INTENDED USE

Quick & Clear II Pregnancy test is for the rapid qualitative determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. This test is for professional use.

SUMMARY & EXPLANATION

Human Chorionic Gonadotropin (hCG) is a glycoprotein hormone which is secreted by the developing placenta after fertilization.[1] The appearance and increased levels of hCG provide an excellent indicator of pregnancy. The hCG hormone doubles approximately every 2.2 days during the first trimester.[2] Detectable levels start at 5 mIU/mL during the first week of gestation and rise to 100,000 mIU/mL at 2 to 3 months. High risk terminations may be associated with a slow rise in hCG levels.[3] During the 2nd and 3rd trimester, hCG levels decline 10% to 15% from peak concentrations.[1]

PRINCIPLE OF THE TEST

Quick & Clear II Pregnancy test is a rapid qualitative test to detect the presence of hCG in urine. The test uses a membrane coated with anti-hCG antibodies in the Test Zone and anti-mouse antibodies in the Control Zone. As the test begins, the specimen mixes with the dye conjugate (anti-hCG) and then begins to migrate through the membrane. If hCG is present, it will react with the pre-coated antibodies in the Test Zone and form a colored line. Negative specimens will not react in the Test Zone. Both positive and negative specimens should form a colored line in the Control Zone which indicates proper procedural technique, specimen volume, and test performance.

PRECAUTIONS

1. Test devices should remain in the sealed pouch until ready for use.
2. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
3. The test device should be discarded in a proper biohazard container after testing.
4. Do not use test kit beyond the expiration date.

REAGENTS

Test device containing monoclonal hCG colored conjugate and polyclonal anti-hCG coated on a membrane.

STORAGE AND STABILITY

Store at room temperature (15° to 30°C). The test device must remain in the foil pouch until ready for use. Sealed pouches are good until the expiration date listed on the pouch.

SPECIMEN COLLECTION AND PREPARATION

Urine - Urine specimens should be collected in a clean, dry container. Randomly collected specimens can be used. However, the first morning urine generally contains the highest concentration of hCG. If urine samples exhibit visible precipitates, the specimen should be filtered, centrifuged, or allowed to settle to obtain clear aliquots.

Specimen Storage - Specimens may be refrigerated (2° - 8°C) and stored up to 72 hours prior to assay. If specimens are refrigerated, they must be brought to room temperature before testing. If testing is delayed more the 48 hours, the specimens should be frozen. Frozen specimens should be thawed and mixed before testing.

PROCEDURE

Materials Provided

Test Device
Disposable Specimen Dropper

Materials Required But Not Provided

Specimen collection device and container

Directions For Use

Allow specimen and/or controls to reach room temperature (15°C to 30°C) prior to testing.

1. Remove the test device from the sealed pouch and place it on a level, dry surface.
2. Dispense 3 drops (approx. 0.12mL) of the urine specimen into the sample well. Wait for colored lines to appear.
3. Read results after 3 minutes. Some positive results may be observed in 60 seconds or less depending on the concentration of hCG. Specimens containing levels of hCG below 20mIU/mL may show color development over time, therefore, do no read results after 10 minutes.

INTERPRETATION OF RESULTS

Negative Results

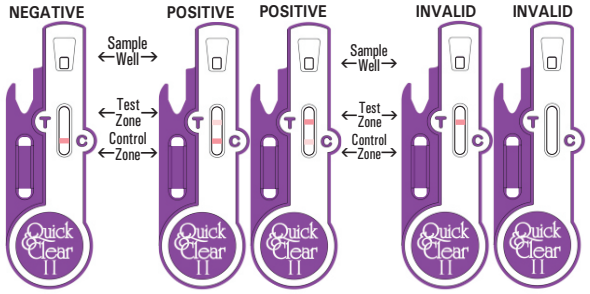
The test is negative if only one colored line appears in the Control Zone. This indicates the absence of detectable levels of hCG.

Positive Results

The test is positive if two colored lines appear. One colored line will appear in the Test Zone and one in the Control Zone. This indicates the specimen contains detectable levels of hCG. Any colored line in the Test Zone should be considered positive. Specimens containing levels of hCG below 20 mIU/mL may show color development over time. The colored line in the Control Zone may be lighter or darker in color than the line in the Test Zone.

Invalid Results

The test is invalid if a colored line fails to appear in the Control Zone, even if a colored line appears in the Test Zone. If this occurs, add 2 additional drops of specimen and wait 3 minutes. If a colored line still does not appear in the Control Zone, the test is invalid and should be repeated with a new test device.



QUALITY CONTROL

Each test device includes an internal procedural control in the Control Zone. Both positive and negative specimens should form a colored line in the Control Zone which indicates proper procedural technique, specimen volume, and test performance. Refer to your Standard Operating Procedure and/or Quality Assurance Plan for all other quality control requirements.

LIMITATIONS

1. A number of conditions other than pregnancy may produce elevated levels of hCG such as trophoblastic disease, choriocarcinoma, embryonal cell carcinoma, Islet cell tumors, and other carcinomas.[4]
2. If urine specimens are too dilute, false negative results may occur due to low levels of hCG below the sensitivity of the test. If pregnancy is still suspected, a first morning urine should be collected 48 hours later and tested.
3. False positive results may be due to detectable levels of hCG remaining several weeks after a normal pregnancy, delivery by cesarian section, spontaneous or therapeutic terminations.[5]
4. Very low levels of hCG may be found in ectopic pregnancies[6] and additional testing may be necessary using a quantitative assay.
5. Natural termination occurs in 22% of clinically unrecognizable pregnancies, and 31% of pregnancies overall.[7] This may produce positive results when testing early in the pregnancy followed by negative results after the natural termination. In cases exhibiting weak positive results, it is good laboratory practice to confirm results by retesting with a first morning urine 48 hours later.
6. All clinical and laboratory findings should be evaluated before making a definitive diagnosis.

EXPECTED VALUES

Urine specimens from healthy men and healthy non-pregnant women should not contain detectable levels of hCG. Healthy pregnant women should have hCG present. The amount will vary greatly with gestational age and between patients. First morning urine specimens approximate serum hCG levels which reach 5 to 50 mIU/mL within 1 week of gestational age.[2] Quick & Clear II Pregnancy test can detect pregnancy as early as 1 day after a missed menses. Since levels of 20 mIU/mL of hCG have been observed as early as 3 to 4 days after implantation, hCG may be detected before a first missed menses.[8]

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using Quick & 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 & Clear II Pregnancy test and the other commercially available test.

Sensitivity and Specificity

Quick & Clear II Pregnancy test detects hCG concentrations of 20 mIU/mL and greater. Specimens containing less than 20 mIU/mL of hCG may also test positive. Suspected low hCG levels should be evaluated considering all possible clinical conditions associated with low hCG levels. The test has been standardized to the World Health Organization 3rd International Standard. The addition of LH (300 mIU/mL), FSH (1000 mIU/mL) and TSH (1000 µIU/mL) to negative and positive urine specimens showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive samples. None of the substances at the concentration tested interfered in the assay.

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Glucose	2 g/dL
Atropine	20 mg/dL	Hemoglobin	1 mg/dL

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Quick & Clear II

Pregnancy Test

For the Rapid Qualitative Determination
Of Human Chorionic Gonadotropin (hCG)
in Urine

One-Step format with built-in quality control check
Add 3 drops of the specimen and see results
in 3 minutes
Sensitive to 20 mIU/mL of hCG
Room Temperature Storage

In Vitro Diagnostic Medical Device

Temperature Limitation:
15° to 30°C (59° to 86°F)

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