



HORMONELife™

Pregnancy Test Cassette Rx

Cat. No.: See Box Label

CLIA CATEGORIZATION: WAIVED

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

For *in vitro* diagnostic use only. It is intended for prescription use.

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 and hTSH and hFSH. HORMONELife™ Pregnancy Test Cassette Rx is aimed to be a hCG specific test by using a monoclonal antibody against highly purified β -hCG.

HORMONELife™ Pregnancy Test Cassette Rx is a rapid qualitative assay and based on the principle of double antibodies sandwich immunoassay for determination of hCG in urine. When the urine sample is added to the sample well, 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 Test Zone (T) and anti-mouse IgG on the Control Zone (C) coated in the membrane. If the hCG is at or above 25 mIU/mL, colored bands will appear both in Test Zone (T) and Control Zone (C) which indicates positive result. If the hCG is zero or below 25 mIU/mL, no colored band will appear in the Test Zone (T), only a colored band in Control Zone (C) which indicates negative result. To serve as a procedure control, a colored band will appear in the Control Zone (C) if the test has been performed properly.

REQUIRED MATERIAL

MATERIALS PROVIDED

1. HORMONELife™ Pregnancy Test Cassette Rx (s), each in one pouch with a dropper and desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Package Insert

MATERIALS NOT PROVIDED

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

PRECAUTIONS

1. The test kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use the test kit beyond expiration date.
4. Do not use the test 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

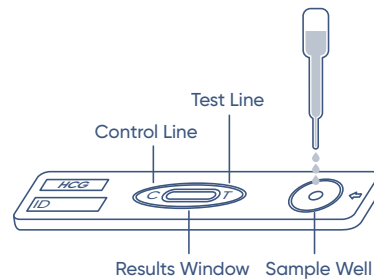
Any urine specimen is appropriate for testing but the first morning urine specimen is optimal because of its highest concentration of hCG. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing. Urine specimens may be collected in any clean, dry, plastic or glass container.

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 cassette and urine have to be at room temperature 64°F–86°F (18°C–30°C) for testing.
2. Remove the cassette from the foil pouch by tearing at the notch and place it on a level surface.
3. Holding a sample dropper vertically, add exactly four drops of the urine specimen to the sample well (with an arrow marked).
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):

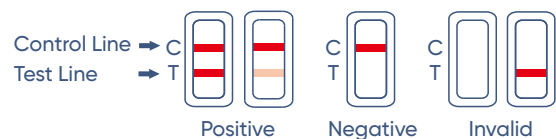
Only one colored band appears in the Control Zone (C). No apparent band in the Test Zone (T). This indicates that no pregnancy has been detected.

Positive (Pregnant):

Distinct colored bands appear in the Control and Test Zones. It indicates that pregnancy has been detected. The color intensity of the test bands may vary since different stages of pregnancy have different concentrations of hCG.

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. If test still fails, please contact the distributor from whom you purchased the product with the lot number.



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

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band 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 will 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

1. 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.
2. If the 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.
3. 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.
4. 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.
5. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
6. Sterility treatments based on hCG may cause false results. Consult your physician.
7. When hCG level is very high, it may present a negative result because of the 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, HORMONELife™ Pregnancy Test Cassette Rx is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy

The performance of HORMONELife™ Pregnancy Test Cassette Rx is compared with a commercially available hCG competitive test. Among 619 urine specimens, both assays identified 375 negative and 244 positive results. In the study, HORMONELife™ Pregnancy Test Cassette Rx showed > 99.5% overall agreement when compared with the competitive test.

Competitive Test	HORMONELife™ Pregnancy Test Cassette Rx		
	+	-	Total
+	244	0	244
-	0	375	375
Total	244	375	619

Positive Percent Agreement: > 99.5 %

Negative Percent Agreement: > 99.5%

Overall Percent Agreement: > 99.5%

Sensitivity and Specificity

The test limit of HORMONELife™ Pregnancy Test Cassette Rx 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 µIU/mL) were added to the negative (0 mIU/mL hCG).

Results Concentration (mIU/mL)	Positive Results	Negative Results	Total Number of Standard
	+	-	
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. None of the substances at the concentration tested interfered with the assay.

Acetaminophen	20 mg/dL	Gentisic 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/dL		

LINEARITY/ASSAY REPORTABLE RANGE

Considering the hook effect in immunoassay, we investigate hCG assay range. Spiking high hCG concentration solution to negative urines from female or male, in spited samples, 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 hCG concentration at range 25 mIU/mL–100 IU/mL. If hCG level is above 100 IU/mL, the hook effect may be observed.

BIBLIOGRAPHY

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ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll-Free Number 1-888-444-3657 (9:00 a.m. to 5:30 p.m. CDT M-F). or reach out to us via our website:



www.hormonellife.com

MEANING OF SYMBOLS ON PACKAGE



Keep away from sunlight



Store between 39°F–86°F (4°C–30°C)



Keep dry



Do not re-use



Consult instructions for use



In vitro diagnostic medical device

Distributed by Wondfo USA Co., Ltd.

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Made in China

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物料编码: 13029886 项目名称: HCG尿卡说明书Rx(210x285mm)美国HORMONElife

尺寸(长*宽*高): 210x285mm 颜色:  C83M100K44  C76M56Y20K29 材质: 80g双铜 工艺:

折页方式: 长边风琴2折3页+左右对折 修改内容: ☐文字 ☐颜色 ☐尺寸 ☐工艺 ☐材质 ☐其他 ☐无

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