

CLIA CATEGORIZATION: WAIVED

Dealmed HCG Pregnancy Test Strip is a rapid, one step test for the detection of human chorionic gonadotropin (hCG) in urine.

It is intended for prescription use only.

For *in vitro* diagnostic use.

INTENDED USE

Dealmed HCG Pregnancy Test Strip is a rapid pregnancy test. It detects the presence of human chorionic gonadotropin (hCG) at the concentration of 25 mIU/mL or above. hCG is a marker for pregnancy which appears in urine very early during pregnancy.

PRINCIPLE

Human Chorionic Gonadotropin (hCG) is one of the glycoproteins secreted by the placenta. It contains α - and β -subunits. The α -subunit of hCG shows cross-reactions with hLH, hTSH and hFSH because of similarities in the amino acid sequences. However, the β -subunit of hCG is specific and shows the lowest cross reactions in assays. The antibodies, which were used before in hCG detection, were directed against the whole hCG molecule, and therefore regularly presented cross reactions with hLH, hTSH and hFSH. Dealmed HCG Pregnancy Test Strip is aimed to be the hCG specific test by using a monoclonal antibody against highly purified β -hCG.

The kit is a rapid qualitative assay and based on the principle of double antibodies sandwich immunoassay for determination of hCG in urine. When the strip is immersed to a urine sample, the urine migrates upward by chromatographic, hCG will be captured by β -hCG monoclonal antibody in sample pad and then meet α -hCG monoclonal antibody on the T line and anti-mouse IgG on the C line coated in the membrane. If the hCG is at or above 25 mIU/mL, red bands will be appeared both in T line and C line which indicates positive result; If the hCG is zero or below 25 mIU/mL, no red band will appear in the T line, only a red band in C line which indicates negative result. To serve as a procedure control, a colored line will appear at the C line if the test has been performed properly.

REQUIRED MATERIAL

MATERIAL PROVIDED

1. One pouch containing a strip and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Package Insert.

MATERIAL NOT PROVIDED

1. A clean, dry, plastic or glass container to collect the urine.
2. Timer (watch or clock)

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test strip cannot be used more than once.
3. Do not use test kit beyond expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.

STORAGE AND STABILITY

1. Store at 39°F-86°F (4°C-30°C) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.
4. Preferably open the pouch only shortly before the test.

SPECIMEN COLLECTION AND PREPARATION

SPECIMEN COLLECTION

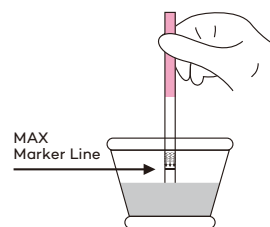
Any urine specimen is appropriate for pregnancy testing but the first morning urine specimen is optimal because of its highest concentration of hCG. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

SPECIMEN STORAGE

Urine specimens may be stored at 36°F-46°F (2°C-8°C) for up to 48 hours prior to testing. For longer storage, specimens may be frozen and stored below -4°F (-20°C). Frozen specimens should be thawed and mixed before testing.

DIRECTIONS FOR USE

1. The test strip and urine have to be at room temperature 65°F-86°F (18°C-30°C) for testing.
2. Remove the test strip from the sealed pouch.
3. Immerse the strip into the urine with the arrow pointing towards the urine. Take the strip out after 5 seconds and lay the strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).
IMPORTANT: Do not allow the urine level to exceed the MAX Marker Line, otherwise the test will not perform correctly.
4. Read results in 3-5 minutes. **Do not read results after 5 minutes.**



INTERPRETATION OF RESULTS

(Please refer to the illustration below)

Negative (Not Pregnant):

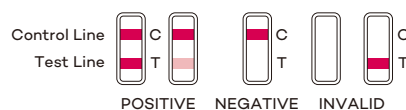
Only one colored band appears in the Control Zone (C). No apparent band in the Test Zone (T). This indicates that no pregnancy has been detected.

Positive (Pregnant):

Distinct colored bands appear in the Control and Test Zones. It indicates that hCG at the concentration of 25 mIU/mL or above has been detected. The color intensity of the test bands may vary since different stages of pregnancy have different concentrations of hCG hormone.

Invalid:

No visible band at all, or there is a visible band only in the Test Zone (T) and not in the Control Zone (C). Repeat with a new test kit. If test still fails, please contact the distributor where you purchased the product with the lot number.



NOTE: If the color in the Test Zone (T) is weak, it is recommended that repeat the test in 48 hours.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the Control Zone (C) is the internal procedural control if the proper testing procedure is followed. 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.

A positive hCG control (containing 25- 250 mIU/mL hCG) and a negative hCG control (containing 0 mIU/mL hCG) may be evaluated to verify proper test performance.

LIMITATIONS

- As it is with any diagnostic procedure, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
- If a urine sample is too dilute (ie, low specific gravity), it may not contain the representative level of hCG. If pregnancy is still suspected, another urine specimen should be collected 48 hours later and tested.
- Low concentration of hCG in a very early pregnancy can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
- Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
- A normal pregnancy can not be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
- Sterility treatments, based on hCG may cause false results. Consult the physician.
- When hCG is very high, it may present a negative result because of hook effect. Diluting the sample is necessary in this situation.

EXPECTED RESULTS

Negative results are expected in healthy non-pregnant women and healthy men. Although the hCG levels in normal early pregnant women are variable, Dealmed HCG Pregnancy Test Strip is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

ACCURACY

The result from Dealmed HCG Pregnancy Test Strip is compared with that from a commercially available hCG urine pregnancy test. Among 619 urine specimens, both assays identified 375 negative and 244 positive results. In the study, Dealmed HCG Pregnancy Test Strip showed > 99.5% overall agreement when compared with other hCG urine pregnancy test.

REFERENCE HCG METHOD

		Dealmed HCG Pregnancy Test Strip		
		+	-	Total
Comparison Test	+	243	1	244
	-	1	374	375
	Total	244	375	619

Agreement of the positive with comparison test: >99.5 %
 Agreement of the negative with comparison test: > 99.5%
 Total agreement with comparison test: > 99.5%

SENSITIVITY AND SPECIFICITY

The test limit of Dealmed HCG Pregnancy Test Strip is 25 mIU/mL or greater. The test has been standardized to the W.H.O. Standard. No cross reaction appears when hLH (300 mIU/mL), hFSH (300 mIU/mL) and hTSH (1,000 mIU/mL) were added to the negative specimen (0 mIU/mL hCG).

Results	Positive Results	Negative Results	Total Number of Standard
Concentration (mIU/mL)	+	-	
0	0	5	5
12.5	0	5	5
18.75	0	5	5
25	29	1	30
50	10	0	10
100	5	0	5

INTERFERING SUBSTANCES

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20 mg/dL	Centesic acid	20 mg/dL
Acetylsalicylic acid	20 mg/dL	Glucose	2 g/dL
Ascorbic acid	20 mg/dL	Hemoglobin	20 mg/dL
Atropine	20 mg/dL	Tetracycline	20 mg/dL
Caffeine	20 mg/dL	Ampicilline	20 mg/dL
Albumin	20 mg/mL		

None of the substances at the concentration tested interfered in the assay.

LINEARITY/ASSAY REPORTABLE RANGE

Considering a hook effect in immunoassay, we investigate hCG assay range. Spiking high hCG concentration solution to negative urines from female or male, the concentration of hCG is from 500 IU/mL to 10 mIU/mL in spiked samples, each sample is tested repeatedly.

hCG Concentration	Test Result
hCG 10 mIU/mL	-
hCG 15 mIU/mL	-
hCG 20 mIU/mL	-/+
hCG 25 mIU/mL	+
hCG 100 mIU/mL	++
hCG 500 mIU/mL	+++
hCG 1000 mIU/mL	+++
hCG 5 IU/mL	++
hCG 25 IU/mL	+
hCG 100 IU/mL	+
hCG 200 IU/mL	-/+
hCG 500 IU/mL	-

The result showed the test can detect the hCG concentration at range 25 mIU/mL—100 IU/mL. If hCG level is above 100 IU/mL, a hook effect may be observed.

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MEANING OF SYMBOLS ON PACKAGE

	Keep away from sunlight		Temperature limit		Keep dry
	Do not re-use		Batch code		Use-by date
	In vitro diagnostic medical device		Consult instructions for use		Contains sufficient for <n> tests

MANUFACTURED FOR:

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