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

All substances listed in mg/dL unless otherwise noted.

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

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

BIBLIOGRAPHY

1. Batzer FR. "Hormonal evaluation of early pregnancy", *Fertil. Steril*. 1980; 34(1): 1-13
2. Catt KJ, ML Dufau, JL Vaitukaitis "Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte", *J. Clin. Endocrinol. Metab*. 1975; 40(3): 537-540
3. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade "Serum human chorionic gonadotropin levels throughout normal pregnancy", *Am. J. Obstet. Gynecol*. 1976; 126(6): 678-681
4. Lenton EA, LM Neal, R Sulaiman "Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy", *Fertil. Steril*. 1982; 37(6): 773-778
5. Steier JA, P Bergsjo, OL Myking "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy", *Obstet. Gynecol*. 1984; 64(3): 391-394
6. Dawood MY, BB Saxena, R Landesman "Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma", *Obstet. Gynecol*. 1977; 50(2): 172-181
7. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross "Ectopic production of human chorionic gonadotropin by neoplasms", *Ann. Intern Med*. 1973; 78(1): 39-45

Re-order:
Cat. No. B1077-23

Hospital and surgery centers call:
1.800.964.5227

Physician offices call:
1.888.444.5440

For Technical Support please call:
1.866.211.7853

Art specifications:
IFU insert - 14"W x 8.5"H (2-sided)
Do not alter art or size.
All art prints 100% Black.
Folder 925

hCG Combo
Rapid Test

Cat. **B1077-23**

A rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine.

For professional *in vitro* diagnostic use only.

CLIA COMPLEXITY: For Urine – waived
For Serum – moderately complex

INTENDED USE
The hCG Combo Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine to aid in the early detection of pregnancy.

SUMMARY
Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both serum and urine as early as 7 to 10 days after conception.[1-4] hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period,[2-4] and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both serum and urine 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.

The hCG Combo Rapid Test qualitatively detects the presence of hCG at the sensitivity of 10 mIU/mL in serum and 20 mIU/mL in urine. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in serum or urine. At the level of claimed sensitivity, the hCG Combo Rapid Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

Distributed by:
Cardinal Health
Waukegan, IL 60085 USA Rev. C 9/14
cardinalhealth.com
Made in China

DN: 1155904805

PRINCIPLE

The hCG Combo Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding serum or 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.

REAGENTS

The test cassette contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test cassette should be discarded in a proper biohazard container after testing.
- The test cassette should not be reused.
- Discard the test cassette if package is torn, ripped or if cassette itself is damaged.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2°- 30°C (36°- 86°F). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use.
DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Serum Assay

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

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.

Specimen Storage

Serum or urine specimen may be stored at 2°- 8°C (36°- 46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C (-4°F). Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Thirty (30) individually packaged test cassettes each containing one disposable specimen dropper.
- One directional insert

Materials Required But Not Provided

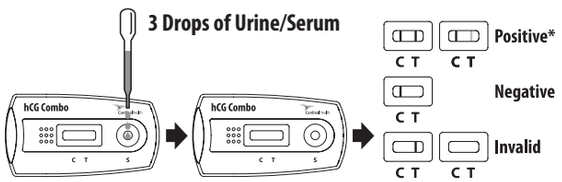
- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test cassette, serum or urine specimen and/or controls to equilibrate to room temperature 15°- 30°C (59°- 86°F) prior to testing.

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or urine (approx. 100 µL) to the specimen well(s) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well(s). See the illustration below.
3. Wait for the red line(s) to appear. Read the result at 3-4 minutes when testing a urine specimen, or at 5-6 minutes when testing a serum specimen. Do not interpret results after the appropriate read time. It is important that the background is clear before the result is read.

INTERPRETATION OF RESULT



POSITIVE*: **Two distinct red lines appear**. One line should be in the control region (C) and another line should be in the test region (T).

NOTE: A sample hCG concentration below the cut-off level of this test might result in a weak line appearing in the test region (T) after an extended period of time. A line in the test region (T) seen after the read time could be indicative of a low hCG level in the sample. If such results are seen, it is recommended that the test be repeated with a new sample in 48-72 hours or that an alternate confirmation method is used.

NEGATIVE: **One red line appears in the control region (C)**.
No apparent red or pink line appears in the test region (T).

INVALID: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and call Technical Services at 1.866.211.7853.

***NOTE**: The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control.
It confirms sufficient specimen volume and correct procedural technique.
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.

It is recommended that a positive hCG control (containing ≥20 mIU/mL hCG in urine or ≥10 mIU/mL hCG in serum) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance. For urine testing, controls should be tested with each new lot or shipment of product, with each new operator, monthly as a check on continued storage conditions, or as otherwise required by your laboratory's internal quality system procedures. For serum testing, federal, state, and local guidelines should be followed.

LIMITATIONS

1. 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.
2. 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 serum or urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in serum and urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,[5] a test result that is weakly positive should be confirmed by retesting with a first morning serum or urine specimen collected 48 hours later.
4. This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect hCG degradation products and therefore may disagree with the results of this rapid test.
5. 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.[6-7] Therefore, the presence of hCG in a serum or urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
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.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their serum and urine specimens. The amount of hCG will vary greatly with gestational age and between individuals.

The hCG Combo Rapid Test has a sensitivity of 10 mIU/mL in serum and 20 mIU/mL in urine and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the hCG Combo Rapid Test and another commercially available serum/urine membrane hCG test. The urine study included 100 specimens and both assays identified 50 negative and 50 positive results. The serum study included 100 specimens and both assays identified 50 negative and 50 positive results. The results demonstrated 100% overall agreement (for an accuracy of > 99%) of the hCG Combo Rapid Test when compared to the other serum/urine membrane hCG test.

Sensitivity and Specificity

The hCG Combo Rapid Test detects hCG at concentrations of 10 mIU/mL or greater in serum and 20 mIU/mL or greater in urine. 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 (10 mIU/mL hCG in serum; 20 mIU/mL hCG in urine) specimens showed no cross-reactivity.

Art specifications:

IFU insert - 14"W x 8.5"H (2-sided)
Do not alter art or size.
All art prints 100% Black.
Folder 925

Black　50% Black　30% Black

Attention: By approving the enclosed design draft, you (ABON's Customer) accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, you (ABON's Customer) are responsible for the cost of any inventory which is deemed unsuitable for sale.

注　　意：作为**ABON**的客户，一旦你批准所附的设计稿后，即代表你已接受承担设计正确性的所有责任。如物料在随后的印刷和生产过程中发现有任何不适合销售的错误，你将负责承担任何库存的费用。

☐ US　☐ OUS　☐ DOMESTIC　☐ OTHER

Description 描述	Cardinal FHC-A202 English insert	***Part Number*** PN号码	1155904805	***Size*** 尺寸	355.6*215.9mm
Printing Contents 印刷内容	／	***L Number*** L号码	／	***Size*** 尺寸	／
Designer 设计者	Amy	***Design Date/Version*** 设计日期/版本	Sep. 11, 2014/B	***Mold Num.*** 模具号	／
Artwork Checked By 设计审核		***Material/ Checked By*** 材质/审核	80g双铜		
Approved By Customer/Date 客户确认/日期		***Approved By Marketing/Date*** 市场部确认/日期			
Approved By QA/RA/Date ***QA / RA***确认/日期		***Approved By P.M.T. /Date*** 产品管理确认/日期			
Approved By ABON QA/Date ***ABON QA***确认/日期		***Effective Date*** 生效日期			