standardized to the WHO 2rd International Standard 80/552.

2. Specificity: Samples containing 200 mIU/ml hFSH, 250 uIU/ml hTSH and 5 mIU/mL hCG yielded color less intensive than that of 20 mIU/ml hLH Reference. At the levels tested, none of these substances interfered with the expected test results.

#### Proov hCG Tests

1. Sensitivity: This sensitivity level has been confirmed with hCG standards in urine. The results demonstrated that the analytical sensitivity of the test (the lowest concentration that yields 100% positive results) is 10 mIU/mL.

2. Specificity: The test was determined from cross reaction studies with known amounts of luteinizing hormone (LH), follicle stimulating hormone (FSH), and thyroid stimulating hormone (TSH). The addition of LH (500 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 uIU/mL) to hCG negative and positive specimens showed no cross-reactivity.

#### Proov FSH Tests

1. Sensitivity: This sensitivity level has been confirmed with FSH standards in urine. The results demonstrated that the cut-off of the test is 10 mIU/ml. The test has been standardized to the World Health Organizaion (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 uIU/mL TSH to hCG negative and positive specimens showed no cross-reactivity.

#### Proov PdG Tests

1. Sensitivity: PdG > 5 ug/ml The sensitivity level has been confirmed using PdG spiked in negative urine samples and urine collected over the menstrual cycle. These results demonstrated that the cut-off of was found to be 99% accurate at detecting PdG when at a concentration of > 5 ug/ml.

2. Specificity: PdG 0 – 5 ug/ml. The test was determined from cross reaction studies with known amounts of exogenous interferents such as Luteinizing Hormone (LH), Human chorionic gonadotropin (hCG), which yielded results that shows no cross-reactivity.

### REFERENCES

1. Johnson SR, Miro F, Barrett S, Ellis JE. Levels of urinary human chorionic gonadotrophin (hCG) following conception and variability of menstrual cycle length in a cohort of women attempting to conceive. *Curr Med Res Opin.* 2009 Mar; 25(3):741-8

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(suppl 1):i169-170

3. Cole LA, Ladner DG, Byrn FW. The normal variabilities of the menstrual cycle. *Fertil Steril.* 2008 Apr 21. [Epub ahead of print] 21. Data on file

4. 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 Pres

## Have Questions/Concerns? WE'RE HERE FOR YOU!

Visit us online: [proovtest.com](https://www.proovtest.com)

Send us an email: [info@proovtest.com](mailto:info@proovtest.com)

Call us toll-free: **1-833-PROOV-IT** (833-776-6848)

Monday-Friday 9am – 5pm Mountain Time

Proov

5485 Conestoga Ct. #210

Boulder, CO, USA 80301