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Review on Pregnancy Testing Kit Analysis

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ABSTRACT



Healthcare professionals and the general public both often use pregnancy tests. The measurement of human chorionic gonadotrophin (HCG) in urine is a prerequisite for all tests. None of the other pregnancy-specific agents that have been suggesting as pregnancy tests can match the sensitivity and practicality of the immunoassay of HCG. Additionally, ultrasound detection is less sensitive than HCG analysis. The latest generation of tests is based on monoclonal antibodies to the beta-subunit of HCG; this feature allows for outstanding sensitivity because it essentially precludes the chance of cross-reaction with pituitary luteinizing hormone (L.H.). It is crucial to understand that the 'beta-subunit' antibody reacts with both intact HCG, which constitutes the majority of pregnancy serum, and beta-subunit fragments (beta-core), which include the majority form in the urine. Non-pregnant persons' blood and urine both have trace quantities of HCG. Around 6-8 days after fertilization, HCG from the implantation blastocyst first manifests in the mother's blood; levels quickly increase to peak at 7-10 weeks. Urine may show positive findings with most modern pregnancy test kits (sensitivity 25 units per liter) 3-4 days after implantation; by seven days (the time of the anticipated period), 98% of results will be positive. One week following the missed period, a negative test almost always indicates that the lady is not pregnant. False positive test results brought on by interfering elements are highly improbable with today's test kit generation. It is unlikely that new tests or alternative technology will be able to achieve the degree of sensitivity and specificity that pregnancy tests have currently attained.

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INTRODUCTION

The first was a kit for a quick and accurate pregnancy test. After that, the dual-specific non-competitive sandwich assays and the in-vitro test for allergy diagnosis were performed. Then, the solid phase radioimmunoassay and a solid phase binding assay for vitamin B12 were performed. At the time, the university didn't demonstrate much interest in supporting ideas that could lead to commercial products. I even heard scathing criticism from a few university friends. The last 20 years have seen a complete shift in this mentality. Today, the government encourages colleges to promote inno-

vations and offer the necessary tools to assist with their preservation and commercialization. But each of the inventions of the 1960s began with a few original discoveries that led to technical advancement. The development of assay techniques with distinctive properties and the ensuing hunt for suitable applications led to the invention of pregnancy and allergy tests. The diagnostic test kit industries were pioneered by Organon in Holland with its pregnancy test kit and Pharmacia in Sweden with its radioimmunoassay test kits. Pharmacia Diagnostics rose to prominence as one of the world's top manufacturers of diagnostic test kits, and it has remained so in the area of allergy diagnostics [1].

Definition

A testing kit, often known as a test kit, is an invitro diagnostic tool made up of reagents, articles, or any combination of these, and it is designed to be used to carry out a specific test for reagent testing, pregnancy testing, or soil testing.

Types of Testing Kits

The types of testing kits shown in Figure 1.

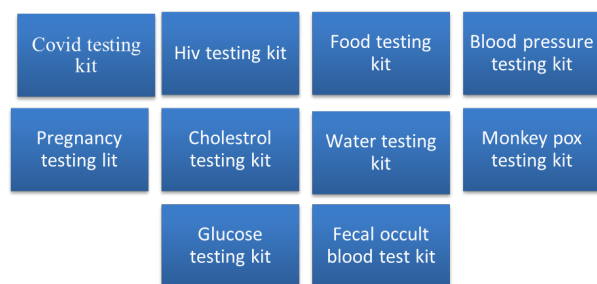


Figure 1: Types of Testing Kits

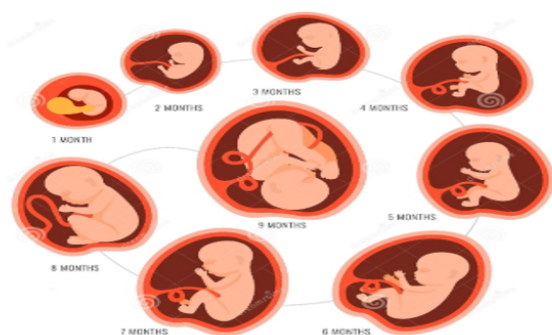


Figure 2: Stages of Pregnancy

Pregnancy

The period of a woman's life during which one or more infants develop inside her is known as pregnancy, also known as gravidity or gestation. Multiple pregnancies entail having many children, such

as twins. A sexual encounter or assisted reproductive technologies can result in pregnancy. It culminates in childbirth and typically lasts 40 weeks from the Last Menstrual Period (LMP), a date the patient, ideally, is aware of. This is roughly nine lunar months, with a month lasting about 291-292 days. About 38 weeks have passed since conception. A fetus is a word used until birth to describe the growing child during the first eight weeks after the beginning. The period of a woman's life during which one or more infants develop inside her is known as pregnancy, also known as gravidity or gestation. Patients frequently refer to the fetus as a "baby." Missed periods, sensitive breasts, nausea and vomiting, hunger, and frequent urination are just a few early pregnancy symptoms. A urine pregnancy test can be used to confirm pregnancy; most frequently, the patient does the test at home, followed by a series of blood tests in the doctor's office. The period during which one or more kids develop is known as pregnancy, gravidity, or gestation. A hormone called Human Chorionic Gonadotropin is found in urine and blood tests. During the first few days of pregnancy, your body quickly accumulates this hormone, created by the placenta, shortly after the embryo connects to the uterine lining. Most of your pregnancy symptoms are brought on by this abrupt change in hormone levels [2].

Definition

The period when the fertilized egg develops in the uterus between conception (the fertilization of an egg by a sperm) and birth. The average human pregnancy lasts 288 days. The zygote begins to divide, and after 5-7 days of division and growth, it adheres to the uterine wall, developing into an embryo and the placenta [3].

Stages of Pregnancy

Approximately >280 days, >9 months, >40 weeks, or >3 trimesters make up a typical pregnancy.

First Trimester [Week 1-12]

Almost every organ system in the body experiences hormonal changes during the first trimester of pregnancy. The infant proliferates. In this trimester, the primary organs begin to develop, and menstruation has halted.

Mood swings, headaches, and morning sickness are among the symptoms and indicators of pregnancy.

1. The baby's brain, heart, and spinal cord have started to develop.
2. The eighth week is when the baby's heart begins to beat.

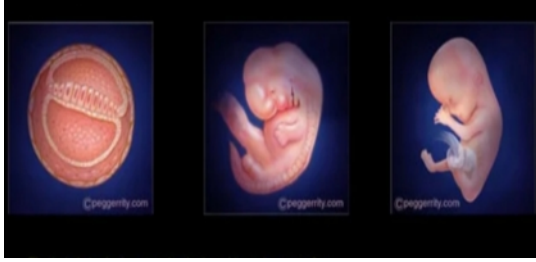


Figure 3: Development of an Embryo in the First Trimester

3. The development of the sex organs.
4. The Face begins to take shape.
5. After eight weeks, the fetus is around 2.5 cm long and more human-like in appearance.
6. We can determine if he is a boy or a girl at 12 weeks, and the infant can first.

Second Trimester [Week 13 -28]

The majority of early pregnancy symptoms will eventually go away. Additional symptoms include heartburn, limb swelling, and back pain. Breast and abdominal stretch marks. The size of the uterus will increase quickly. Blow and heart rate is increased to meet the fetus's needs. Bone and muscle tissue are still forming.

1. In the sixteenth week, skin starts to form.
2. At 20 weeks, the infant can hear and swallow.
3. In the 24th week, your baby's head starts to sprout natural hair.
4. The lungs develop but do not function.
5. At the end of the third trimester, the baby is currently 30 cm long.



Figure 4: Development of the Baby in the Second Trimester

Third Trimester [Week 29-40]

Your fetus expands, and the body organs develop during this third trimester. The fetus moves around

a lot, particularly during the 27th and 32nd weeks. In the uterus, a fetus is typically in a head-down position. Mother's breath is short. The mother's belly button can spit out. The breast first produces colostrum [Rich yellow milk].



Figure 5: Development of Baby in the Third Trimester

At 34 weeks, the baby's bones have finished developing.

1. The ability to notice changes in light and to open and close the eyes. By the conclusion of the 37th week, the baby is deemed full-term, and the organs are prepared for independent function.
2. The baby may become head down for delivery as the due date approaches.

Diet and Source

Month 1

1. Green leafy vegetables, such as spinach, rocket, and parsley, are high in folate.
2. Legumes [lentils, beans, chickpeas] and whole grains. Natural remedies for minimizing nausea and vomiting in the early stages of pregnancy. It has been demonstrated that giving 40 mg of vitamin B6 twice daily is helpful.

Month 2

1. Ginger can help with nausea. Try adding two tablespoons of grated ginger to boiling water for tea, eating crystallized ginger candies, or cooking with ginger powder.
2. Good sources of vitamin E to minimize the risk of miscarriage include almonds, olive oil, hazelnuts, and egg yolk.

Month 3

1. Water: To keep your infant hydrated, consume at least ten glasses of water daily in addition to fruits and vegetables that are high in water content.

2. Ginger, keep taking ginger if you're still feeling queasy this month.

Month 4

1. Eating more high-quality proteins, such as eggs, improves your consumption of iron-rich foods.
2. Eat foods strong in iron, such as leafy greens, with every meal and a supply of vitamin C to boost the body's absorption of iron from non-animal sources (lemon juice, capsicum, or pepper).

Month 5

1. Calcium is essential for a baby's bones, teeth, heart, and muscles.

Suitable sources

1. Small fish with palatable bones
2. Tahini
3. Leafy green vegetables
4. Dairy items

Your body cannot store vitamin C, so it's crucial to get it regularly through foods like tomatoes, broccoli, and oranges.

Month 6

1. To avoid constipation, eat whole grains, fruits, vegetables, and legumes.
2. Need 25 to 30 g of fiber daily, about the same as five large apples and 2 cups of lentils.
3. As a home cure for constipation, take 1 tbsp of psyllium dissolved in a glass of water before night to promote a healthy bowel movement the next day.

Month 7

An adequate protein intake is essential for the fetus' development during pregnancy. For a healthy pregnancy, most women require 80 grams or more of protein per day.

Suitable sources

1. Red meat and poultry that is free-range.
2. Natural-raised eggs

3. Unprocessed soy products like tempeh, beans, and peas.

4. Seeds and nuts.

Month 8

The third trimester is when a baby's brain grows and develops quickly, thanks to omega-3 fatty acids.

1. Oily fish, such as salmon and sardines, are good providers of omega-3.
2. Hazelnuts, pecans, and walnuts
3. crushed flax seeds
4. It has been demonstrated that sour cherries encourage sound sleep.
5. Before going to bed, try consuming a glass of unsweetened cherry juice.

Month 9

1. Consuming one clove of garlic every week, garlic has been shown to lower the risk of premature labor.
2. Dates, six dates per day throughout the last four weeks of pregnancy.
3. Eating two handfuls of raisins a week reduces the likelihood of early work [4].

Foods Avoid During Pregnancy

1. Uncooked or raw meats
2. Cold-cured meat slices
3. Raw (sashimi/sushi) fish
4. Creamy cheeses
5. Snack salads
6. The raw egg
7. Fresh produce that hasn't been washed
8. Caffeine Level

Signs and Symptoms

1. Minimal spotting and cramps
2. Period missed
3. Fatigue
4. Nausea

5. Aching or tingling breasts
6. A lot of urinating
7. Bloating
8. Travel sickness
9. Mood changes
10. Temperature variations

Other Signs Include

1. Their blood pressure is high.
2. Profound exhaustion and heartburn
3. Rapid heartbeat
4. Changes to the breasts and nipples Weight gain

Pregnancy Testing Kit

Introduction

The earliest known pregnancy test was developed around 1350 BC and stated, "If the veins in her arm beat against thy hand, thou shalt say he is pregnant." This proves how long medicine has been interested in developing reliable methods to determine whether a woman is pregnant. Hippocrates described a technique to identify pregnancy about 400 BC when he said, "Ingest honey in water: if pregnant, uncomfortable stomach distention will follow. In the Middle Ages, "piss-prophets" used uroscopy to detect pregnancy. A pregnant woman's urine was supposed to float on top of milk around 1200 AD. Black streaks on an iron needle that had been dipped in a woman's urine were thought to be an indication of pregnancy around 1500 AD. In France in the 19th century, a "cysteine pellicle" material was identified in urine and used to determine pregnancy. The AZ test, the first pregnancy test with a scientific basis, was first described by Asheim and Zondek in 1928. Between 1929 and 1950, the bioassay and subsequent trials were developed based on the detection of hCG in a pregnant woman's urine. For these studies, weight changes in the uterus, prostate, or seminal vesicles of rabbits, rats, or mice, as well as changes in gamete production in toads, were used. Beginning around 1960, immunological methods were developed to identify hCG and determine pregnancy. The early antibody-based hCG assays used heme or latex agglutination to find immunoreactive hCG in a pregnant woman's urine. In 1971 and 1974, the radio immune test for hCG and the radioreceptor hCG assay were first made available. The latest generation of at-home pregnancy tests was introduced in the 1990s. Monoclonal antibodies and

visual markers are used in an immunochromatographic manner in these tests. It can identify pregnancy as early as 15 days after ovulation or one day after a missed period, and results are available in just five minutes [5].

Modern Pregnancy Tests

After scientists started injecting urine into mice and rabbits, the first accurate pregnancy test became available in the 1920s. Similar to how it did in humans, the hormone hCG, only found in pregnant women's urine, made a mammal's ovaries expand and produce an egg. The animal is pregnant if it ovulates. By the 1940s, scientists had switched to African clawed frogs from rabbits. Except that frogs lay their eggs externally, the test functioned similarly. Instead of slaughtering and dissecting rabbits for research, ovulation in frogs might be studied. The newest immune chromatographic or lateral flow tests need the woman to dip a test stick in her urine and wait for the results, which usually take a few minutes. If there is any hCG in the blood, it will bind to a specific antibody that is colored labeled and move along a test strip due to capillary action. Complex responsible for a line or positive symbol appearing. This line or cross would not show up without hCG, suggesting a negative result [6].

Human chorionic gonadotropin [hCG] detection is the foundation of pregnancy testing. The purpose of a pregnancy test is to determine if a woman suspected of being pregnant has human chorionic gonadotropin in her urine. It is possible to do biological and immunological tests to determine whether hCG is present in a pregnant woman's urine.

Pregnancy tests are C.D.s that patients use most frequently, whether at home or in a clinical setting. To deliver precise findings in less than 5 minutes, the latest generation of pregnancy tests based on monoclonal antibodies was created in the 1990s. 99% of home pregnancy tests are accurate, on average [7].

The reasons for erroneous findings in home pregnancy tests include testing before there is enough human chorionic gonadotrophin (hCG) in the urine, trouble comprehending product instructions, and difficulties appropriately interpreting test results.

Definition

Pregnancy tests, which determine whether or not a female is pregnant, detect the amount of hCG in the body. Using a pregnancy test kit to look for the female pregnancy hormone, human chorionic gonadotropin (hCG), in blood or urine, and ultrasound imaging are the two basic methods. A blood test for hCG can be used to determine the earliest pregnancy [8].

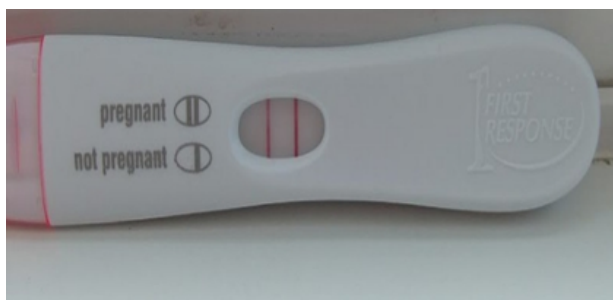


Figure 6: Modern Hormone Pregnancy Test, showing a Positive Result

Pregnancy Testing Methods

Pregnancy testing methods are two types.

Human Chorionic Gonadotropin[hCG]

hCG, a glycoprotein hormone discovered in the early 20th century, rises swiftly in the first few weeks of pregnancy and usually peaks between 8 and 10 weeks gestation. What will become the placenta produces hCG. Urine or blood samples can be used for hCG testing in a medical facility. Generally, the tests used to find hCG in blood or urine are trustworthy and affordable. The earliest hCG can be identified in a blood sample is as early as six days after ovulation and, on average, 8–10 days after ovulation. Blood and urine both have higher concentrations of hCG. Consequently, a urine test may still be harmful even after a positive blood test. A glycoprotein called human chorionic gonadotropin, which has 91 amino acids, comprises two distinct, non-covalently connected subunits. Serum and urine both contain diverse hCG metabolites in different forms. The most important documents include intact hCG nicked intact hCG (where there is a nick in the -polypeptide chain, typically between amino acid positions 40 and 50 from the -subunit's N-terminal end free hCG), and free nicked hCG, WHO International Standards have been produced. Later in pregnancy, free-core, a distinct type detected in urine, becomes the predominant form. As early as 7 to 10 days after conception, hCG can be seen in urine and serum during a healthy pregnancy. After the first missed period, hCG levels frequently reach 100 mIU/mL, 2,3,4 continue to increase, culminating at 100,000–200,000 mIU/mL around 10–12 weeks into pregnancy [9].

The rapid rise in hCG concentration during early fetal growth and its subsequent presentation in the urine and serum shortly after conception makes it an ideal diagnostic for early pregnancy identification. The Card Pregnancy Test is a quick test with a sensitivity of 25 mIU/mL that qualitatively identifies the presence of hCG in urine samples [10].

Qualitative Tests

Qualitative tests yield yes/no or positive/negative results based on the presence of the hCG beta subunit in blood or urine. On a qualitative level, the criteria for a positive test are frequently based on an hCG cut-off where at least 95% of pregnant women would have a result on the day of their first missing period. Qualitative urine pregnancy tests have varying degrees of sensitivity. High-sensitivity tests may detect hCG levels between 20 and 50 mill international units/mL (mIU/mL). Low-sensitivity assays can identify hCG groups between 1500 and 2000 mIU/mL and establish the efficacy of a medication-assisted abortion. Qualitative urine tests for home use are commonly made as lateral flow assays [11].

Quantitative Tests

Quantitative analyses determine the precise concentration of hCG in the sample. Blood tests can identify hCG levels as low as one mIU/mL, and doctors routinely declare a pregnancy test positive at five mIU/mL [12].

Urine Pregnancy Test

One of the most widely used methods of determining pregnancy is the urine pregnancy test. It operates by determining hCG concentrations in the urine. Home pregnancy tests are urine examinations that can be carried out in solitude. Today's market is filled with a range of urine pregnancy tests. The sensitivity of each test varies, with some urine tests able to identify hCG levels as low as 15 ml/u. You typically deposit one to several drops of pee on a chemical test strip that has been prepared or insert the strip into the urine stream when performing an at-home pregnancy test. The ribbon is made specifically to find hCG. For several of these tests, hCG can be detected in your urine around ten days after conception. However, taking it after your missing period reduces the risk of a false-negative test [13].

Performing a Home Pregnancy Urine Test

Although the process differs from test to test, performing a pregnancy test at home is simple. Before using the exam, make sure to read the instructions that come with it. Additionally, make sure the expiration date hasn't already passed. Most urine tests include a diagnostic strip that may identify hCG when exposed to urine. Although you should always read the instructions on the container, the following guidelines usually work well for home pregnancy urine tests:

1. Take the test strip out of its packaging.
2. Dip the test strip into a cup of urine or insert it into your urine stream.

3. Permit the given time to pass.

The test strip should have changed colors or shown a pregnancy indicator if you are pregnant.

Mechanism of Pregnancy Tests

It operates on the immune chromatography tenet. The sandwich ELISA technique and the immunochromatographic test share the same fundamental principles. The sole distinction is that capillary action causes an immunological reaction on the chromatographic paper. This technique applies two types of targeted antibodies to the antigen [14]. A different antibody is labeled with colloidal gold and inserted into a sample pad, while one of the antibodies is fixed on the chromatographic paper. The sample pad is linked to the membrane’s end to complete an immunochromatographic unit. On the sample pad, the liquid sample is dropped. The sample’s antigen forms an immunocomplex with the colloidal gold-labeled antibody. When an antibody is immobilized on a membrane, its complex comes into touch with it as it travels with the liquid sample. Next, the antibody that has been immobilized forms an immuno-complex with it. This produces a red-purple line that is colored. The membrane will display a reddish-purple line if an attractive antigen is present [15].

Due to the urine’s rapid membrane migration, it is possible to determine if the hCG antigen is present or absent within 15 minutes.

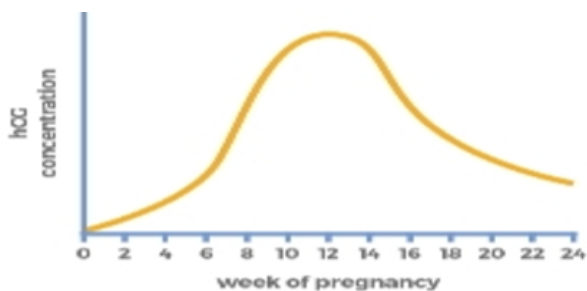


Figure 7: Week of Pregnancy vs hCG Concentration

Components of pregnancy testing kit device: The immunoassay strip/pad and the housing are the two main parts of a home pregnancy test.

A monoclonal antibody (MAb), a protein that reacts with any hCG found in the urine, is coated on the immunoassay strip. If the hCG level is consistent with recognized pregnancy levels, this reaction changes color.

Immunoassay Strip

Nonwoven fibers are compressed into a thin strip and coated with reactive antibodies to create the

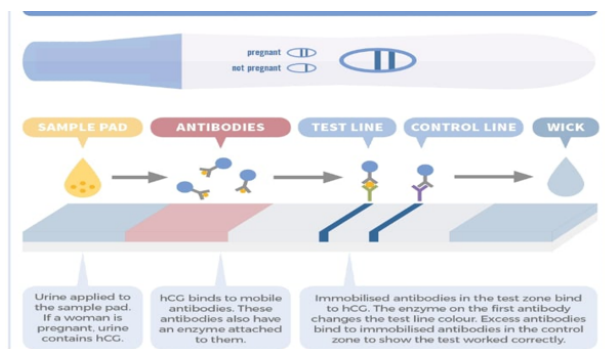


Figure 8: Mechanism of Urine Pregnancy Test

immunoassay strip. A color change results from the antibodies’ interactions with the pregnancy hormone.

Absorbent Pad

The absorbent pad used to contact the urine stream in the direct application type of test extends from the test chamber. The immunoassay strip touches the liquid after the place has absorbed it.

Plastic Housing

The test strip and the absorbent pad are housed in a two-piece container that shields them from environmental toxins and makes the device portable.

The test and control zones of the strip may be seen through a leak-proof, clear plastic glass on the side of the housing, which also prevents urine from accidentally splashing over the test strip [16].

Urine Collection Cup/Vials and Reagents

A plastic collection cup includes test kits that need separate urine collection. Additionally, they could come with plastic vials containing pre-measured reagent amounts that must be mixed with the urine before smearing on the test strip.

Control: It includes antibodies that detect free latex or colloidal gold (goat polyclonal antibodies) to ensure the test was successful.

Test: It has a particular capture molecule that only binds to particles with an analyte (antigen or antibody molecule) fixed [17].

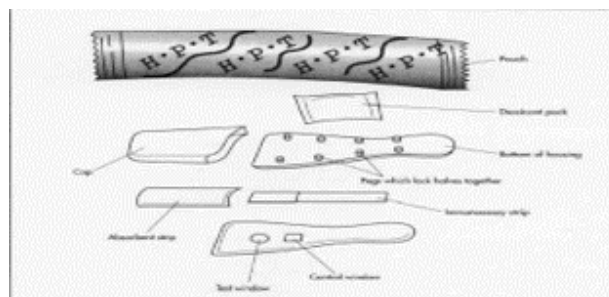


Figure 9: Components of the Testing Kit

Specimen for Urine Pregnancy Test

Any random urine sample is taken and placed in a clean, dry, and detergent-free area. At least 12 days must pass following the first missing menstrual period before it can be collected. If the test is repeated after a week and the findings are negative.

The procedure of the Urine Pregnancy Test

1. Test kits can be kept at room temperature for storage.
2. Take the test equipment out of the pouch and use it immediately.
3. Position the test instrument on a smooth, clean surface.
4. Start the timer while transferring three complete drops of urine to the specimen using the dropper held vertically. Avoid creating air bubbles.
5. Watch for the band to start playing.
6. Review the outcome in 15 minutes.

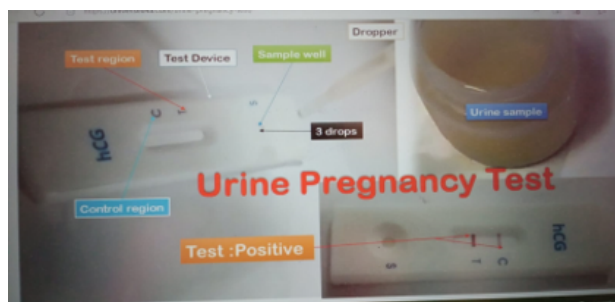


Figure 10: Procedure of Urine Pregnancy Test

Result Interpretation of Urine Pregnancy Test

1. Only the band at the control region tested negative.
2. Both bands in the test (T) control regions are positive.
3. Test invalid if there is no band or a band in the test zone [18].

Blood Pregnancy Test

Pregnancy blood tests are carried out in a medical facility or at your doctor's office. They measure the hCG levels in your blood to identify pregnancy. There are two varieties of blood tests for pregnancy:

Quantitative Blood Test

The quantitative blood test measures the precise concentration of hCG in your bloodstream to identify

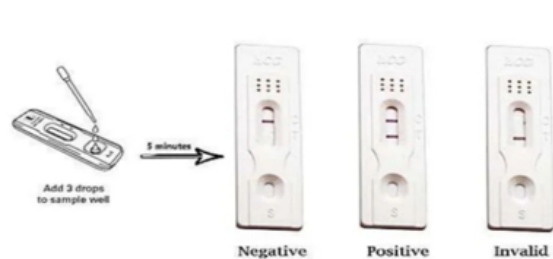


Figure 11: Result Interpretation of Urine Tests

pregnancy. Additionally, it can be used to determine how far along in your pregnancy you are [19].

Qualitative Blood Test

The qualitative blood test identifies the presence of hCG in your blood as a sign that you are pregnant. It merely offers a yes-or-no response as to whether you are pregnant and does not measure your hCG levels [20].

Conducted a Blood Test

1. Professionals in the medical field conduct blood pregnancy tests in a clinic or office setting. It is very similar to a quick blood test.
2. Because they are expensive and frequently yield the same results as a urine test, blood tests are not commonly performed. A little blood sample is used for this pregnancy test, which is then examined at a hospital or doctor's office.
3. This blood test can identify the number of pregnancy hormones in your body and detect whether it is there.
4. In rare cases, such as for women undergoing infertility treatments or when the healthcare provider suspects there may be an issue, a blood test for pregnancy may be performed.
5. For this test, a sample of your blood is taken and sent to a lab for analysis. These blood tests are more sensitive than urine tests because they may pick up on insufficient quantities of hCG. That suggests that they can respond more precisely nine to twelve days after fertilization, which is very early in pregnancy.
6. Results could appear in as little as a few hours or as long as a day [21].

Your healthcare professional may also use a blood test to compare the levels of hCG throughout the pregnancy. During the first several weeks of pregnancy, your hCG levels typically double every two days. The levels can indicate a problem with the

pregnancy if they don't increase. Extremely high hCG levels could indicate twin gestation or a problem with the pregnant woman.

Procedure

Conducted a blood test

Professionals in the medical field conduct blood pregnancy tests in a clinic or office setting. It is very similar to a quick blood test.

1. Alcohol will be used to clean a place on your arm.
2. Your arm gets pricked with a needle.
3. The needle draws blood into a little tube.
4. The tube is delivered to a lab where it will be examined. Results of pregnancy tests usually take one or two days [22].

Accuracy

When used by knowledgeable technicians, home pregnancy test kits are nearly as accurate (97.4%) as professional laboratory testing, according to a systematic evaluation that was published in 1998. Consumer use, however, reduced the accuracy to 75% since many customers either misinterpreted or ignored the kits' instructions, according to the reviewers [23].

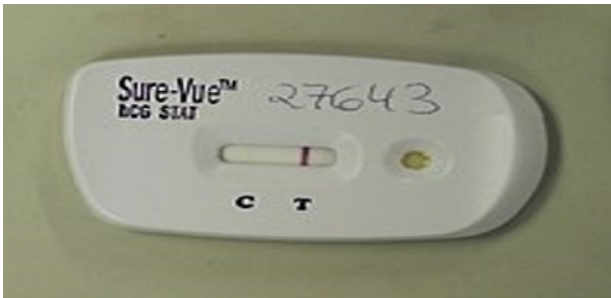


Figure 12: The Control Line of this Pregnancy Test is Blank, Making the Test Invalid

False Positive

Pregnancy test results that are falsely positive are uncommon and can happen for several reasons, including:

Improper test administration and user interpretation Biochemical conception and non-pregnant production of the hCG molecule can occur in certain liver diseases, cancers like choriocarcinoma and other germ cell tumors, IgA deficiencies, heterophile antibodies, enterocystoplasties, gestational trophoblastic diseases (GTD), and gestational



Figure 13: This Pregnancy Test Displays the Control Line on the Left, Demonstrating the Accuracy of the Results, on the Right Side, a Gray-Purple Line, In addition to the Test Line, Indicates the Patient is Pregnant

trophoblastic neoplasms, as well as other conditions. Germs and blood in the urine Even if a pregnancy is present, incorrect evaporation lines may appear if a home pregnancy test is examined outside the recommended 3-5 minute window or reaction time. False positive results on tests that have been used after expired are also possible.

'Phantom hCG,' caused by people with human anti-animal or heterophilic antibodies, can result in false positive pregnancy tests. In addition, malignancy, quiescent pregnancy, pituitary sulfated hCG, familial hCG syndrome, and pituitary sulfated hCG can all result in false positives. As a result of pharmaceutical use, Those who use the risks of the following medication have falsely positive urine tests: chlorpromazine, promethazine, phenothiazines, methadone, aspirin, carbamazepine, and medicines that increase urinary pH [24].

False-Negative

Inadequate testing can result in erroneous negative results. Early in pregnancy, hCG levels rise quickly, and the possibility of false negative test results reduces as the pregnancy progresses [25]. Less sensitive urine tests and qualitative blood tests may not be able to detect pregnancy three to four days after implantation. There is little probability that a late menstrual cycle may lead to a false negative because menstruation typically starts 14 days after ovulation. It's possible that ovulation won't happen when it should in the menstrual cycle. Even in people with a history of regular menstrual cycles, several factors might cause unexpectedly early or late ovulation. False negative results are most frequently caused by the "hook effect," which occurs when a very high hCG concentration is tested without dilution and yields an inaccurate result [26].

The hCG levels are measured semi-quantitatively using a multilayer urine pregnancy test (MLPT). This test can help determine whether a pharmaceutical

abortion was successful. The hCG levels are measured between 25 and 99, 100 and 499, 500 and 1999, 2000 and 9999, and above 10,000 mIU/mL.

Efficacy of Urine vs. Blood Pregnancy Tests

There is a need for blood pregnancy tests because of the complications. Since urine tests are inexpensive, painless, easy to use, and can be performed in the privacy of one's home, they are typically employed for most pregnancies. These tests are also accurate and give doctors speedy results with more specific pregnancy information [27].

Ultrasonography

Pregnancy detection and diagnosis are also possible uses for obstetric ultrasonography. Before getting an ultrasound, a positive urine pregnancy test at home is rather typical. Abdominal and vaginal ultrasounds can be performed, although the vaginal version enables earlier pregnancy visibility [28]. Obstetric ultrasound can detect a fetal pole between 5.5 and 6 weeks of gestation, the yolk sac between 5 and 6 weeks, and the gestational sac (a collection of intrauterine fluid) between 4.5 and 5 weeks. Utilizing ultrasound, multiple gestations can be identified [29].

1. A piezoelectric crystal transducer produces high-frequency U.T. wave pulses.
2. The ultrasound screen shows the echos, or reflected waves, from distinct uterine regions.
3. It is the most accurate way of pregnancy detection.
4. It is possible to see the gestational ring as early as the fifth week of pregnancy.
5. Heartbeat by the tenth week and fetal movement by the eleventh [30].

Examples of Home Pregnancy Testing Kits Brands

1. I-can one-step pregnancy test device
2. Get news hCG pregnancy test kit
3. Prega news hCG pregnancy test kit
4. CiplaMamaxpert Rapid pregnancy detection kit
5. Ovlo plus pregnancy test kit
6. Accurate advanced Hcg pregnancy test kit
7. Plush preg-oh! Pregnancy kit test
8. Pergamon test kit
9. IS IT a Pregnancy test kit
10. Medrol pregnancy urine test strips [31].

CONCLUSION

Home pregnancy tests are the most popular diagnostic tests used at home and in a clinical environment. False negative or positive results could have significant repercussions, such as a young woman becoming pregnant without her consent. This is crucial for medical practitioners since they must be aware of the diagnostic potential, accuracy, and potential limitations of home pregnancy test to counsel patients appropriately. In the USA, stringent standards and definitions are in place to guarantee that all commercially available tests function satisfactorily. Assessment is carried out in Germany and other European nations by a notified organisation that has been granted accreditation by the relevant authorities of E.U. member states. In order to issue C.E. marking in line with the New Approach directives, notified organisations are capable of completing conformity assessments; however, these assessments are not based on standard definitions. Therefore, it would be especially appreciated if a set of standard definitions and testing standards were defined.

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Conflict of Interest

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