



CLARITY 2000 MIU Pregnancy Test (Cassette)

One step assay
Instant visual results
Accurate detection
For in vitro qualitative diagnostic use

INTENDED USE

The **CLARITY 2000 MIU Pregnancy Test** is a qualitative immunoassay for the detection of HCG in urine.

SUMMARY AND EXPLANATION OF THE TEST

This pregnancy test is based on the detection of the human chorionic gonadotropin (hCG) in urine. HCG is a hormone produced by the placenta. In normal subjects, hCG in urine and serum provides an early indication of pregnancy. The 2000 MIU Pregnancy Test uses a mouse monoclonal antibody specific to hCG in a one-step lateral flow chromatographic immunoassay to instantly and accurately detect hCG at the level close to or greater than 2000 mIU/ml.

PRINCIPLE OF THE PROCEDURE

This assay is a one-step lateral flow chromatographic immunoassay. The test strip in the device consists of a conjugate pad containing mouse monoclonal anti-hCG antibody conjugated to Colloidal Gold, and a nitrocellulose membrane strip containing a test line (T line) and a control line (C line).

EXPECTED VALUES

This test is capable of detecting hCG at a level of 2000 mIU/ml. In normal subjects, hCG in urine and serum provides an early indication of pregnancy. In a 28-day cycle with ovulation occurring at day 14 hCG can be detected in urine and serum in minute quantities around day 23, or 5 days before the expected menstruation. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period with a mean concentration of 50,000 mIU/ml. Concentrations as high as 100,000 mIU/ml have been reported in normal pregnancies during the first trimester.

REAGENTS AND MATERIALS SUPPLIED

1. Test Device and Dropper pipette sealed in foil pouch
2. Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection container
2. Timer or watch

STORAGE AND STABILITY

Store the kit at room temperature (2-25°C). Kit contents are stable for at least 18 months or until the date printed on the label, whichever comes first.

Do not freeze the kit as this may cause malfunction of the kit.

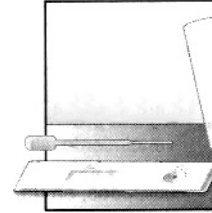
Exposing the kit to the temperatures over 30°C will reduce the shelf life of the kit. For example, one week at 45°C will reduce the shelf life of the kit by 10 weeks.

SPECIMEN COLLECTION

1. Urine specimen may be collected in a clean container. No centrifugation or filtration of urine is required.
2. Serum specimen may be collected following standard clinical procedure.
3. Specimens may be kept at room temperature for 2 hours, if specimens cannot be tested after collection, they should be stored refrigerated at 2-8°C for use to 3 days and at -20°C or lower. Do not mix specimens.

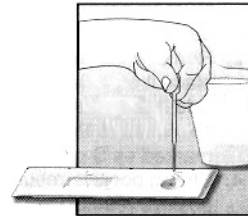
PRECAUTION

1. Do not open the sealed pouch, unless ready to operate the assay.
2. Do not use expired kit.
3. Dispose of all specimens and used assay materials in a proper biohazard container.
4. The instructions must be followed to obtain accurate results.



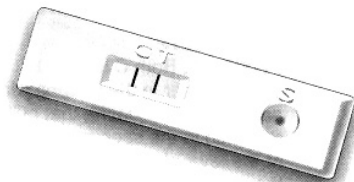
ASSAY PROCEDURE

1. Refrigerated specimens or other materials must be equilibrated to room temperature before testing.
2. Remove the test device from pouch and place it on a flat surface.
3. Add 3 drops (about 100µl) of the specimen to the sample well marked as S on the device.
4. Strong positive results may be observed in 2-3 minutes. Weak positive results may take longer time, up to 5 minutes. Do not interpret the results after 10 minutes.



INTERPRETATION OF RESULTS

1. **POSITIVE:** Both C line and T line appear in the viewing window accordingly, indicating the hCG is detected in the specimen at the level close to or higher than 2000 mIU/ml.
2. **NEGATIVE:** Only one line, the C line, appears in the control region, indicating that there is no hCG detected in the specimen and the result is negative. If pregnancy is suspected, repeat the test after 2 or 3 days with new devices and fresh samples.
3. **INVALID:** No band visible in the control region within 5 minutes. Repeat the assay with a new test device.



+ (Positive)



OVERALL ACCURACY

The overall accuracy is ≥ 99%

SENSITIVITY

The sensitivity is 2000 mIU/ml.

SPECIFICITY

The specificity is 100%

QUALITY CONTROL

INTERNAL QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

EXTERNAL QUALITY CONTROL

In addition to your laboratory's standard quality control procedures, it is recommended that a positive and negative external control be tested once within each box.

LIMITATIONS

1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
2. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. A number of conditions other than pregnancy, including trophoblastic disease, ectopic pregnancy or molar pregnancy and certain non-trophoblastic neoplasms cause elevated levels of hCG. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

REFERENCES

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