FRENOVO

Human Chorionic Gonadotropin (hCG) Rapid Test Kit

Instructions For Use

PRODUCT NAME

Human Chorionic Gonadotropin (hCG) Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test is a lateral flow,qualitative immunoassay. It is intended for qualitative detection of hCG, with a minimum detection concentration of 25 mIU/mL in human urine, serum and plasma samples, aim to assist of clinical diagnosis of pregnancy.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Human chorionic gonadotropin(hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in urine, serum or plasma as early as 7 to 10 days after conception. hCG levels continue to rise very rapidly, frequently 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. The appearance of hCG in urine, serum or plasma soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test is a rapid test that qualitatively detects the presence of hCG at the sensitivity of 25 mIU/mL in human urine, serum and plasma samples. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine, serum or plasma samples. At the level of claimed sensitivity, FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding urine specimen to the specimen well of the test cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

MATERIALS PROVIDED

Each kit contains:
1. Test Devices: 25 pieces test devices individually pouched.
2. Droppers: 25 pieces droppers of 25 ul
3. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Micropipette

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Human Chorionic Gonadotropin (hCG)) Rapid Test is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The used test device should be discarded according to local regulations.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not use the kit past the expiration date (this date is printed on the kit box).
5. Adequate lighting is required to read the test results.
6. The result should be read immediately after the end of the 5 minutes incubation time following the addition of specimen. Do not read results beyond 10 minutes.

STORAGE INSTRUCTIONS

1. FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test kit should be stored between 2-30°C and the shelf life is 24 months.
2. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
3. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

Urine Assay

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Serum or plasma Assay

Blood should be collected aseptically into a clean tube without anticoagulants (Serum) or with anticoagulants (Plasma). Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.

Specimen Storage

Urine or serum or plasma specimens may be stored at 2-8ºC for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20ºC. Frozen specimens should be thawed and mixed before testing.

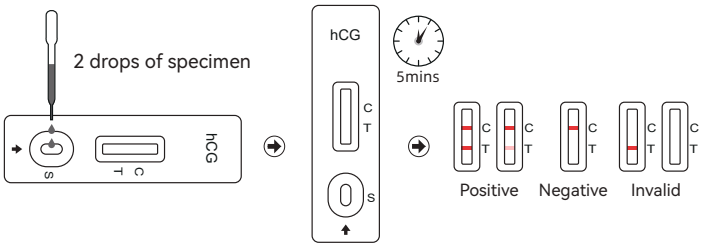
QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST PROCEDURE

Allow the tests and specimens to reach room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 2 full drops of specimen (approx. 50 µL) to the specimen well of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

Please refer to the illustration above

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that HCG has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line T appear, HCG has been detected and the result is positive.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line, and the test shall be conducted again.

LIMITATIONS

1. FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. 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.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.

4. This test may produce false positive results. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
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. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
7. 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.

PERFORMANCE CHARACTERISTICS

Accuracy
A multi-center clinical evaluation was conducted comparing the results obtained using FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test to another commercially available urine and serum or plasma hCG Rapid test. The urine study included 413 specimens, and both assays identified 296 negative and 117 positive results. The serum study included 200 specimens, and both assays identified 141 negative and 59 positive results. The plasma study included 200 specimens, and both assays identified 141 negative and 59 positive results. The results demonstrated a >99% overall accuracy of FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test when compared to the other urine and serum or plasma hCG Rapid test.

hCG Reference Method (Urine)				
Method		Other hCG Rapid Test		Total Results
FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test	Results	Positive	Negative	
	Positive	117	0	117
	Negative	0	296	296
Total Results		117	296	413
Sensitivity: 100% (96.9%~100%)		Specificity: 100% (98.8%~100%)		
Accuracy: 100% (99.1%~100%)		97.5% Confidence Intervals		

hCG Reference Method (Serum)				
Method		Other hCG Rapid Test		Total Results
FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test	Results	Positive	Negative	
	Positive	59	0	59
	Negative	0	141	141
Total Results		59	141	200
Sensitivity: 100% (93.9%~100%)		Specificity: 100% (97.4%~100%)		
Accuracy: 100% (98.2%~100%)		97.5% Confidence Intervals		

hCG Reference Method (Plasma)				
Method		Other hCG Rapid Test		Total Results
FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test	Results	Positive	Negative	
	Positive	59	0	59
	Negative	0	141	141
Total Results		59	141	200
Sensitivity: 100% (93.9%~100%)		Specificity: 100% (97.4%~100%)		
Accuracy: 100% (98.2%~100%)		97.5% Confidence Intervals		

Interfering substances:
A study was conducted to determine the following potentially interfering substances, which were added to hCG negative and positive specimens, then tested with FRENOVO Human Chorionic Gonadotropin (hCG)) Rapid Test, tested no interfered.

Compounds	Conc.mg/dL	Compounds	Conc.mg/dL
Acetaminophen	20	Acetone	1000
Acetylsalicylic Acid	20	Acetoacetic Acid	2,000
Ampicillin	20	Ascorbic Acid	20
Atropine	20	Albumin	2,000
ß-Hydroxybutyrate salt	2000	Benzoylecgonine	10
Bilirubin	20	Brompheniramine	20
Caffeine	20	Cannabinol	10
Clomiphene	100	Cocaine	10
Codeine	10	Cholesterol	500
Creatine	20	Dextromethorphan	20
DMSO	5%	EDTA	80
Ephedrine	20	Ethanol	1%
Estriol	2	Estrone 3-Sulfate	10
Gentisic Acid	20	Glucose	2,000
Hemoglobin	1,000	Heroin	1
Ibuprofen	20	Methadone	10
Methamphetamine	10	Methanol	10%
Morphine	0.6	Oxalic Acid	40
Phenothiazine	20	Phenylpropanolamine	20
Pregnanediol	2	Salicylic Acid	20
Tetracycline	20	Triglycerides	1,200
Theophylline	20	Urea	2,000
Uric Acid	20		

Cross-Reactivity
A study was conducted to determine the cross-reactivity of the test with compounds in either negative or positive specimen. The test has been standardized to the W.H.O. Fourth International Standard (75/589). The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity with FRENOVO Human Chorionic Gonadotropin (hCG) Rapid Test .

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks		

Hangzhou Frenovo Biotech Co., Ltd.
Address: Room 401,Building 26, Room 401&301,Building 27,No.488-1,Donghu North Road, Donghu Street,LinPing District,Hangzhou City,Zhejiang Province.China.
Tel: +86-571-89170657
Email: business@frenovo.com

INSTRUCTION APPROVAL AND REVISION DATE

Revision Date: 2025.10.22

Approval Date: 2025.10.22

Date of Issue: 2025.10.22