



Pregnancy Test Training Manual



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Introduction

Welcome to the Quick & Clear II Pregnancy Test Training Manual. The purpose of this manual is to provide you with information and resources to administer the Quick & Clear II Pregnancy Tests. We believe that the better informed you are, the better able you will be to serve your clients.

In this manual you will find:

- **A Study Guide:** This guide is designed to train volunteers and staff to use and read the Quick & Clear II Pregnancy Tests. This guide addresses commonly asked questions and provides easy-to-understand answers.
- **A Pre-Test, Post-Test, and Answer Key:** The Pre-Test evaluates your staff's current knowledge of the pregnancy test process. The Post-Test is intended to measure what was learned after reading the study guide. The Answer Key provides the correct answers to the tests. You may choose to utilize these tools in your staff and volunteer training based on your center's specific needs.
- **Technical Bulletins:** These reference tools address some of the more technical details of urine-based pregnancy testing. These bulletins give insight into factors that can affect pregnancy testing and provide explanations for situations that may occur when testing at your center.
- **Wall Poster:** This easy-to-understand wall chart provides instructions on administering and reading the tests. It is perfect for posting in the area where the tests are conducted.
- **Early Test Disclaimer:** This is a sample form that can be used with clients to help explain in simple terms the issues involved with early pregnancy testing. Sharing this knowledge with your clients gives them a more realistic understanding of what can be expected when testing before the first missed period.
- **Client Information Brochure:** This is a client information page that we have designed for your clients who would like more information about the accuracy and sensitivity of the Quick & Clear II Pregnancy Tests. This page can be copied and distributed.



Study Guide

Quick & Clear II Pregnancy Tests are highly sensitive urine-based tests that can be confidently used to indicate pregnancy. This study guide is designed to provide information about using and reading the tests. We at the Heritage House believe that the more you know, the better prepared you are to serve your clients . . . and that's important to all of us. As an added benefit, by purchasing your pregnancy tests from the Heritage House, your center is supporting the Hope House Maternity Home and three Living Hope Pregnancy Clinics in rural Arizona and a Maternity Home and Center in Ethiopia. A portion of the proceeds from the tests are used to support these ministries. We appreciate that your center is using the Quick & Clear II Pregnancy Tests and we are dedicated to providing continued service and support.

What is hCG?

Human chorionic gonadotropin, or hCG, is a protein hormone produced by the placenta.

What does hCG have to do with pregnancy tests?

Urine-based pregnancy tests analyze the presence of 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 is produced in minute amounts and then, rising exponentially, the concentration doubles approximately every 2.2 days.

What does "the hCG level rises exponentially" mean?

This means that in a normal pregnancy, hCG doubles approximately every 2.2 days. Because of this, testing very early in pregnancy can give a negative result. Yet 2 days later, because the hCG level has doubled, testing can register positive.

What does mIU/mL mean?

mIU/mL is the unit of measure for hCG. It stands for mili International Units of hCG per milliliter of urine. Simply put, it is a measure of the concentration of hCG in the client's urine.

Do all pregnancy tests have the same sensitivity to hCG?

No. There are many types of tests on the market for both professional and home use. They have different sensitivity levels for detecting hCG. Some over-the-counter home tests only detect 150 - 250 mIU's of hCG. This means they may not pick up the pregnancy until well after the first missed period. The Quick & Clear II Pregnancy Test, one of the most sensitive urine-based tests available, detects concentrations as low as 20 mIU/mL.

Are the levels of hCG in all pregnant women the same in any given week of pregnancy?

No. The production of hCG can vary greatly from woman to woman in any given week of pregnancy with as much as a 20-fold variation in individual levels. Some women with high hCG may come up positive on the test very early, while others with low hCG may not show up until after the first missed period. In a recent study, reported in the *Journal of American Medical Association*, 10% of 250 women tested had not even implanted by the first missed period. Therefore, their hCG was so low that no urine test could detect it.



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How early can Quick & Clear II Pregnancy Tests give positive results?

Because our test is so sensitive, it may pick up a positive result as early as 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 as hCG levels are just beginning to build. However, when testing this early, the results should be verified after the first missed period. This is because, although the test picks up the presence of hCG, it does not guarantee a viable pregnancy. hCG may also be produced by an EPL or "early pregnancy loss." This is an embryo which 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 (second week after conception) like a normal-term pregnancy. When EPL occurs, hCG concentration in the urine reaches a peak 2 weeks after conception then rapidly declines.

What is the significance of Early Pregnancy Loss (EPL)?

Most women are unaware that they have had an EPL. EPL's are much more common than people realize. Some reports indicate that EPL's may occur in 31% of pregnancies overall.¹ CPC lay counselors need to be aware that women may get a positive result from a test taken before the first missed period. However, the fertilized egg may not implant correctly, or the uterus may reject the embryo. An EPL can delay menses up to three days which would further lead the client to believe she is pregnant, while in reality that is no longer the case.

Can this explain why two tests, taken a few days apart, give conflicting results?

Yes it can. This happened to one center. A young woman took a home pregnancy test a few days *before* she missed her period and it was positive. She then came to the center a week later and was sure she was pregnant as her period still had not started. But the center's test came back negative. By the time she came to the center she had experienced an Early Pregnancy Loss. Her hCG had dropped to undetectable levels. The client was urged to get a blood test, which verified the center's results. It is good to understand this issue as you may have a similar case occur.

If a client is tested before her first missed period should she be retested if her period still has not started after 31 days?

Yes. If you test earlier than 31 days, you should advise the client that, even if it is negative, a test should be given at 31 days to verify the results if her menses still has not started. This is because her hCG level may have been too low to register on the first test. Or, if the test reads positive, the client needs to be advised that there is still a chance of Early Pregnancy Loss. It is our recommendation, and that of the leading hCG researcher, Dr. Laurence Cole of the University of New Mexico, that any test that indicates possible pregnancy before 31 days after the start of the last menses should be repeated on or after the 31st day. This assures accurate detection of a viable pregnancy.

Are there any other factors that may give conflicting test results at two different times?

Yes. Another factor is how diluted the urine is at the time of the test. The more concentrated the urine, the greater the concentration of hCG. Remember, women's levels of hCG can vary mark-



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edly. If a woman who has low levels of hCG takes a pregnancy test early in her pregnancy using her first morning urine, it may come out positive because of the higher concentration of hCG. If she then goes to a center later in the day after consuming liquids, her urine will be very diluted and there may not be a high enough level of hCG to detect. If there is a question about the test results, confirm the results by retesting the client with a first morning urine sample.

For early pregnancy tests, should we tell our clients to give us their first morning urine?

Yes. In fact, when results vary or are questionable, the client should be retested with first morning urine. If this is not possible, they need to limit liquid intake and go as long as possible without urinating before they come in. Remember, the more concentrated the urine is, the more concentrated hCG will be. In such cases it may also be a good idea to wait 48 hours before retesting so that the hCG level can double to a more detectable level.

Are there any other conditions that may produce false readings?

There are some medical conditions that will skew the test results. They are complicated and uncommon. If a client tests negative after 31 days and her period does not start, she should be encouraged to see her doctor. He will be able to order a blood test that will determine if hCG is present and if there are any 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.

How does the information that the client provides play a role in the testing?

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.

How are Quick & Clear II Pregnancy Tests done?

To use the test, place it on a level, dry surface and put on protective gloves. Then take the dropper from the package and squeeze the bulb at the top of the dropper to remove the air. Place the tip of the dropper in the urine and release the bulb while holding the dropper upright. While continuing to hold the dropper upright, squeeze the bulb to release three drops of urine in close succession into the sample well. After the urine has moved across the testing window, set your timer for three minutes and wait for the results. Do not immediately dispose of the urine in case there is any need to redo the test. Within three minutes the control line "C" will begin to turn pink. If the test is positive, another pink line will appear under the "T" or Test zone. If the test is negative, the zone under the "T" will not change color. The test line may show a variety of shades of pink from light to bright depending on the levels of hCG. If any shade of pink appears, even a very slight line, the test should be considered positive. If no pink line occurs in the control zone "C" add two additional drops of specimen and wait three minutes. If a colored line still does not appear in the Control Zone the test is invalid. High sensitivity urine-based pregnancy tests performed on specimens containing levels of hCG below 20 mIU may show color development over time, indicating the need to retest in 48 hours. Do not read the test after ten minutes.

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

Pre-Test

1. What is human chorionic gonadotropin (hCG)? _____.
2. What does a urine pregnancy test detect? _____.
3. How often does hCG double? _____.
4. T F Urine-based pregnancy tests have differing sensitivity levels.
5. The Quick & Clear II Pregnancy Test detects hCG as low as _____ mIU.
6. T F Levels of hCG in all women are the same at any given week of pregnancy.
7. According to an article in the Journal of the American Medical Association, what percentage of pregnancies had not implanted on the first day of their missed period? _____ %
8. Why is implantation a key factor in testing for pregnancy? _____
_____.
9. Two factors that affect how early a pregnancy test can detect hCG are:
when _____ occurs and the client's personal _____ level.
10. What does EPL stand for? _____
11. What should you do if a client tests positive before her first missed period? _____.
12. What should you do if a client tests negative before her first missed period? _____.
13. Concentration of hCG is greatest in the _____ urine.
14. What affect does drinking fluids have on the urine? _____.
15. Why can this be a problem? _____.
16. T F Caffeine can affect the results of the test.
17. T F Clients always provide accurate information about menses, menstrual cycles and sexual activity.
18. When doing the Quick & Clear II Pregnancy Test, you put _____ drops of urine into the well and wait _____ minutes.
19. If you have any doubt about test results, what should you do? _____.

Post-Test

1. What is human chorionic gonadotropin (hCG)? _____.
2. What does a urine pregnancy test detect? _____.
3. How often does hCG double? _____.
4. T F Urine-based pregnancy tests have differing sensitivity levels.
5. The Quick & Clear II Pregnancy Test detects hCG as low as _____ mIU.
6. T F Levels of hCG in all women are the same at any given week of pregnancy.
7. According to an article in the Journal of the American Medical Association, what percentage of pregnancies had not implanted on the first day of their missed period? _____ %
8. Why is implantation a key factor in testing for pregnancy? _____
_____.
9. Two factors that affect how early a pregnancy test can detect hCG are:
when _____ occurs and the client's personal _____ level.
10. What does EPL stand for? _____
11. What should you do if a client tests positive before her first missed period? _____.
12. What should you do if a client tests negative before her first missed period? _____.
13. Concentration of hCG is greatest in the _____ urine.
14. What affect does drinking fluids have on the urine? _____.
15. Why can this be a problem? _____.
16. T F Caffeine can affect the results of the test.
17. T F Clients always provide accurate information about menses, menstrual cycles and sexual activity.
18. When doing the Quick & Clear II Pregnancy Test, you put _____ drops of urine into the well and wait _____ minutes.
19. If you have any doubt about test results, what should you do? _____.

Answer Key

1. What is Human chorionic gonadotropin (hCG)? **hormone, protein hormone, or a hormone produced by the placenta**
2. What does a urine pregnancy test detect? **the presence of hCG**
3. How often does hCG double? **approximately every 2.2 days**
4. **T** F Urine-based pregnancy tests have differing sensitivity levels.
5. The Quick & Clear II Pregnancy Test detects hCG as low as **20** mIU.
6. T **F** Levels of hCG in all women are the same at any given week of pregnancy.
7. According to an article in the Journal of the American Medical Association, what percentage of pregnancies had not implanted on the first day of their missed period? **10%**
8. Why is implantation a key factor in testing for pregnancy?
hCG isn't released until after implantation occurs
9. Two factors that affect how early a pregnancy test can detect hCG are:
when **implantation** occurs and the client's personal **hCG** level.
10. What does EPL stand for? **Early Pregnancy Loss**
11. What should you do if a client tests positive before her first missed period?
retest at or after 31 days after the first day of her last period
12. What should you do if a client tests negative before her first missed period?
retest at or after 31 days after the first day of her last period
13. Concentration of hCG is greatest in the **first morning** urine.
14. What affect does drinking a lot of fluids have on the urine? **it dilutes the urine**
15. Why can this be a problem? **the more diluted the urine, the less concentrated the hCG will be**
16. T **F** Caffeine can affect the results of the test.
17. T **F** Clients always provide accurate information about menses, menstrual cycles and sexual activity.
18. When doing the Quick & Clear II Pregnancy Test, you put **3** drops of urine into the well and wait **3** minutes.
19. If you have any doubt about test results, what should you do? **retest with first morning urine**



Early Test Disclaimer

Dear Client:

Because you are taking a pregnancy test before your first missed period, we would like to explain a few things to you. Our test is very sensitive and can give positive results in as little as seven days after conception. However, there are some issues with taking a test so early.

When you conceive, your body produces a hormone called hCG. As time passes, the hCG increases in your system. Our test detects hCG in your system which indicates whether or not you are pregnant. Every woman is different though, and some women produce more hCG than others.

If your test comes out negative, it does not necessarily mean you are not pregnant. Your hCG level might not have been high enough to detect. You need to wait until 31 days after the first day of your last period and then test again.

If your test comes out positive, it means there is hCG in your system, which is a good indication that you are pregnant. But, there is something called EPL, or Early Pregnancy Loss, that can happen very early in pregnancy. This is when the fertilized egg fails to implant in the uterus. Or, if it is defective, it may implant and then be rejected. This happens much more than people realize. Some research shows that this happens as often as successful pregnancy. So, even though the test detects hCG, you may experience EPL and not continue the pregnancy. Again, you need to be retested 31 days after the first day of your last period to be sure you have not experienced EPL.

If you have read this and understand it, please sign below:

_____ Date: _____



What You Should Know

The Quick & Clear II Pregnancy Test is a professional quality test. It is as sensitive as those used in doctor's offices and women's clinics. It is considerably more sensitive than most home pregnancy tests (see below). The Quick & Clear II Pregnancy Test can show a positive result as early as seven days after conception.

How urine based pregnancy tests work: When you conceive, your body produces a hormone called hCG. As time passes, the concentration of hCG increases in your system. Urine based pregnancy tests detect the presence of this hormone. When the hormone level rises to 20 mIU/ml (which is a very small amount), the Quick & Clear II Pregnancy Test will indicate a positive test result. Each woman's body is unique and responds differently to pregnancy. Because of this, you may see positive results as early as seven days after conception or as late as 1 week after your first missed period, depending on your body's production of hCG.

Understanding the results of your test: If your test comes out **negative**, it does not necessarily mean you are **not** pregnant. Your hCG level might not have reached the necessary 20 mIU/ml level. You need to wait until 31 days after the first day of your last period and then test again.

If your test comes out **positive**, it means there is hCG in your system, which is a good indication that you are pregnant. But, there is something called EPL, or Early Pregnancy Loss, that can happen very early in pregnancy. This is when the fertilized egg fails to implant in the uterus. Or, if it is defective, it may implant and then be rejected. This happens much more than people realize. Some research shows that this happens as often as successful pregnancy. So, even though the test detects hCG, you may experience EPL and not continue the pregnancy. Again, you need to be retested 31 days after the first day of your last period to be sure you have not experienced EPL.

Clinical Sensitivity: A multi-center clinical evaluation was conducted comparing the results obtained using Quick and Clear II Pregnancy tests and another commercially available membrane test. The study included 148 urine specimens and both assays identified 84 negative and 64 positive results. The results demonstrated a 100% overall agreement between Quick and Clear II Pregnancy tests and the other commercially available test.

Home pregnancy tests purchased at the store are often less sensitive than professional tests. 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/ml of hCG detectable
Confirm 1-Step	25 mIU
First Response	25 mIU
Equate (Wal-Mart)	25 mIU
Fact Plus Midstream	25 mIU
Clearblue Digital	50 mIU
Walgreen's Cassette	50 mIU
CVS "Early Result" Cassette	50 mIU



Negación Temprana de la Prueba

Estimada cliente:

Como estás realizando la prueba de embarazo antes de haberte faltado el primer período, nos gustaría explicarte algunas cosas. Nuestra prueba es muy sensible y puede arrojar resultados positivos en poco tiempo: de siete días después de la concepción. Sin embargo, el hacer la prueba tan temprano tiene sus dificultades.

Cuando concibes, tu cuerpo produce una hormona llamada hCG (por sus siglas en inglés). A medida que pasa el tiempo, la hCG aumenta en tu organismo. Nuestra prueba detecta la hCG en tu organismo, lo cual indica si estás o no embarazada. Sin embargo, cada mujer es diferente, algunas mujeres producen más hCG que otras.

Si tu prueba arroja un resultado negativo, ello no significa necesariamente que no estás embarazada. Puede ser que tu nivel de hCG no esté lo suficientemente elevado para ser detectado. Es necesario que esperes hasta 31 días después del primer día de tu último período y entonces realizar la prueba otra vez.

Si tu prueba arroja un resultado positivo, ello significa que la hCG está presente en tu organismo, lo cual es una buena indicación de que estás embarazada. Pero existe lo que se llama PTE o Pérdida Temprana del Embarazo, que puede pasar muy temprano en la gestación. Ello ocurre cuando el óvulo fecundado no se implanta en el útero. O, si es defectuoso, puede que se implante y luego sea rechazado. Ello ocurre mucho más a menudo de lo que la gente cree. Algunas investigaciones han arrojado que ocurre tan a menudo como los embarazos exitosos. Por consiguiente, aunque la prueba detecte la hCG, puede que experimentes la PTE y que tu embarazo no continúe. De nuevo, debes volver a realizar la prueba 31 días después del primer día de tu último período, para asegurar que no estás experimentando la PTE.

Si has leído y entendido esta explicación, por favor firma debajo:

_____ Fecha: _____



Qué Usted Debe Saber Sobre Su Prueba del Embarazo

La Prueba de Embarazo Quick & Clear es un aparato que efectúa una prueba de calidad profesional. Es tan sensible como los que se usan en los consultorios médicos y las clínicas de mujeres. Es considerablemente más sensible que la mayoría de los aparatos caseros de prueba de embarazo. La Prueba de Embarazo Quick & Clear puede arrojar un resultado positivo tan pronto como de siete días después de la concepción.

Cómo funcionan las pruebas de embarazo que se basan en la orina: Cuando concibes, tu cuerpo produce una hormona que se llama hCG (por sus siglas en inglés). A medida que pasa el tiempo, la concentración de hCG aumenta en tu organismo. Las pruebas de embarazo que se basan en la orina detectan la presencia de esta hormona. Cuando el nivel de hCG aumenta hasta alcanzar 20 mIU (que es una cantidad muy pequeña), la Prueba de Embarazo Quick & Clear registra un resultado positivo. Cada cuerpo femenino es diferente y responde de manera diversa al embarazo. Debido a ello, puede que veas un resultado positivo tan pronto como de siete días después de la concepción o tan tarde como una semana después de haberte faltado tu primera regla, dependiendo de la cantidad de hCG que tu organismo produzca.

Cómo entender los resultados de la prueba: Si la prueba resulta negativa, ello no necesariamente significa que no estás embarazada. Puede que tu nivel de hCG no haya alcanzado los 20 mIU/ml. Es necesario que esperes hasta que pasen 31 días después del primer día de tu última regla y entonces volver a realizar la prueba.

Si la prueba resulta negativa, ello significa que hay hCG en tu organismo, lo cual es un buen indicio de que estás embarazada. Pero existe lo que se llama PTE, o Pérdida Temprana del Embarazo, que puede ocurrir muy temprano en el embarazo. Ello tiene lugar cuando el óvulo fecundado no se implanta en el útero o, si es defectuoso, puede que se implante pero luego sea rechazado. Este fenómeno ocurre más a menudo de lo que la gente se da cuenta. Algunas investigaciones han mostrado que pasa tan a menudo como los embarazos exitosos. De manera que aunque la prueba detecte la hCG, puede que tengas una PTE y que tu embarazo no continúe. De nuevo, debes volver a realizar la prueba 31 días después del primer día de tu última regla, para estar segura de que no has tenido una PTE.

Los aparatos caseros de prueba de embarazo que se compran en la tienda son a menudo menos sensibles que los aparatos profesionales. La Prueba de Embarazo Quick & Clear es uno de los aparatos más sensibles que están disponibles y, por lo tanto, es capaz de detectar la hCG cuando otros aparatos no lo son.

Prueba de Embarazo Quick & Clear	20 mIU/ml detectables de hCG
First Response	25 mIU/ml
Equate (Wal-Mart)	25 mIU/ml
Fact Plus Midstream	25 mIU/ml
Clearblue Easy Digital	50 mIU/ml
Walgreen's	50 mIU/ml
CVS "Early Result" Cassette	50 mIU/ml