PregaScreen™

Preganancy Detection Kit

Mylab Discovery solutions

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INTENDED USE

Pregnancy Detection Kit is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in human urine to aid in the early detection of pregnancy. This test provides a presumptive diagnosis for pregnancy.

MATERIALS PROVIDED

Dropper Model / For Mini Model

1 Test/Kit: 1xTest Card; 1xSample Dropper

2 Tests/Kit: 2xTest Cards; 2xSample Droppers

3 Tests/Kit : 3XTest Cards; 3XSample Droppers

5 Tests/Kit: 5xTest Cards; 5xSample Droppers

Material Required but Not Provided -
Specimen collection container, Timer

Midstream Model

1 Test/Kit: 1xTest Card

2 Tests/Kit: 2xTest Cards

3 Tests/Kit : 3xTest Cards

5 Tests/Kit: 5xTest Cards

Material Required but Not Provided-Timer

Dipstick Model

1 Test/Kit : 1x Dipstick

2 Tests/Kit : 2x Dipsticks

3Tests/Kit : 3x Dipsticks

5 Tests/Kit : 5x Dipsticks

Material Required but Not Provided-Specimen collection container, Time

PRECAUTIONS

1. Please read all the information in this insert before performing the test.
2. For the qualitative detection of human Chorionic Gonadotropin (hCG) in human urine.
3. The test should remain in the sealed pouch or closed canister until ready to use.
4. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
5. The used test should be discarded according to local regulations.

STORAGE

Store as packaged in the sealed pouch at 2°C-30°C. Do not freeze. Do not use beyond the expiration date.

SPECIMEN COLLECTION

Dropper Model / Mini Model / Dipstick Model

The urine must be collected in a clean, dry plastic or glass container. The first morning urine is preferred since it generally contains the highest concentration of hCG. However, urine collected at any time of day may be used. Urine samples exhibiting visible precipitates should be centrifuged, or allowed to settle to obtain clear supernatant for testing. Urine may be stored at 2-8 ºC for up to 48 hours prior to assay. Urine containing excessive bacterial contamination should not be used as this may cause spurious results.

Midstream Model

Sample collection is not required. The test is to performed immediately on midstream urine.

DIRECTIONS FOR USE

General

1. Read the entire procedure carefully prior to performing the tests.
2. Allow the test card, urine to equilibrate to room temperature prior to testing.

For Dropper Model / For Mini Model

1. Remove the test card from the sealed pouch and use it as soon as possible but within 30 min after removal from pouch, especially if the room temperature is more than 30°C and in high humidity environment.
2. Place the test card on a clean and level surface. Hold the dropper vertically and transfer 2 full drops of urine to the specimen window (S) of the test card, and then start the timer.
3. Avoid trapping air bubbles in the specimen window (S). Wait for colored bands to appear. Interpret the result within 5 minutes. Do not interpret results after 10 minutes.

For Midstream Model

1. Remove the test card from the sealed pouch and use it as soon as possible but within 30 min after removal from pouch, especially if the room temperature is more than 30°C and in high humidity environment.
2. Remove the Cap and turn around the midstream to show the Absorbent Tip. Hold the card by the Thumb Grip with the exposed absorbent tip pointing downward. Urinate on the absorbent tip directly till it is thoroughly wet (at least 5 seconds). Be careful and do not urinate in the result Window.
3. Re-cap the test card and lay it on a flat surface with window side up. Wait for pink-colored lines to appear. Read results within 5 minutes. Do not read results after 10 minutes.

For Dipstick Model

1. Remove the dipstick from the sealed pouch and use it as soon as possible but within 30 min after removal from pouch, especially if the room temperature is more than 30°C and in high humidity environment.
2. Place the container containing urine specimen on a flat surface, then with arrows pointing toward the urine specimen, immerse the dipstick vertically in the urine specimen for at least 5-10 seconds. Do not pass the maximum line on the dipstick when immersing the strip.
3. Place the dipstick on a non-absorbent flat surface , start the timer. Read results within 5 minutes. Do not read results after 10 minutes.

READING THE TEST RESULTS

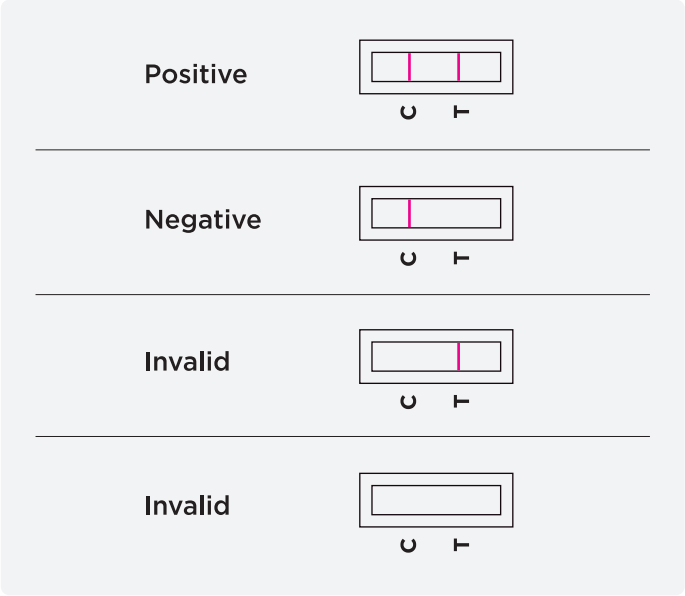
Negative:
Only one colored line appears in the Control region (C) showing negative for hCG.

Positive:
In addition to the colored line in the control region (C) a clearly colored line also appears in the test region (T) indicating a positive result and that the sample contains hCG.

Invalid:
If no colored line appears in the control region (C) & appears in test region (T), indicating a invalid result and the test should be repeated with new test card.

Invalid:

If no colored line appears in the control region (C) & test region (T), indicating a invalid result and the test should be repeated with new test card.



QUALITY CONTROL

A procedural control is included in the test. A red coloured line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance when a new shipment of test cards is received.

LIMITATION

1. This test is a qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. Very dilute urine specimens as indicated by low specific gravity may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be obtained 48-72 hours later and tested.
3. 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
4. Very low levels of hCG (less than 50m IU/ml) are present in urine 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 interpreted in conjunction with other clinical and laboratory data.
5. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine as determined by using this kit should not be used to diagnose pregnancy unless these conditions have been ruled out.
6. 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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3. Steier JA, P Bergsjo, OL Myking Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy, Obstet. Gynecol. 1984; 64(3): 391-394
4. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade "Serum human chorionic gonadotropin levels throughout normal pregnancy", Am. J. Obstet. Gynecol. 1976; 126(6): 678-681
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GLOSSARY OF SYMBOL

IVD	*In Vitro* Diagnostic Use		Manufacturer		Manufacturing Date		Expiry Date	LOT	LOT Number	30°C 86°F 2°C 36°F	Store at 2°C to 30°C
	Single Use	Σ	Number of tests in the pack		Do not use if pouch or kit damaged		Caution		Read package insert before use		
REF	Catalogue Number		Keep Dry		Keep away from sunlight						

Mylab Discovery solutions

Mylab Discovery Solutions PVT. LTD.
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