

Proov[™] is a single step qualitative test that measures the presence of certain progesterone metabolites in urine that increase significantly after ovulation and remain elevated during pregnancy. For in vitro external use only.



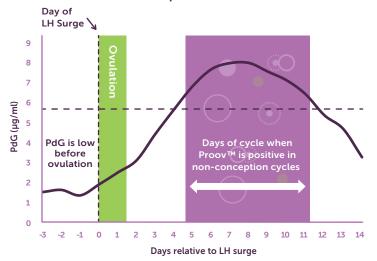
HOW DO PROOV™ TESTS WORK?

Progesterone is a hormone that helps prepare the female body for conception and supports pregnancy. Levels of Progesterone in the female body are low in the first half of the menstrual cycle. After the ovary releases an egg (ovulation) the corpus luteum produces progesterone, causing progesterone levels to rise. If conception occurs, progesterone is then produced by the placenta and remains high throughout pregnancy. Pregnanediol Glucuronide (PdG) is the major urine metabolite of Progesterone. Proov™ tests measure the presence of PdG in urine, which has been shown to directly correlate with the presence of progesterone in blood. According to the GLOWM (Global Library of Women's Medicine), PdG levels in urine typically rise 24-36 hours after ovulation. If conception does not occur, PdG levels will decrease and menstruation will occur. If conception does occur, PdG levels will remain high throughout the duration of the pregnancy. Measuring PdG levels can aid in confirming ovulation and monitoring progesterone during pregnancy.

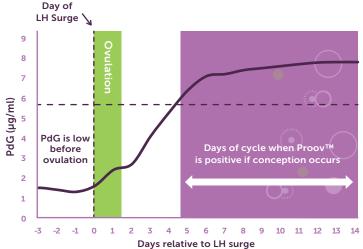
WHAT DO YOU WANT TO PROOVTM?

Proov[™] tests are designed to allow women to monitor progesterone during ovulation and pregnancy. Follow the directions below to determine the best testing method for your application. Proov[™] tests do not replace medical advice and are not intended to treat any condition or disease.

Average amount of Pregnanediol (PdG) in female urine if conception does not occur



Average amount of Pregnanediol (PdG) in female urine if conception occurs



CONFIRMING OVULATION

A single negative ProovTM test followed by a single positive test is needed to confirm ovulation. ProovTM tests are negative prior to ovulation and turn positive 3-7 days after ovulation. To confirm ovulation, suggested testing protocol is:

- Test once on cycle day 5, 6, 7 or 8 (Cycle day 1 is defined as the first day of menstrual flow); the test will be negative.
- Begin testing again 3 days after peak fertility (Positive OPK/LH surge or peak cervical mucus observation)
- Stop testing when Proov[™] tests turn positive (single line).

TRYING TO CONCEIVE

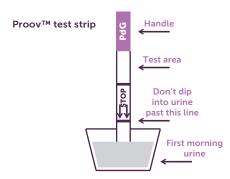
Progesterone levels need to be elevated at the time of implantation (7-10 days after ovulation) in order to achieve a successful pregnancy*. Suggested testing protocol is:

- Begin testing 4 days after peak fertility (Positive OPK/LH surge or peak cervical mucus observation).
- Continue to test daily until 10 days past ovulation.
- Proov[™] tests will be positive when progesterone levels are elevated.

PROGESTERONE DURING PREGNANCY

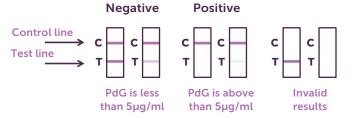
Progesterone levels need to remain elevated throughout pregnancy. To monitor progesterone levels during pregnancy, the suggested testing protocol is:

- Begin testing 6 days after peak fertility is observed (Positive OPK/LH surge or peak cervical mucus observation).
- Continue to test as needed during pregnancy.
- Proov[™] tests should remain positive throughout pregnancy.



INSTRUCTIONS FOR USE

- Collect first morning urine in a clean, dry plastic or glass container (not provided). First morning urine gives the best results.
- 2. Remove the test strip from the sealed pouch.
- **3.** Dip the strip into the urine for 3-5 seconds with the arrows pointing towards the urine. Lay the strip flat on a clean surface. *IMPORTANT: Do not dip the strip past the STOP line or the test will not work properly.*
- **4.** Read the results in 5 minutes. Do not read results after more than 15 minutes.



READING YOUR RESULTS

Negative result (Low PDG): When two pink lines appear, PdG levels in the urine are low. Test line can be lighter than the control line. Your urine contains less than 5µg/ml of PdG.

Positive result (high PDG): If you see a very faint grey line or no line in the test area, your test is positive. There is more than 5µg/ml of PdG in your urine.

Invalid: Test is invalid if no lines or no control line is seen. Please contact us at info@proovtest.com if your test fails.

PRECAUTIONS

- 1. Tests are for external use only. Do not swallow.
- 2. Discard after use. Test strip cannot be used more than once.
- 3. Do not use past expiration date.
- 4. Do not use if pouch is not sealed properly
- **5.** Keep out of reach of children.
- **6.** Read all instructions prior to use. Improper usage may give invalid results.
- 7. Proov™ should not be used as a form of birth control.
- 8. Consult a doctor if your menstrual cycles are irregular or long.

STORAGE AND STABILITY

- **1.** Store tests at room temperature (68-78°F) 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.** Test usage after the expiration date printed on pouch may provide invalid results.

Q&A's

- **1. Do I need to use first morning urine?** The test is most accurate with first morning urine. For best results, only use first morning urine for testing.
- 2. My test has two lines, that is a positive test right? No, 2 pink lines is a negative result and 1 line is a positive result.
- 3. The test line is lighter than the control line. What does that mean? If you see 2 pink lines, one in control area and one in test area, the test is negative for PdG.
- 4. When do Proov™ tests typically turn positive? Proov™ tests turn positive anywhere between 2-7 days after ovulation and remain positive until 1-3 days before next menstrual period or if conception occurred, will remain positive throughout pregnancy.
- 5. I still see a very faint, greyish line in the test line area. Is my test positive? Yes, occasionally there are compounds in the urine that react with the test line area and create a very slight greyish evaporation line. If your test has no pink color in the test line area, it is considered positive.
- 6. Do alcohol or medications affect the results? Yes, hormonal birth control (pills, patches, rings, etc) and any medication containing natural or synthetic progesterone will affect your results.
- 7. I have taken these tests as directed and I never get a positive result, do I have low progesterone? Proov™ tests do not replace medical advice. If you never get a positive result, you should consult your physician and inform them of this information so they can properly diagnose you.
- 8. How does urine PdG level correlate to blood progester one levels? Positive Proov™ test results were observed when serum progesterone was greater than 10ng/ml (~32nmol/L).
- 9. Do PdG levels always correlate with blood progesterone levels? Mostly yes, however, our studies show 7-12% of women don't metabolize progesterone into PdG at high enough levels to result in a positive PdG test result.
- 10. I got a positive pregnancy test result, but my Proov™ tests are negative, what does that mean? If your Proov™ test results are negative, you should consult your physician and inform them of this information.
- 11. I keep seeing dye streaks on my test, what is going on?
 Dipping the test into urine for too long can cause the test
 to not process well and make it hard to read. If this happens
 we suggest only dipping the test into urine for 3 seconds.
- 12. What is peak cervical mucus? Egg white cervical mucus (EWCM) is a type of cervical fluid that is produced right before ovulation, during a time when you are most fertile. It strongly resembles raw egg whites and is very stretchy and/or watery.
- **13.** Who do I contact if I have questions? Please visit our website www.proovtest.com or contact us by email info@proovtest.com if you have any questions or concerns about this product.

Proov™ tests are patent-pending, FDA-registered, and manufactured in a cGMP facility for exclusive use by: MFB Fertility, Inc. 1630A 30th Street PMB 143, Boulder. CO 80301

