HORMONElife™

Early Result
Pregnancy Test Strip Rx

Catalogue No. See Box Label

INTENDED USE

HORMONElife™ Early Result Pregnancy Test Strip Rx is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your physician.

All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

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

PRINCIPLE

HORMONElife™ Early Result Pregnancy Test Strip Rx is a rapid qualitative assay and based on the principle of double antibodies sandwich immunoassay for determination of specific concentration of hCG in urine. When the absorbent end of strip is immersed into a urine specimen, the urine will be introduced into the chromatographic membrane. The hCG will be captured by β - hCG monoclonal antibody in sample pad. As the conjugate moves forward on the membrane, it will attach to the α - hCG Monoclonal antibody in the Test Zone (T), and form the colored band. Any specimen with the test will result in the colored band to appear in the Control Zone (C). This band is formed by the binding of the polyclonal antibodies (Anti-mouse IgG) and the sample-colloidal gold conjugate. Presence of this band indicates that the test has been performed correctly.

REQUIRED MATERIAL

Material Provided

1. HORMONElife™ Early Result Pregnancy Test Strip Rx (s), each in one pouch with desiccant. The desiccant is for storage purposes only and is not used in the test procedures.
2. One (1) Package Insert

Material Not Provided

1. A clean, dry, plastic or glass container to collect the urine. (Optional)
2. Timer (Watch or Clock)

PRECAUTIONS

1. The test kit is for external use only. Do not swallow.
2. Single-use device. Do not reuse.
3. Do not use the 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. Please perform the test as soon as possible after opening the pouch.

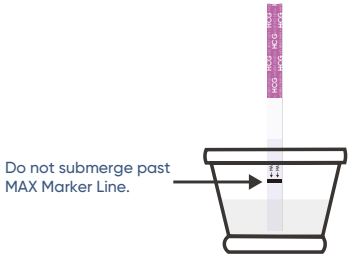
SPECIMEN COLLECTION AND PREPARATION

Specimen Collection
Any urine specimen is appropriate for pregnancy test. 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 be settled to obtain a clear specimen for testing.

Specimen Storage
Urine specimens can 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 should be at room temperature 59°F~86°F (15°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 until the dye rises and lay the strip flat on a clean, dry, non-absorbent surface.
   IMPORTANT: Do not allow the urine level to exceed the MAX Marker Line, otherwise the test will not perform correctly.
4. The complete reaction time of 5 minutes is required. Read results at 5 minutes. **Do not read results after more than 10 minutes.**

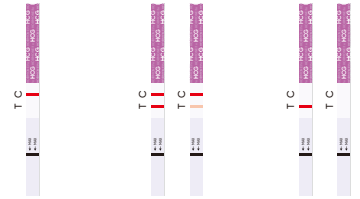


INTERPRETATION OF RESULTS

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 you are pregnant. The color intensity of the test lines may vary since there are different concentrations of hCG hormone in different stages of pregnancy.

Invalid:
There is a visible colored band only in the Test Zone (T) or no any visible colored band in both zones. Repeat with a new test. If test still fails, please contact the distributor with the lot number.



Negative (Not Pregnant) | **Positive** (Pregnant) | **Invalid**

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.

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. Dilute urine samples (i.e. with low specific gravity) may not contain a representative level of hCG, potentially leading to a false negative result. If pregnancy is still suspected, an early morning urine sample (first) should be collected 48 hours later and tested.
3. In very early pregnancy, false negative results may occur when the level of hCG is below the sensitivity level of the test. If pregnancy is suspected, an early morning (first) urine sample should be collected and retested 48 hours later.
4. A significant number of first trimester pregnancies terminate for natural reasons. It is recommended that weakly positive test results should be confirmed by retesting an early morning (first) urine sample 48 hours later.
5. Elevated levels of hCG can be caused by a number of conditions other than pregnancy, such as trophoblastic disease and some non-trophoblastic neoplasms. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
6. Ectopic pregnancies typically produce lower levels of hCG than normal pregnancies. Consult physicians when ectopic pregnancy is suspected.
7. Any medical procedure which involves hCG, such as fertility treatments, may cause false results. Consult physicians.
8. When the concentration of hCG is very high, it may present a negative result because of hook effect. So diluted sample is necessary in this situation.
9. When hCG β -core fragment is at greater than 250,000 pmol/L, it may interfere the test.

PERFORMANCE CHRATERISTIC

Accuracy
100 urine samples were tested with HORMONElife™ Early Result Pregnancy Test Strip Rx and predicate device. Each sample was tested by three professionals with three lots of devices.

HORMONElife™ Device Viewer A-Lot I	Predicate device	+	-
	+	49	0
	-	0	51
HORMONElife™ Device Viewer A-Lot II	Predicate device	+	-
	+	49	0
	-	0	51
HORMONElife™ Device Viewer A-Lot III	Predicate device	+	-
	+	49	0
	-	0	51

HORMONElife™ Device Viewer B-Lot I	Predicate device	+	-
	+	49	0
	-	0	51
HORMONElife™ Device Viewer B-Lot II	Predicate device	+	-
	+	49	0
	-	0	51
HORMONElife™ Device Viewer B-Lot III	Predicate device	+	-
	+	49	0
	-	0	51

HORMONElife™ Device Viewer C-Lot I	Predicate device	+	-
	+	49	0
	-	0	51
HORMONElife™ Device Viewer C-Lot II	Predicate device	+	-
	+	49	0
	-	0	51
HORMONElife™ Device Viewer C-Lot III	Predicate device	+	-
	+	49	0
	-	0	51

According to the results of the above tables, the total conformity rate is 100%.

Sensitivity

Urine standards containing intact hCG at concentrations of 0, 5, 7.5, 8, 9, 10, 15, 20 mIU/mL were tested with the devices. The results demonstrated that the cutoff of the device is 8 mIU/mL and the analytical sensitivity of the device is 10 mIU/mL.

Concentration (mIU/mL) \ Results	Positive results +	Negative results -	Total number of standard
0	0	60	60
5	0	60	60
7.5	18	42	60
8	30	30	60
9	53	7	60
10	60	0	60
15	60	0	60
20	60	0	60

Specificity and Cross Reactivity

To evaluate cross-reactivity, negative and positive urine samples (0 mIU/mL hCG and 10 mIU/mL hCG) were spiked with various concentrations of potential cross reactants. The reactants show no cross reactivity at the following concentrations.

Reactant	Concentration
hLH	500 mIU/mL
hFSH	1,000 mIU/mL
hTSH	1,000 μIU/mL
hCGβ-core fragment	250,000 pmol/L

False Positive Rate Study

In this study, 300 non-pregnant females tested their own urine samples using HORMONElife™ Early Result Pregnancy Test Strip Rx. The obtained results show that the test strip yields 0.3% false positive results.

Group \ Lot	I	II	III
Pre-menopasual	0+/34-	0+33-	0+/33-
Peri-menopasual	1+*/32-	0+/34-	0+/33-
Post-menopasual	0+/33-	0+/33-	0+/34-

*This result was from a 49-year-old woman. The ultrasound scan showed non pregnancy.

Early Pregnancy Test Study

In this study, total 585 urine samples from 65 characterized cycle segments of conceptive cycles were collected from 65 pregnant women. All samples were tested and the following table is the summary of the data.

Day relative to EMP	# of cycles positive for hCG	% cycles positive for hCG
EMP	65/65	100%
EMP-1	65/65	100%
EMP-2	64/65	98%
EMP-3	63/65	97%
EMP-4	58/65	89%
EMP-5	44/65	68%
EMP-6	25/65	38%
EMP-7	9/65	14%
EMP-8	4/65	6%

Precision

Negative samples were spiked with varying hCG concentrations: 0, 2.5, 5, 7.5, 8, 10, 15, 20, 25, 50mIU/mL. The above samples were tested in replicates of 10 by three operators with three batches of HORMONElife™ Early Result Pregnancy Test Strip Rx in five consecutive days.

LOT \ Concentration (mIU/mL)	0	2.5	5	7.5	8	10	15	20	25	50
Lot I	50-/0+	50-/0+	50-/0+	36-/14+	24-/26+	0-/50+	0-/50+	0-/50+	0-/50+	0-/50+
Lot II	50-/0+	50-/0+	50-/0+	35-/15+	25-/25+	0-/50+	0-/50+	0-/50+	0-/50+	0-/50+
Lot III	50-/0+	50-/0+	50-/0+	36-/14+	24-/26+	0-/50+	0-/50+	0-/50+	0-/50+	0-/50+

Effect of Urinary Specific Gravity

Urine samples with density ranges (1.000-1.035) were collected and spiked with hCG at 0mIU/mL, 10mIU/mL and 100mIU/mL. Each sample was tested with three batches of HORMONElife™ Early Result Pregnancy Test Strip Rx. The results demonstrate that changes in urinary specific gravity of 1.000 to 1.035 do not affect the test result.

Effect of Urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with hCG at 0 mIU/mL, 10 mIU/mL and 100 mIU/mL concentration. Each sample was tested by three batches of HORMONElife™ Early Result Pregnancy Test Strip Rx. The results demonstrate that changes in pH of 4 to 9 do not affect the test result.

Interfering Substance

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	B-hydroxybutyrate	2000 mg/dL
Ephedrine	20 mg/dL	Phenylpropanolamine	20 mg/dL
Phenothiazine	20 mg/dL	EDTA	80 mg/dL
Salicyclic Acid	20 mg/dL	Benzoylecgonine	10 mg/dL
Cannabinol	10 mg/dL	Codeine	6 ug/dL
Ethanol	1.0%	Bilirubin	2 mg/dL
Atropine	20 mg/dL	Pregnanediol	1500 ug/dL
Thiophene	20 mg/dL	Ketone	20 mg/dL

None of the above substances interfered with the assay.

Hook Effect/ Assay Reportable Range

Considering a hook effect in immunoassay, we investigate the assay range of the test device. Negative urine samples were spiked with varying hCG concentrations (6,250, 12,500, 25,000, 50,000, 100,000 and 200,000 mIU/mL). All tested concentrations gave a positive result. The spiked samples were tested by 3 different lots and 3 different operators. The results demonstrated that no hook effect was observed at hCG concentrations ranging from 6,250 to 200,000 mIU/mL.

ASSISTANCE

If you have any additional questions or concerns regarding 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.hormonelife.com

BIBLIOGRAPHY

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INDEX OF SYMBOLS

Keep away from sunlight	Store between 39°F-86°F (4°C-30°C)	Keep dry
Do not re-use	IVD *In vitro* diagnostic medical device	Consult instructions for use

Distributed by Wondfo USA Co., Ltd.
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Rel.: 2025/09/23

Wondfo 万孚	物料编码：13029213	项目名称：10mIU hCG条Rx说明书(210x285mm)美国HORMONElife		
	尺寸(长*宽*高)：285x210mm	颜色：C83M100K44 C76M56Y20K29	材质：80g双铜	工艺：
	折页方式：长边风琴2折3页+上下对折	修改内容：□文字 □颜色 □尺寸 □工艺 □材质 □其他 □无		
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