Pregnancy One Step Rapid Test (Cassette)
CLIA Waived

INTENDED USE

The Pregnancy One Step Rapid Test (Cassette) is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy. For professional use only.

SUMMARY AND EXPLANATION

Human chorionic gonadotropin(hCG) is a glycoprotein hormone produced in pregnancy that is made by the developing embryo after conception and later by the syncytiotrophoblast. In normal pregnancy, hCG can be detected in urine as early as 1-2 weeks after conception. hCG levels continue to rise very rapidly, usually exceeding 100 mIU/mL by the first missed menstrual period, and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. Early pregnancy testing, in general, is based on the detection or measurement of hCG. The Pregnancy One Step Rapid Test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. Positive specimens react with the specific antibody-hCG-colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. At the level of claimed sensitivity, the Pregnancy One Step Rapid Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE OF THE TEST

Human chorionic gonadotropin (hCG) is a hormone, produced by the developing placenta shortly after the conception and secreted into the urine. The pregnancy test contains antibodies which specifically react with this hormone.

When the strip is immersed into a urine specimen, capillary action carries the specimen to migrate along the membrane. When hCG in the sample reaches the Test Zone region of the membrane, it will form a colored line. Absence of this colored line suggests a negative result.

To serve as a procedure control, a colored line will appear at the control zone region, if the test has been performed properly.

MATERIALS SUPPLIED

1. Instructions for use.
2. Pregnancy Test pouches each containing a cassette, dropper, and desiccant. The desiccant is for storage purposes only and is not used in the test procedures.1Instructions for use.

REAGENTS

Coated Antibodies:Control region: Goat anti-mouse (IgG) polyclonal antibody
Test region: Mouse monoclonal anti-hCG antibody A
Labeled Antibodies:Colloidal gold conjugate of monoclonal anti-hCG antibody B

MATERIALS REQUIRED BU NOT PROVIDED

1. Clock or Timer 2. Specimen collection containers. 3. Latex gloves.

STORAGE

1. Store at 2ºC to 30ºC (35 - 86ºF) in the sealed pouch up to the expiration date. If stored in the refrigerator, allow to warm to room temp. before performing the test. The test can be stored at Room Temperature for up to 18 months or up to the expiration date listed on the label. Open the pouch just a few minutes before running the test.
2. Keep away from sunlight, moisture and heat. Do not use the kit if the pouch is punctured or is not well sealed.
3. **DO NOT FREEZE.** 4. Preferably open the pouch shortly before the test.

WARNINGS AND PRECAUTIONS

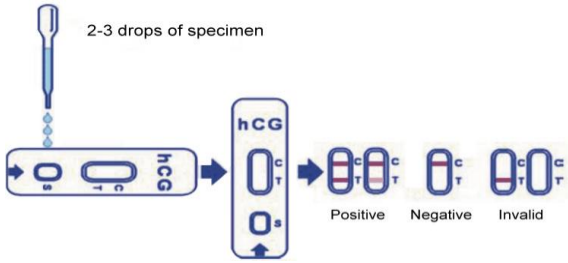
1. This test is designed for "*in vitro diagnostic*" use.
2. Read instructions carefully before using this test.
3. This kit is for external use only. Do not swallow.
4. Do not use the test kit beyond expiry date.
5. Do not use the kit if the pouch is punctured or is not well sealed.
6. Keep out of the reach of children.
7. Urine specimens may be infectious; Insure proper handing and discard all used devices according to the local regulations.
8. The test is for single use. Do not reuse it.

COLLECTION AND STORAGE OF SPECIMENS

Any urine specimen is appropriate for pregnancy testing but the first morning urine specimen is optimal because of its highest concentration of HCG. Urine should be collected in a clean container prior to testing.

ASSAY PROCEDURE

1. Remove a Testing Device and dropper from the foil pouch by tearing at the notch then place it on a level surface, and use it as soon as possible.
2. Holding a Sample Dropper vertically, add exactly 2-3 drops of urine specimen to the sample well marked S.



3. Do not read before 5 minutes or after 10 minutes.

Positive (Pregnant）Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). This means you are probably pregnant.

Negative (Not pregnant) One red line appears in the control region (C).No apparent red or pink line appears in the test region (T).This means you are probably not pregnant.

Invalid The result is invalid if no red line appears in the control region (C), even if a line appears in the test region (T). You should repeat the test with a new strip.

NOTE: *if the test line is weak, it is recommended that the test be repeated in 48 hours*

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is considered an internal procedural control. It confirms that the reagents are working properly, sufficient specimen volume was used, and correct procedural technique was used. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the result may be invalid.

It is recommended that commercially available assayed quality control materials are evaluated to verify proper test performance. The control materials should contain positive and negative controls, and the positive control should be appropriate for the cutoff (25 mIU/mL). Control materials should be the same matrix as the samples (urine). Use of patient samples as controls is not appropriate due to storage and stability.

It is recommended to perform quality control testing with each new lot, each new shipment, or every 3 months (depending which comes first).

If the test does not show any Control or Test line in the window or a smudged or partial line, the test should be discarded. Do not report the results. Run the test again with a new cassette and follow the procedure exactly. If the second test does not show lines, please contact Technical Services at (866) 982-3818(hours: 8 AM to 5 PM Central Time; Mon. - Fri.).

LIMITATIONS

1. You should not rely on results of pregnancy tests alone to determine clinical status.

2. If a urine sample is too dilute (ie, low specific gravity) it may not contain a 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. Certain health conditions, such as an ovarian cyst or ectopic pregnancy (pregnancy outside the uterus), can cause a false or irregular results.
6. Prescribed treatments containing hCG may cause false results.
7. The test is for early detection of pregnancy only.
8. Positive results from very early pregnancy may later prove negative due to natural termination of the pregnancy.
9. Elevated levels of hCG have been found in patients with gestational and non-gestational trophoblastic disease. Where appropriate, these conditions should be ruled out before a diagnosis of pregnancy is reached.
10. Abnormal pregnancy (e.g. ectopic) cannot be distinguished from normal pregnancy based on hCG measurements alone.
11. Negative results obtained before the time of the expected period may be false negative results.
12. Drugs which contain hCG (such as Pregnyl, Profasi, Pergonal, APL) can give a false positive result.

EXPECTED RESULTS

Negative results are expected in healthy non-pregnant women. Healthy pregnant women have hCG present in their urine specimens. The amount of hCG will vary greatly with gestational age and between individuals. The Pregnancy One Step Rapid Test can be used as early as the first day of the missed period. The Pregnancy One Step Rapid Test has a sensitivity of 25 mIU/mL.

PERFORMANCE CHARACTERISTICS

Detection limit:

The sensitivity of the device was tested by spiking 81 negative urine serum samples (from non-pregnant females or males) with varying concentrations (15, 20, 25, 30 and 35 mIU/mL) of hCG (Genway, Catalog: 20-783-70022). The result is traceable to the WHO International Standard 4th of HCG (25 mIU/mL). The test shows a cut-off of 25mIU/mL of HCG. Results are summarized below:

		Results	
		+	-
HGC concentration (mIU/mL)	15	0	81
	20	3	78
	25	37	44
	30	80	1
	35	81	0

Linearity/assay reportable range:

Hook effect was evaluated by spiking high hCG concentrations (50 IU/mL, 100 IU/mL, 200 IU/mL, 300 IU/mL and 500 IU/mL) into negative urine samples and evaluating the test result lines of 3 lots. Results indicate that for urine samples with HCG > 300 IU/mL, hook effect can be found.

Potential interference and cross reactors:

An interference study was carried out by adding known amounts of potential interfering substances to urine samples that contains 5 and 50 mIU/mL of hCG, and evaluated the test result lines. No interference was observed for the following compounds at the concentrations added:

Acetaminophen 21.16 mg/dL; Acetylsalicylic acid 64.8 mg/dL; Ascorbic acid 6340 µg/dL; Atropine 926.1 µg/dL; Caffeine 6214.4 µg/dL; Tetracycline 1777.6 µg/dL; Ampicillin 5.94 mg/dL; Bilirubin 18.71 mg/dL; Hemoglobin 2.0 g/L; Glucose 1000 mg/dL; and Protein 120 g/L and Albumin 60 g/L.

No cross-reactivity was observed for urine samples up to the following concentrations: LH (300 mIU/mL), FSH (500 mIU/mL), TSH (200 mIU/mL) and β-Core HCG (200 µg/mL).

Potential interfering factors of sample conditions and testing environment (sample pH, sample SG and testing temperature) were also evaluated. No influence was found in the studied range.

Reproducibility

Reproducibility of the device was evaluated by testing negative urine samples spiked with hCG (to 15 mIU/mL, 20 mIU/mL, 25 mIU/mL, 30 IU/mL and 35 IU/mL hCG) run 27 times within run with 3 lots of test strips (total N = 81). The results are summarized below:

		Site						Total	
		1		2		3			
		+	-	+	-	+	-	+	-
HGC concentration (mIU/mL)	15	0	27	0	27	0	27	0	81
	20	0	27	1	26	2	25	3	78
	25	11	16	13	14	13	14	37	44
	30	26	1	27	0	27	0	80	1
	35	27	0	27	0	27	0	81	0

Accuracy

A clinical trial was conducted in 3 sites, using specimens from one hundred and sixty-seven (167) women enrolled to participate in the study. The study was designed to demonstrate correlation between the Orient Gene Pregnancy One Step Rapid Test and another Home Pregnancy test. Study participants were asked to retain urine samples and provide them to the study coordinator. And they are divided into 5 panels based on their clinical situations:

Panel	Clinical situations	Number of Participants
A	Female patients not pregnant and at age of 18-40	30
B	Premenopausal patients not pregnant and at age of 40-55;	27
C	Patients suspected to be pregnant for missing of expected period.	56
D	Patients in very early pregnancy (0-30 days),	27
E	Pregnant patients in the first trimester (31-100days).	27

The study coordinator tested each sample using both the Orient Gene Pregnancy One Step Rapid Test and the predicate test.

		Predicate device		
		Positive	Negative	Total
Test device	Positive	72	1	73
	Negative	3	91	94
	Total	75	92	167

Agreement= (163/167)*100%= 97.6% (95% C.I. = 95%-100%)

The possible reasons of discrepant results may lie in the following aspects:

a. The concentrations of some specimens were around the cutoff and the colors of the test lines were light and vague, which lead to different result interpretation from different technicians;

Bibliography

1. L. A. Bastian, K. Nanda, V. Hasselblad, and D. L. Simel, Diagnostic Efficiency of Home Pregnancy Test Kits: A Meta-analysis. Arch Fam Med, September 1, 1998; 7(5): 465 - 469.

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