FAMWELL

HCG Pregnancy Rapid Combo Test

Instructions For Use

For *In Vitro* Diagnostic use only

R_x Only

REF 01PCTA0025 25 tests/box

Manufactured for Boston Easy Biotech, Inc

200 Brickstone Square, Suite 104, Andover, MA 01810

FAMWELL

Instructions for HCG Pregnancy Rapid Combo Test

Product Name

Famwell HCG Pregnancy Rapid Combo Test

Intended Use

Famwell HCG Pregnancy Rapid Combo Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum to aid in the early detection of pregnancy.

The test is for health care professionals use including professionals at point of care (POC).

Summary

Human Chorionic Gonadotropin (HCG) is a hormone produced by the trophoblastic tissue and it appears at around the 8-9th day after ovulation, or around the 4th day after conception. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period. In healthy females, HCG in serum or urine provides an early indication of pregnancy.

HCG consists of two subunits, alpha and beta. The alpha subunits of these various glycoprotein hormones are structurally very similar, but beta subunits differ in amino acid sequences. These differences are responsible for their biological and immunological specificity.

Principle

The kit is a double antibody sandwich immune-chromatographic assay that detects the presence of HCG in human serum or urine specimens. Anti β-HCG antibodies conjugated with colloidal gold is deposited on the conjugate pad, and Anti α-HCG antibodies are immobilized on the test line of the nitrocellulose membrane. When the specimen is applied, the gold-antibody conjugate is rehydrated and the HCG, if there is sufficient hCG in the specimen, interacts with the gold-conjugated antibodies. The antigen-antibody-gold complex then migrates towards the test window until the Test Zone (T) where it gets captured by immobilized antibodies, forming a visible red-purple line (Test line), indicating a positive result. If HCG is absent from the specimen, no red-purple line will be visible in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a red-purple control line in the Control Zone (C) indicates an invalid result.

Composition

Composition	Amount	Specification
IFU	1	/
Test cassette	25	Each sealed foil pouch containing one test device and one desiccant
Pipette	25	/

Materials required but not provided

•Specimen collection containers •Timer

Storage and Stability

Stored at 4℃~ 30℃ in a dry place and avoid direct sunlight. The shelf life is 24 months (see the label for the specific batch number and expiration date). Do not freeze.

Specimen Collection and Handling

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Serum

1. For serum specimen, collect blood in a tube without anticoagulant and allow it to clot.
2. Separate serum from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for long periods of time.
4. If specimens cannot be tested immediately, they may be stored at 2~8°C for up to 48 hours or 3 months at -20℃.

Urine

1. Any urine specimen is appropriate for HCG testing. However, urine specimens collected early in the morning are mostly recommended as the HCG concentration is the highest at that time.
2. Urine specimens may be collected in any clean and dry plastic or glass container (not provided).
3. If specimens cannot be assayed immediately, they may be stored at 2~8°C for up to 48 hours prior to testing.

Test Procedure

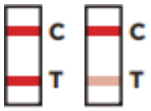
1. Please allow refrigerated or frozen specimens to equilibrate to room temperature before testing.
2. Remove the test device from the foil pouch by tearing at the notch. And place the test device on a flat surface.
3. Apply 3 drops (around 80μL) of specimen without air bubbles into the specimen well.
4. Read results at 5 minutes. Follow the instructions under the "Results Interpretation" section.
5. Some specimens may produce positive results in as fast as 1 minute. Do not read the result after 10 minutes.

NOTE: Do not read the result after 10 minutes. To avoid confusion, discard the test device after reading the results.

Results Interpretation

1. **Positive:** Two purple-red lines appearing at both test line (T) and control line (C) indicates positive result.

Positive

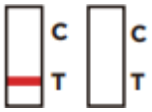


2. **Negative:** **Only one red line appears in the control region (C).** No apparent line in the test region (T).

Negative

3. **Invalid: Control line (C) fails to appear.** Insufficient specimen volume or incorrect test procedure are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, you should immediately stop using the kit with the same LOT No. and contact your local distributor.

Invalid



Quality Control

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. 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 a positive hCG control (containing 10-100mIU/ml hCG) and a negative hCG control (containing "0"mIU/ml hCG) be evaluated to verify proper test performance when a new shipment of tests is received. Quality control materials should be analyzed in accordance with state, federal, and local regulations.

Performance Characteristics

1. Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the Famwell HCG Pregnancy Rapid Combo Test with another commercially available urine and serum hCG Rapid test. The urine study included 108 specimens, and both assays identified 52 negative and 56 positive results. The serum study included 102 specimens, and both assays identified 47 negative and 55 positive results. The results demonstrated a 100% agreement of the Famwell HCG Pregnancy Rapid Combo Test with the other urine and serum hCG Rapid test.

hCG Reference Method (Urine)

Pregnancy Rapid Combo Test Cassette	**Predicated Device**	
	Positive	**Negative**
Positive	53	0
Negative	0	52

hCG Reference Method (Serum)

Pregnancy Rapid Combo Test Cassette	**Predicated Device**	
	Positive	Negative
Positive	58	0
Negative	0	49

The study results show 100% agreement for all samples.

2. Sensitivity and Cross-Reactivity

The Famwell HCG Pregnancy Rapid Combo Test detects hCG at a concentration of 20mIU/mL or greater for urine and 10mIU/mL or greater for serum.

The test has been standardized to the 5th edition WHO hCG International Standard. The addition of LH (500mIU/ml), FSH (1,000mIU/ml), and TSH (1,000μIU/ml) to negative and positive specimens showed no cross-

reactivity.

3. Precision

This study is performed in 3 sites. Three lots of product were tested with 0, 5, 10, 12.5, 15, 17.5, 20, 30, 50, 100mIU/mL hCG urine specimen and 0, 2.5, 5, 7.5, 10, 12.5, 15, 20, 50mIU/mL hCG serum specimen. The results as following:

Urine:

hCG Concentration (mIU/mL)	Site 1		Site 2		Site 3		Total result	
	-	+	-	+	-	+	-	+
0	30	0	30	0	30	0	90	0
5	30	0	30	0	30	0	90	0
10	30	0	30	0	30	0	90	0
12.5	23	7	24	6	24	6	71	19
15	14	16	14	16	13	17	41	49
17.5	6	24	7	23	5	25	18	72
20	0	30	0	30	0	30	0	90
30	0	30	0	30	0	30	0	90
50	0	30	0	30	0	30	0	90
100	0	30	0	30	0	30	0	90

Serum:

hCG Concentration (mIU/mL)	Site 1		Site 2		Site 3		Total result	
	-	+	-	+	-	+	-	+
0	30	0	30	0	30	0	90	0
2.5	30	0	30	0	30	0	90	0
5	30	0	30	0	30	0	90	0
7.5	13	17	14	16	15	15	42	48
10	0	30	0	30	0	30	0	90
12.5	0	30	0	30	0	30	0	90
15	0	30	0	30	0	30	0	90
20	0	30	0	30	0	30	0	90
50	0	30	0	30	0	30	0	90

4. Interfering Substance

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

Items	Concentration	Items	Concentration
Acetaminophen	20 mg/dL	Albumin	2,000mg/dL
Acetoacetic Acid	2000mg/dL	Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL	Acetylsalicylic acid	20 mg/dL
Bilirubin	40mg/dL	Caffeine	20 mg/dL
Codeine	20 mg/dL	Ephedrine	20 mg/dL
EDTA	80 mg/dL	Ethanol	1%
Gentisic Acid	20 mg/dL	Glucose	2000mg/dL
Hemoglobin	2000mg/dL	Methadone	20mg/dL
Phenylpropanolamine	20mg/dL	Phenothiazine	20mg/dL
Pregnanediol	2mg/dL	Salicylic Acid	20mg/dL
Benzoylecgonine	10mg/dL	Cannabinol	10mg/dL
Methanol	10%	Estriol-17-beta	2mg/dL
Thiophene	20mg/dL	Ampicillin	20mg/dL
hCG-β core fragment	2μmol/L	Uric Acid	20 mg/dL
B-hydroxybutyrate	2000mg/dL	Ketone	20mg/dl
Tetracycline	20mg/dL	Triglycerides (serum only)	1200mg/dL
Total cholesterol (serum only)	250mg/dL		
High-density lipoprotein (serum only)	70mg/dL		

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

Limitations

1. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. The Famwell HCG Pregnancy Rapid Combo Test is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
3. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
4. This test may produce false positive results. A number of conditions other than pregnancy can cause elevated levels of hCG.
5. This test may produce false negative results. False negative results may occur when the levels of hCG are below the sensitivity level of the test.
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.

Precaution

1. Use fresh specimens whenever possible.
2. Do not read results after 10 minutes as they are invalid and may be wrong.
3. The product should be used as soon as possible once the foil pouch is opened, in case of long-term exposure to environment.
4. Follow standard biosafety guidelines for handling and disposal of potential infective material.

References

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3. L.A. Cole. Hyperglycosylated hCG Original Research Article Placenta, Volume 28, Issue 10, October 2007, Pages 977-986.
4. Gerhard, et al. "Vaginal sonography versus serum human chorionic gonadotropin in early detection of pregnancy." American Journal of Obstetrics and Gynecology 158.Part 1(1988):608-612.
5. Ayala, Aquiles R., H. Bustos, and R. M. Aguilar. "Daily rhythm of serum human chorionic gonadotropin and human chorionic somatomammotropin in normal pregnancy." International Journal of Gynaecology & Obstetrics the Official Organ of the International Federation of Gynaecology & Obstetrics 22(1984).

Basic Information

Manufactured for Boston Easy Biotech, Inc
200 Brickstone Square, Suite 104, Andover, MA 01810
Tel.: 1-800-678-6081, (9 am – 5 pm, Mon – Fri) Email: order@beb.bio
www.beb.bio

Index of Symbols

	Do not reuse	IVD	For in vitro diagnostic use only
4℃ 30℃	Stored between 4~30℃		Consult instruction for use
	Caution	LOT	Lot number
	Use by	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Do not use if package is damaged	REF	Catalogue number

No.: Q/JSRDY752-1.0-01
Effective Date: January 3,2025