

Technical Bulletin Index

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The following Technical Bulletins are intended to provide more in-depth information concerning the use and reading of the Quick & Clear II Pregnancy Tests. These bulletins will give you a better understanding of the factors that affect urine-based pregnancy tests. We are providing these bulletins as a reference tool because we believe the better informed you are, the better you will be able to assist your clients.

We are dedicated to providing continued service and support. Should you have any questions about the Quick & Clear II Pregnancy Tests please call the Heritage House at 800-858-3040 and we will be glad to assist you.

Reported occurrence with the Quick & Clear II Pregnancy Test:

The client reported that she tested negative using a home pregnancy test. The client came into the center some time afterward and tested positive using the Quick & Clear II Pregnancy Test.

Potential factors:

- **Sensitivity of the test:** Over-the-counter home pregnancy tests are often less sensitive than the Quick & Clear II Pregnancy Test. To determine pregnancy, urine-based tests analyze the presence of a hormone called human chorionic gonadotrophin or hCG. hCG is released into the mother’s circulation almost immediately after implantation (5-8 days after conception). Pregnancy tests detect hCG in the urine at differing levels. The Quick & Clear II Pregnancy Test is one of the most sensitive available and therefore may be able to detect hCG when other tests cannot.

Quick & Clear II Pregnancy Test	20 mIU of hCG detectable
Confirm 1-Step	25 mIU
EPT +/- Test	25 mIU
Equate (Wal-Mart)	25 mIU
Fact Plus Midstream	25 mIU
Clearblue Digital	50 mIU
Walgreens	50 mIU
CVS “Early Result” Cassette	50 mIU

An October 2001 JAMA article ([JAMA. 2001;286:1759-1761](#)) stated that the highest possible screening sensitivity for any hCG-based pregnancy test conducted on the first day of a missed period is 90 percent, as 10 percent of women may not have implanted yet. The authors estimate that the highest possible screening sensitivity of a home pregnancy test by one week after the first day of the missed period is 97 percent.

- **Increasing hCG:** The appearance and increased levels of hCG provide an excellent indicator of pregnancy. The hCG hormone doubles approximately every 2.2 days during the first trimester. Detectable levels start at 5 mIU/mL during the first week of gestation and rise to 100,000 mIU/mL at 2 to 3 months. A client can test negative on a home pregnancy test and positive a day or more later at your clinic because of the exponential rise of hCG. Between the two tests the client’s hCG may have increased to a more detectable level.
- **Concentration of hCG:** hCG is most concentrated in first morning urine. As a client drinks liquids and voids throughout the day, the hCG in her system will become diluted. The time of day a test is performed can have an impact on the detection of hCG. If there is a question on the test, confirm the results by retesting with a first morning urine sample 48 hours later.
- **User error:** Another factor can be a poorly administered home test – using the wrong sample size, the wrong incubation time, etc.

If a test is in question it is recommended that a retest be conducted in 48 hours using first morning urine.

Reported occurrences with Quick & Clear II Pregnancy Tests:

The client reported that she tested positive using a home pregnancy test. The client came into the center some time afterward and tested negative using the Quick & Clear II Pregnancy Test.

Potential factors:

- **Early Pregnancy Loss or EPL:** To determine pregnancy, urine-based tests analyze the amount of a hormone called human chorionic gonadotrophin or hCG. hCG is released into the mother's circulation almost immediately after implantation (5-8 days after conception). hCG may also be produced by an EPL or "early pregnancy loss." This is an embryo who fails to implant properly in the uterus or is rejected by the uterus. It is followed by a normal or slightly heavier than normal menstrual period which may be 2 to 3 days late. hCG levels may rise in the week following implantation like a normal-term pregnancy. When EPL occurs, hCG concentration in the urine reaches a peak 2 weeks after conception then rapidly declines.

These types of occurrences have been reported with all brands of urine-based tests for hCG, not just the Quick & Clear II Pregnancy Test. This is because all tests are based on the same immunoassay technique. Natural termination of pregnancy occurs in 22% of clinically unrecognizable pregnancies and 31% of pregnancies overall.¹ This may produce positive results when testing early in the pregnancy followed by negative results after the natural termination. The concentration of hCG decreases rapidly after an early pregnancy loss and would explain the resultant negative test.

- **Concentration of hCG:** hCG is most concentrated in first morning urine. As a client drinks liquids and voids throughout the day, the hCG in her urine will become diluted. The time of day a test is done can have an impact on the detection of hCG. If there is a question on the test, confirm the results by retesting with a first morning urine 48 hours later.
- **User error:** Another factor, although less likely, can be a poorly administered home test – using the wrong sample size, the wrong incubation time, etc. If you suspect such a case, we suggest that you record the type of home test given, the date it was given, the date the clinic test was administered, and, most importantly, whether the client's pregnancy is confirmed.

If a test is in question, it is recommended that a retest be conducted in 48 hours using first morning urine. If a client has not started menses at 31 days after the first day of her last menses, it is recommended that a retest be conducted with first morning urine.

1. Wilcox EG, Weinberg CR, O'Connor JF et al: Incidence of early loss of pregnancy. N Eng J Med 319:189-194, 1988

Conducting hCG tests early in pregnancy:

Urine-based pregnancy tests analyze the presence of a hormone called human chorionic gonadotropin or hCG. The appearance and increased levels of hCG provide an excellent indicator of pregnancy. hCG is released into the mother’s circulation almost immediately after implantation (5-8 days after conception). hCG begins with minute amounts and then doubles every 2.2 days. The Quick & Clear II Pregnancy Test, one of the most sensitive urine-based tests available, detects concentrations as low as 20 mIU/mL. The amount of hCG a woman produces varies greatly. Below is a chart that shows the variation possible in hCG levels.

Chart of hCG Hormone Ranges During Human Pregnancy*

The hCG hormone level in the human body doubles approximately every 2.2 days during the first trimester of pregnancy. Detectable levels of hCG start at 5 mIU/ml during the first week of gestation and rise to 100,000 mIU/ml at 2 to 3 months. Values decline to 10% to 15% of peak concentrations during 2nd and 3rd trimesters. In normal circumstances, first morning urine samples approximate serum hCG levels which reach 5 to 50 mIU/mL within one (1) week of gestational age.

<i>After Conception Week of Pregnancy:</i>	<i>Normal HCG Levels: mIU/mL</i>
1	5 - 50 (avg. 14)
2	5 - 50 (avg. 21)
3	5 - 50 (avg. 42)
4	10 - 425
5	19 - 7,340
6	1,080 - 56,500
7-8	7,650 - 229,000

*The above table shows the typical ranges in hCG levels during pregnancy. *Statistically, the ranges are necessarily broad as each pregnancy cycle and hormone level is unique to the individual and extreme readings either way are possible in a very small percentage of pregnancies. However the table does clearly indicate the rapid increase in hCG hormone during the first trimester. (Craig Medical, 2002)*

The earliest urine hCG-based pregnancy tests can detect hCG is seven days post conception (21 to 24 days after the first day of the last period) depending on when implantation occurs and the client’s personal hCG levels. If hCG is detected at this early stage, the test line would be expected to be light pink as hCG levels are just beginning to build.

According to an October 2001 JAMA article (JAMA. 2001;286:1759-1761), the highest possible screening sensitivity for a urine-based pregnancy test conducted on the first day of a missed period is 90 percent, as 10 percent of women may not have implanted yet.

The Quick & Clear II Pregnancy Test can detect pregnancy as early as seven to ten days post conception. Since levels of 20 mIU/mL of hCG have been observed as early as 3 to 4 days after implantation, hCG may be detected before a first missed menses.

Special consideration should be given when conducting early testing for hCG in light of the above information. If a test is in question it is recommended that a retest be conducted in 48 hours using first morning urine. If a client has not started menses at 31 days after the first day of her last menses it is recommended that a retest be conducted with first morning urine. If the test is still negative it is recommended that the client visit a doctor. The doctor will be able to order a blood test that will determine if hCG is present and if there are other medical concerns.

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Factors that affect pregnancy testing

Urine-based pregnancy tests analyze the presence of a hormone called human chorionic gonadotrophin or hCG. The appearance and increased levels of hCG provide an excellent indicator of pregnancy. hCG is released into the mother's circulation almost immediately after implantation (5-8 days after conception). hCG begins with trace amounts and then doubles approximately every 2.2 days. The Quick & Clear II Pregnancy Test, one of the most sensitive urine-based tests available, can detect hCG levels down to 20 mIU.

There are many factors that can effect the production and detection of hCG.

- A number of conditions other than pregnancy may produce elevated levels of hCG such as trophoblastic disease, choriocarcinoma, embryonal cell carcinoma, Islet cell tumors, and other carcinomas.
- Detectable levels of hCG remain for several weeks in a woman's urine after a normal pregnancy, delivery by Caesarean section, spontaneous or therapeutic abortions.
- Abnormally low levels of hCG may be found in ectopic pregnancies.
- Natural termination of pregnancy occurs in 22% of clinically unrecognizable pregnancies, and in 31% of pregnancies overall.¹ This may produce positive results when testing early in the pregnancy followed by negative results after the natural termination. The concentration of hCG decreases rapidly after an early pregnancy loss or EPL.
- The hCG hormone doubles approximately every 2.2 days during the first trimester. Because of the exponential growth of hCG, a woman may be pregnant but not have a detectable level of hCG in her urine. Within a few days her hCG levels may have grown to a detectable amount. There is an expansive range of what is considered "normal" levels of hCG in pregnancy. The lowest of normal levels at 5 weeks of gestation is 19 mIU of hCG.
- hCG is most concentrated in the first morning urine. As a client drinks liquids and voids throughout the day, the hCG in her urine will become diluted. The time of day a test is performed can have an impact on the detection of hCG.
- There are some medical conditions that will skew the test results. They are complicated and rare. If a client tests negative after 31 days and her period does not start, she should be encouraged to see her doctor. The doctor will be able to order a blood test that will determine if hCG is present and if there are other medical concerns. If she tests positive as the result of a medical condition, the doctor will be able to advise her on further medical care.

Self Reporting

- When conducting pregnancy testing it is important to remember that a center is relying on the client's self reporting about the last menses, the regularity or irregularity of her menstrual cycles, and her sexual activity. Clients may inadvertently or intentionally misrepresent this information.

If there is a question on the test, confirm the results by retesting with a first morning urine sample 48 hours later.

1. Wilcox EG, Weinberg CR, O'Connor JF et al: Incidence of early loss of pregnancy. N Eng J Med 319:189-194, 1988

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Potential Test Interference

Medications¹

Most medications, both over-the-counter and prescription drugs, including birth control pills and antibiotics, will not affect the results of urine based pregnancy tests. Only those drugs that have the pregnancy hormone hCG in them can give a *false positive* test result.

Drugs that have hCG in them include Profasi, Pregnyl, Novarel, Pergonal, and Humegon (which are often used for treating infertility).

Alcohol and illegal drugs do not affect urine based pregnancy test results.

Recent Pregnancy, Abortion, Miscarriage

A recent pregnancy, abortion, or miscarriage can contribute to false positive results on a pregnancy test because of residual hCG the client's system. Generally, it can take up to 9 weeks for hCG to leave the system after an abortion or miscarriage and up to 3 weeks after a pregnancy that is carried to term. This time frame may vary from woman to woman.

¹This information is compiled from The National Women's Health Information Center, a Project of the Office of Women's Health in the U.S. Department of Health and Human Services.

Testing the Tests

If a question arises about the accuracy of a urine-based pregnancy test, a simple procedure can be performed to verify that the tests are working correctly. The procedure involves the use of a “control.” A control is a chemical solution that simulates hCG positive urine.

Using a control with Quick & Clear II Pregnancy Tests:

- The control must be refrigerated when not in use.
- Before use, the controls must be removed from refrigeration for 30 minutes to bring them to room temperature. If the control is used before it reaches room temperature, it will still perform accurately, but it will take longer than 3 minutes to develop.
- The positive control is expected to produce a faint line because it is a sample with a low hCG content. The Quick & Clear II Pregnancy Test detects levels of hCG down to 20 mIU/mL, making it one of the most sensitive urine-based pregnancy tests available.

To use the control:

Use the control on a separate test cassette. After letting the control come to room temperature for 30 minutes, administer the test just as if the control was urine ... 3 drops, 3 minutes. If the control produces a positive result you know definitively that the test is working correctly. This is a clinical indicator that all the tests in that lot are also functioning properly. If you wish you may repeat the procedure with additional test cassettes to verify your results.

In the rare case where the test does not react properly to the control, retest with additional test cassettes. Save the tests, the control, and the data you collect and contact Heritage House. If this does occur, further evaluation will need to be conducted at our lab.