HOME URINE PREGNANCY TESTS:
APPLICATION OF IMMUNOLOGY TO PATIENT CARE

Corresponding Author:
Jane E. Krause, MS, RPh
Clinical Associate Professor of Pharmacy Practice
Purdue College of Pharmacy
j krause@purdue.edu

Additional Authors:
E. Denise VanHyfte, PharmD
PGY-1 Pharmacy Practice Resident
Lutheran Health Network
Evanhyyfte@lhn.net

Jenny N. Wulf, PharmD
PGY-1 Pharmacy Practice Resident
Union Hospital
jwulf@uhhg.org

Tony R. Hazbun, PhD
Associate Professor of Medicinal Chemistry and Molecular Pharmacology
Purdue College of Pharmacy
thazbun@purdue.edu

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Goal:
To apply immunology principles when educating and counseling patients regarding home urine pregnancy tests.

Learning Objectives:
Upon completion of this article the learner should be able to:

1. Summarize the history and use of urine pregnancy tests.
2. Describe the immunological principles underlying the use of antibody based urine pregnancy tests.
3. Explain manufacturer claims of accuracy and performance.
4. Explain the possibility for false negative and false positive results.
5. Describe the procedure for patient use of urine pregnancy tests and appropriate counseling points.

Introduction

A “pregnancy test” is defined as a procedure intended to reveal the presence or absence of a pregnancy. Currently, there are over 60 different brands of US Food and Drug Administration (FDA) cleared home pregnancy tests on the market in the United States. Many of the brands are produced by the same manufacturers; according to a market research report, there are 11 different manufacturers of home pregnancy tests. In addition, products may advertise early results, digital results, or low price. With the numerous products available, pharmacists have the opportunity to provide valuable education to patients about selecting a home pregnancy test along with the proper way to perform the test and interpret the results.

Evolution of Home Pregnancy Tests

Women have been attempting to predict pregnancy for centuries. Prior to the 1920s, there was no scientific means of determining pregnancy in a woman. Ancient Egyptian writings tell of women trying to determine pregnancy (and gender of the baby) by using urine to fertilize barley and wheat seeds. If the
barley grew, it was interpreted as being pregnant with a male baby, and if the wheat grew, it was interpreted as being pregnant with a female baby. No growth indicated the female was not pregnant. This historical practice is now considered the first theory noticing a unique substance in the urine of pregnant women.

In the early 1900s, research focused on the human reproduction system with the scientific identification of hormones. During the 1920s, researchers discovered the hormone “human chorionic gonadotropin” (hCG), and the role it plays in pregnancy. In 1927, two scientists, Selmar Aschheim and Bernhard Zondek, developed the “Aschheim-Zondek” test (A-Z test), a bioassay (animal based test) which tested for the presence of hCG by injecting the woman’s urine into an immature female mouse. Researchers determined that injection of hCG into laboratory animals would cause ovulation requiring fatal surgery to determine the test result. In the presence of hCG, the ovaries of the immature laboratory animal would enlarge and show follicular maturation.

In the early 1930s, the “rabbit test”, or "Friedman test", was developed by Maurice Harold Friedman, a physician and physiology researcher at the University of Pennsylvania, as a modification of the A-Z test. The “rabbit test” consisted of injecting the woman's urine into an immature female rabbit and then surgically examining the rabbit's ovaries 36 to 48 hours later to obtain results. The “rabbit test” became a widely used bioassay to test for pregnancy. Although this test was found to be more accurate than the “A-Z test”, both bioassays were expensive, required animal sacrifice, and took several days in the laboratory to complete. With the “rabbit test”, it was a common misconception among the public that the injected rabbit would die only if the woman was pregnant. This led to the phrase "the rabbit died" being used as an expression for a positive pregnancy test.

In 1960, a hemagglutination inhibition test for pregnancy was developed by Leif Wide and Carl Axel Gemzell. Because it used cells, this test was an immunoassay (e.g., based on an antibody-antigen reaction), rather than a bioassay. In this test, a urine sample was combined with antibodies against hCG. In a positive test, red blood cells aggregated in a particular pattern which laboratory personnel interpreted as pregnant. These types of tests became commercially available to healthcare professionals and serve as the precursor to current pregnancy tests. However, there were still problems with these tests including cross-reactivity with medications, and the inability of the test to distinguish between hCG and the luteinizing hormone (LH) causing false positive results.

In the early 1970s, scientists at the National Institutes of Health (NIH) researched the biochemistry of hCG and determined the biological specificity of hCG was in the beta-subunit of the hormone. hCG is one of a family of glycoprotein hormones, the others being LH, follicle stimulating hormone (FSH), and thyrotropin-stimulating hormone (TSH). Each of these consists of two subunits: an alpha-subunit (which is very similar in all four hormones) and a beta-subunit which is unique or characteristic of each individual hormone. Both subunits of the molecule are needed for biological activity but the beta-subunit determines the specificity of action. This discovery proved significant and in 1972, Vaitukaitis, Braunstein, and Ross developed an hCG beta-subunit radioimmunoassay that distinguished between hCG and LH, making it potentially useful as an early test for pregnancy. The ability to measure low levels of hCG in the presence of LH explains the great sensitivity of current pregnancy tests. Interestingly, the radioimmunoassay was also found to be useful for healthcare professionals by allowing them to follow patients being treated for hCG-secreting tumors.

By 1977, the assay process was simplified enough to allow marketing to the general population and the first home pregnancy test became available. Warner-Chilcott introduced e.p.t.™ (“early pregnancy test”), which had been submitted to the FDA for clearance the previous
According to the FDA, one diagnostic assay used by patients at home. Urine pregnancy tests are the most common of SPD Clearblue “pregnant” or “not pregnant.”

Easy’s next generation of hE's developed to indicate pregnancy. Clearblue Easy Unilever introduced the first “one step” test, thereby decreasing wait time to test. In 1988, therei within a single strip and situated within a hand-held applicator. Results would appear within ten minutes and sensitivity improved, thereby decreasing wait time to test. In 1988, Unilever introduced the first “one-step” test, Clearblue Easy™, so named for the blue stripe that developed to indicate pregnancy. In 2003, the next generation of home pregnancy tests appeared with the FDA clearance of Clearblue Easy’s™ digital pregnancy test. In place of a blue line, the indicator screen displayed either “pregnant” or “not pregnant.” (Note: Clearblue™ is currently a registered trademark of SPD Swiss Precision Diagnostics GmbH.)

Urine pregnancy tests are the most common diagnostic assays used by patients at home. According to the FDA, one-third of reproductive-age women have used a home pregnancy test. Throughout recent years, sales of these tests have remained consistent. In 1999, about 19 million home pregnancy tests were sold in the United States, with sales of about $230 million. Similarly, sales of home pregnancy tests in 2009 equaled $227 million.

**Immunological Principles of Home Pregnancy Tests**

**The role of hCG:** Home pregnancy tests rely on the detection of hCG in the urine. The hCG hormone is an ideal marker for the detection of pregnancy due to the physiological fluctuation of hCG levels following implantation of the fertilized egg (or embryo) into the uterine wall. Fertilization takes place in the fallopian tube and once the egg is fertilized, the embryo travels down the fallopian tube to the uterus. Once in the uterus, the embryo implants in the lining of the uterine wall. At this point, the trophoblast cells of the developing placenta begin to produce hCG, and levels continue to increase throughout the early stages of pregnancy. Implantation typically occurs 5-8 days after ovulation; this is the same time that hCG first becomes present in both the plasma and the urine. Twenty milli-international units/milliliter (mIU/mL) is the level of hCG that is typically present in the urine of pregnant women at approximately seven to ten days post ovulation. Throughout pregnancy, hCG levels rise at an average rate of 50% per day and at about 10 weeks peak at an average level of 100,000 (mIU/mL). After 10 weeks the levels will start to decline and typically stabilize near 20,000 mIU/mL for the remainder of pregnancy. In general, hCG levels less than 5 mIU/mL are considered negative for pregnancy, while hCG levels greater or equal to 25 mIU/mL are considered positive for pregnancy.

**Immunology and the mechanism of home pregnancy tests:** Some basic immunology concepts are helpful in understanding the mechanism of home pregnancy tests. Proteins called antibodies are a very important component of the body’s immune system. When the body is exposed to a foreign molecule,
Antibodies are produced that can bind to a specific site on the molecule, and thereby tag it for destruction. This helps to protect the body from invading substances that may lead to illness. The foreign molecule to which the antibody binds is termed the antigen. The specific region of the antigen that is recognized by the antibody is called the epitope, and the location where this binding takes place is the antigen binding site.

How does this information relate to home pregnancy tests? Home pregnancy tests are designed using multiple antibodies. One set of antibodies in a pregnancy test recognizes hCG, which serves as an antigen. Different brands of pregnancy tests utilize different antibodies that typically recognize hCG. However, the specific epitope of hCG that is recognized varies from test to test based on the antibody used. Therefore, the antigen binding site on hCG varies from one pregnancy test to another.

Antibodies are also called immunoglobulins (Ig) and have a characteristic Y-shaped structure that results from the assembly of light and heavy polypeptide chains. The antibody structure consists of two identical copies of a heavy chain and two identical copies of a light chain (see Figure 1), which are named in this manner because of their relative molecular weights. Each chain has a variable region that differs in amino acid sequence between one antibody and another, and the remaining region is constant in sequence. The variable regions of the light and heavy chain form two identical antigen-binding sites. During a pregnancy test it is these variable regions that will bind hCG. The constant region of the heavy chain is an important factor in the pregnancy test because a second antibody recognizes the constant region of the anti-hCG antibody. This second antibody-antibody interaction leads to the formation of the control line within pregnancy tests (see Figure 2).

In addition to their critical role in the immune system, antibodies are important analytical tools due to their ability to bind antigens with high specificity. It is possible to generate an antibody to any antigen of interest by simply injecting the antigen into a host animal capable of mounting an immune response. Typically, the host animal is a mouse or a rabbit. Note that one can generate an antibody that recognizes an antibody from a different species. For example, if a rabbit is injected with a mouse immunoglobulin, then one can collect antibodies from the rabbit that recognize and bind to mouse immunoglobulin. Two different types of antibodies, generated against two different classes of antigens, are used in the home pregnancy test: (i) antibodies that recognize hCG, and (ii) antibodies that recognize immunoglobulins from a different species. The principles of operation of a home pregnancy test are summarized as follows (see Figure 2):  

1. A sample of urine is collected. For the most accurate result, it is suggested to use the first urine in the morning, when hCG levels are most concentrated.

2. Two to three drops of the urine sample are applied to the bottom of the test strip. The strip has two sets of antibodies that recognize and bind to hCG. The first set of anti-hCG antibodies (termed “mobile” antibodies) are localized at the bottom part of the strip or absorbent tip. These antibodies are drawn up the strip by capillary
action as soon as they come in contact with the urine sample. The second set of anti-hCG antibodies (termed “immobilized antibodies”) are fixed to the test region of the strip.

3. If the individual is pregnant, then hCG will form a complex with the mobile anti-HCG antibodies and flow up the strip. Upon reaching the test region, the mobile anti-hCG/hCG complex is captured by the immobilized anti-hCG antibodies. An enzyme on the first set of anti-hCG antibodies produces a color reaction in this region of the strip.

4. Mobile anti-hCG antibodies that are not bound to hCG flow past the immobilized anti-hCG antibodies to the control region, where they are captured by a third set of antibodies that recognize the constant region of immunoglobulins. An enzyme on the first set of anti-hCG antibodies produces a color change in this region of the strip. This step verifies that the mobile anti-hCG antibodies have traveled up the strip and, therefore, ensures that the test has functioned properly.

5. The test is complete within 3–5 minutes. A positive test occurs when hCG is present at levels in excess of the test sensitivity (e.g., 25 mIU/mL).

Manufacturer Claims

All marketed devices claim to be “over 99% accurate” and able to “detect pregnancy by the first day of the expected period”. Some products claim to be able to detect pregnancy even earlier (e.g., 4–5 days before the expected period). Such claims by the manufacturers can be misleading and confusing to patients, and having an understanding of these claims is helpful when counseling patients.

Regulation of pregnancy tests: Pregnancy tests are considered a medical device and must be “cleared” (not “approved”) by the FDA. Pregnancy tests are classified as an hCG test system intended for the early detection of pregnancy and the manufacturer is required to submit a premarket notification, or 510(K). A search of the FDA database with the term “pregnancy” shows that 293 such submissions occurred from 1977 to 2014. The 510(K) submission requires, in part, clinical data supporting what are termed “Performance Characteristics/Laboratory Evaluation”. For example, data must be provided for the following:

- Method Comparison/Accuracy Study: The new device is compared to a predicate or already cleared device. Testing is done by splitting samples between both subjects (home users) as well as professionals. The subjects are to perform the test without guidance or assistance, and the results between both professionals and subjects are compared to determine ease of use. The testing involving the subjects and professionals utilizes the new pregnancy test device being studied as well as a predicate device. Related to this, the statement “over 99% accurate” means that when compared to a predicate device already on the market, the new test will produce the same results as the predicate device at least 99% of the time. The FDA recommends expressing this data in terms of percent accuracy, which should never exceed >99%.
Sensitivity/Detection Limit: The minimum urinary concentration of hCG that can reliably produce positive results is referred to as the detection limit, or sensitivity, of the pregnancy test. The concentrations of hCG at the claimed sensitivity must produce positive results in at least 95% of samples tested. Assay sensitivity should be such that small amounts of hCG will be detected while false-positive results due to the presence of LH will be minimized. Additionally, it is expected that all positive results will have reacted within the time frame specified.

Expected Values: Expected values or pregnancy detection rates may be provided by the manufacturer when testing is done before the day of the expected period (i.e., the percentage rate of detected pregnant results by day relative to the day of the expected period). The manufacturer may state the test is capable of detecting pregnancy by the first day of the expected period and no sooner, unless validated by clinical data.

Sensitivity and timing of use: Home pregnancy tests vary in the level of hCG that they are able to detect. A common detection limit for many pregnancy tests is 25 mIU/mL; however the limits range from 6.3 - 50 mIU/mL. In order to prevent false negative results, a woman must perform the pregnancy test at a time when her urinary hCG concentrations are at or above the detection limit of the test. One study evaluating urinary hCG concentrations in 109 pregnant women, found an average concentration of 137 mIU/mL on the first day of the expected period. However, when adjusting for variability among women in length of menstrual cycles as well as differences in the time between ovulation and next menstrual period, the 10th and 90th percentiles of the hCG concentrations on the first day of the expected period were 15 mIU/mL and 853 mIU/mL respectively.

Inaccuracies

False positives: If a pregnancy test produces a positive result, but the woman is not actually pregnant, it is referred to as a false positive. There are several factors that can lead to false positive results in home pregnancy testing. Some of the contributing factors toward a false positive result include recent birth or miscarriage, menopause, certain fertility medications, as well as various disease states. After giving birth or experiencing a miscarriage, hCG levels can remain elevated for approximately eight weeks. If a woman were to take a pregnancy test within this eight week time frame, it could produce a false positive result.

A “biochemical pregnancy” is when a fertilized embryo implants briefly in the womb (hCG is produced for a short period of time), but the pregnancy does not continue and is followed by normal menstruation. In such a situation, a positive pregnancy test result can happen and several days later, negative results occur. A biochemical pregnancy and resulting positive test result is one of the emotional hazards of
early-detection pregnancy tests. This is different than a later-term miscarriage and women should understand that biochemical pregnancies are not uncommon and most women are not even aware that they were pregnant as a biochemical pregnancy often ends before physical pregnancy symptoms manifest.

Failure to observe manufacturer directions on test interpretation can also be associated with a false positive result. A negative pregnancy test result can appear faintly positive if interpreted after the time interval specified by the manufacturer (e.g., after 10 minutes). Interpreting test results after the time interval specified are considered invalid.

Another contributing factor to inaccuracies caused by false positives is menopause. Women in peri-menopause or menopause may have elevated levels of hCG leading to a positive result on a pregnancy test. The only medications known to produce false positive results are certain fertility drugs that contain hCG (e.g., chorionic gonadotropin for injection). If a woman is using one of these medications it is very important that she is aware of the interactions between pregnancy tests and the fertility treatment. There are also some cancers and medical conditions that can lead to elevated levels of hCG and thereby produce a false positive pregnancy test. Examples of these include choriocarcinoma as well as neoplasms of the ovaries.

The commonality between all of these factors contributing to false positive results is that they all lead to elevated levels of hCG. This shows that it is possible for hCG to be elevated even in the absence of pregnancy. Because of this, a positive home pregnancy test result should always be followed up and confirmed by a physician.

**False negatives:** If a pregnancy test produces a negative result, but the woman is actually pregnant it is referred to as a false negative. Just as with false positive tests, there are several different factors that can contribute to false negative results in home pregnancy tests. Some of the contributing factors include testing too early in pregnancy, using urine that is too diluted, or user error.

The concept of false negative results was discussed briefly as it relates to manufacturer claims of sensitivity. As mentioned previously, the level of hCG must be at or above the detection limit of a test in order to reliably produce a positive result. The most common cause of false negative results is women testing too early in their cycle before the urinary concentrations of hCG are high enough to be detected by the pregnancy test. The timing for when hCG starts to rise is different for every woman due to variability in menstrual cycle lengths as well as time to implantation. In addition, many women do not have accurate estimations of their menstrual cycle dates and this can lead to their testing too early. Understanding this variability and the need to follow-up a negative result with a subsequent pregnancy test is important for the health and safety of both mother and baby.

The other contributors to false negatives are using urine that is too diluted and user error. Urinary concentrations of hCG are most concentrated in the morning, therefore testing with first morning urine can help to decrease the risk of false negatives due to urine that is too dilute. Too much fluid consumption can also lead to urine that is too dilute. If a woman is not able to utilize the first urine of the morning for testing, then decreasing fluid consumption 4 to 6 hours prior to testing can help prevent false negatives.

Finally, user error can also lead to false negative results. In studies where pregnancy tests are performed both by trained technicians and volunteers, there have been significantly more false negative results in the volunteer group versus the trained technician group. These false negatives have been attributed to user error by volunteers not fully understanding product instructions. To prevent this form of false negative results, proper counseling on device use as well as encouraging thorough reading of package instructions prior to testing should
always be done.\textsuperscript{32}

**Interference:** With the development of monoclonal antibodies with a greater degree of specificity to hCG, the rate of interference in home pregnancy testing has declined.\textsuperscript{12} As described in the “Evolution of Home Pregnancy Tests” section of this article, by utilizing the differences in the structures of the beta-subunits, manufacturers have been able to develop monoclonal antibodies extremely specific to hCG, thereby minimizing interference involving LH, FSH, or TSH.

In order for a pregnancy test to be cleared by the FDA, it must undergo interference studies.\textsuperscript{12} A portion of the interference studies include testing the pregnancy kits with urine samples spiked with LH, FSH, and TSH. The hCG antibodies used in the pregnancy tests should be specific enough to not significantly cross-react with these substances. Another aspect of interference studies involves testing the pregnancy kit in the presence of various chemical and biological analytes to determine the effect on functionality and accuracy of the pregnancy test. Examples of these analytes include caffeine, ascorbic acid, hemoglobin, glucose, and albumin. In addition to these studies, pregnancy tests are also evaluated for interference based upon pH level. The home pregnancy tests must pass these interference studies in order to make it to market.

**Patient Use of Home Pregnancy Tests**

It is suggested that a pharmacist offer assistance when he/she notices a patient looking at or purchasing a pregnancy test.\textsuperscript{30} Examples of open-ended questions to ask the patient during this conversation are included in Table 1\textsuperscript{33}. When recommending a home pregnancy test, consideration should be given to the following: test sensitivity [or the hCG threshold at which a positive result is indicated (the lower the number - the more sensitive the test)], ease of use and interpretation of results, and price. In addition to single packs, tests are also sold in twin and triplet packs, which offers a more economical option if testing is done more than once.\textsuperscript{14}

Generic tests (as compared to brand-name tests) are FDA cleared, affordable, and equally reliable. Digital tests tend to be the most expensive. Sensitivity information may be found on the box, package insert, or may be obtained by contacting the manufacturer (phone number given on box and/or package insert). As will be noted on the box, many products give instructions for use in both English and Spanish languages. Steps to follow when using a home pregnancy test are summarized in Table 2\textsuperscript{12,30,34,35}. Reviewing this information with patients will help to ensure the correct use of the product and interpretation of the results.

<table>
<thead>
<tr>
<th>Table 1. Conversation Starter with Patient: Examples of Open-Ended Questions</th>
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<tr>
<td>How can I help you?</td>
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<tr>
<td>Who is the product for? (Is this product for you?)</td>
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<tr>
<td>How late is your period? (What day do/did you expect your period to begin?)</td>
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<tr>
<td>Are your periods usually regular?</td>
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<tr>
<td>What medications do you currently take?</td>
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<tr>
<td>Do you regularly see a physician for any medical conditions?</td>
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<tr>
<td>Have you used a pregnancy test before?</td>
</tr>
<tr>
<td>What preference, if any, do you have between products? (e.g., test stick versus test cassette)</td>
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It is interesting to note a few recent studies involving patient use of pregnancy tests. For example, a recent study of over 100 women showed that greater than 95% preferred holding a “test stick” in their stream of urine as compared to collecting urine in a cup for use with the “test cassette” or immersion of the “test stick”.\textsuperscript{14} This group of women preferred this format because it was the most efficient (involved the fewest steps). Another study showed that one in four women misread results with line-based pregnancy tests where the appearance of colored lines has to be evaluated by the user to determine the result.\textsuperscript{36} This illustrates the importance of patient education with interpreting test results. In addition, the digital display of results (“pregnant, “not pregnant”) with some tests has removed the need for users to interpret line-based results.
### Table 2. Patient Education: Steps in Using Home Pregnancy Tests

**Before Using the Test:**
- Check the expiration date on the package. Do not use a test after its expiration date.
- Store the test in a cool, dry place. Avoid exposure to heat and sunlight. Do not freeze.
- Carefully read the instructions on box and product insert as directions vary between products.

**Using the Test:**
- Follow the directions exactly. If a step requires timing, use a clock with a second hand or a stopwatch.
- Most products recommend the use of the first morning urine. If testing before the period is expected, use first morning urine to maximize the chances of picking up the lower level of hCG. If testing on or after the day when period is expected, in general, she may test urine any time during the day.
- **Test Stick (Figure 3):** Remove test stick from wrapper and remove cap from adsorbent tip; hold the test stick by the thumb grip with the tip pointing downward and result window facing away from body; place the tip in urine stream for length of time recommended by manufacturer OR collect urine in a cup and immerse the entire tip in the urine for the recommended time. Replace the cap while holding the tip downward; lay the stick on a flat, dry surface with the result window facing up.
- **Test Cassette (Figure 3):** Remove the test cassette from wrapper and place on a flat, dry surface; collect urine in a cup (clean and dry); apply indicated number of drops of urine (dropper provided with product) into the round well.
- Test the urine sample immediately if collecting in a cup. If urine must be tested later, keep the sample refrigerated.
- Do not dip the pregnancy test into the toilet bowl as the urine is too dilute.
- Tests are not to be taken internally and are single-use. Do not reuse a test.

**Test Reaction Time:**
- It is important to adhere to the test reaction time. Every test has a time interval that must be respected, typically between five and ten minutes.
- Results determined after the reaction time are considered invalid. A negative test may appear positive after the given reaction time of the test as the chemical composition of urine can cause a “ghost line” or “evaporation line” in the result window in the location of the antibody line.

**Interpreting Results:**
- Although products vary, a positive test (pregnant) will display a “control line” and a “test line”. “Test lines” can appear as a simple color band, a plus sign, or in the case of digital pregnancy test, actual words appear. A faint result/test line is indicative of a positive result as long as the test was interpreted within the given reaction time as specified in the directions.
- The control line indicates that the test has been performed correctly and is functioning properly. If the control line does not appear, the test is considered invalid.

**Follow-Up:**
- Record the results of the test.
- If the test result is positive (pregnant), it is important for the patient to see a physician to confirm and discuss the results. Most healthcare providers also use a urine pregnancy test to confirm. However, a blood test may be used by the healthcare professional to determine the exact level of hCG.
- If the test is negative (not pregnant), repeat the test in 3-7 days if menses has not started. If the repeat test is negative, it is most likely that the patient is not pregnant. If menses does not start within one week and repeat testing is still negative, a woman should call her physician.

**Questions:**
- Questions about the test can be directed to a pharmacist, physician, or to the manufacturer (phone number on the box and/or package insert).
As previously mentioned, package labeling can be confusing. Care must be taken when interpreting “over 99% accurate”.

This accuracy claim is often not what potential users expect as it may refer to the “Method Comparison/Accuracy Study” described earlier which means that when compared to a predicate device already on the market, this test will produce the same results as the predicate device at least 99% of the time. Or, it may refer to a claim of “over 99% accurate” in detecting an existing pregnancy as described earlier in the “Expected Values” (or pregnancy detection rate). In this case, the claim would likely be accompanied by additional qualifying information such as “over 99% accurate at detecting typical pregnancy hormone levels from the day of the expected period”. In addition, percentage rate of detected pregnant results on days prior to the expected period may be presented.

According to Grenache, patients often lack an appreciation of the strengths and limitations of pregnancy tests and rely heavily on marketing claims to guide their purchasing decisions. For example, the labeling on the front of the box may state “over 99% accurate” and “results five days sooner” leading the patient to believe that the product is “over 99% accurate in providing results five days sooner”. On closer inspection, information on the side of the box (or, it may be included in the package insert) explains that the product is “over 99% accurate from the day of the expected period”. It goes onto say that testing one day before the expected period will give a positive result in 95% of pregnant users, testing two days before will give a 90% rate, three days sooner gives a 82% positive rate, and testing 4 days before gives only a 51% positive rate. It is also recommended on the package to test on the first day of the expected period. Clarifying such package information to the patient and distinguishing between percentages related to “Method Comparison/Accuracy Study” and “Expected Values” (pregnancy detection rates) is essential.

**FUTURE TRENDS**

A recent innovation in pregnancy testing involves a point-of-care device relying on a blood sample, which is important when a patient
is unable to produce urine (e.g., due to dehydration, or if the patient is unconscious). The blood based test was cleared by the FDA in 2015 and can detect low levels of hCG with several droplets of blood in 10 minutes and can aid physicians in identifying if a woman is pregnant in an emergency situation.  

An additional trend in pregnancy testing is the desire for more information by the patient and this has become evident with a recently cleared pregnancy test which estimates the number of weeks that have occurred since ovulation. Future tests will likely follow this trend of providing additional information and semi-quantitative measurements.

CONCLUSION

Pregnancy testing has evolved dramatically over the centuries. Today, home urine pregnancy tests provide privacy, convenience, reliable results, and have helped to empower women to maintain control over a portion of their reproductive lives. Pharmacists play a vital role in guiding patients through the vast amount of information available regarding pregnancy tests including the principles of operation and clarification of product labeling. Opportunities for counseling exist during the recommendation for a product, interpretation of test results, and referral of the patient for confirmation or further investigation.
References


