Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep hCG Urine 3.5 mm RapiDip™ InstaTest

REF 113043-1-20

IVD See external Label 2°C 30°C 1 Test

Sensitivity	20 mIU/ml

INTENDED USE

Cortez Diagnostics, Inc. OneStep hCG Urine RapiDip™ InstaTest is a test kit for the determination of hCG (Human Chorionic Gonadotropin) in urine specimens. For professional in vitro diagnostic use only.

SUMMARY AND EXPLANATION

hCG is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in urine as early as 7 to 10 days after conception. hCG levels continues to rise very rapidly, frequently exceeding 100mIU/mL by the first missed menstrual period, and peaking in the 100,000-200,000mIU/mL range about 10-12 weeks into pregnancy. 7,8,9,10 The appearance of hCG in 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.

One Step hCG Pregnancy Test is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 20mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, One Step hCG Pregnancy Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH and hTSH at high physiological levels.

TEST PRINCIPLE

Cortez Diagnostic, Pregnancy Test is a rapid chromatrographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by immersing the test in a urine specimen and observing the formation of pink colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific antibody-hCG-colored conjugate and form a pink colored line at the test line region of the membrane. Absence of this pink colored line suggests a negative result. To serve as a procedural control, a pink colored line will always appear at the control line region if the test has been performed properly.

SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a dry and clean container. The first morning urine specimen is preferred since it usually contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used.

Specimen Storage
Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and stirred before testing.

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 AND COMPONENTS

Materials provided with the test kits

1. One Step hCG Urine Test RapiDip
2. Instructions for use

Materials required but not provided

1. Clean glass or plastic container for specimens collection
2. Timer

ASSAY PROCEDURE

Allow the test and the specimen to equilibrate to room temperature (15-30°C) prior to testing.

To begin testing, open the sealed pouch by tearing along the notch. Remove the test kit from the pouch and use it as soon as possible. Immerse the strip vertically into the urine sample with the arrow end pointing towards the urine. Do not immerse past the "Mark" Line. Take the strip out after 3 seconds and lay the strip flat on a clean, dry, non-absorbent surface.

Wait for pink colored bands to appear. Depending on the concentration of hCG in the test specimen, positive results may be observed in as soon as 40 seconds. However, to confirm negative results, the complete reaction time of 5 minutes is required. It is important that the background is clear before the result is read.

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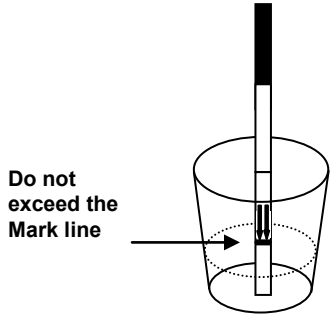
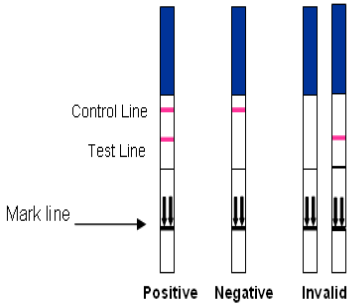


Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

RESULTS

- **Negative:** Only one color band appears on the control region. No apparent band on the test region. This indicates that no pregnancy has been detected.
- **Positive:** Distinct color bands appear on both the control and test regions. Presence of both test line and control line indicate that you are probably pregnant. The color intensity of the test bands may vary since different stages of pregnancy have different concentrations of hCG hormone.
- **Invalid:** No visible band at all or no colored band appears on the control (C) region. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



QUALITY CONTROL

A pink 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.

External controls should be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested at regular intervals as good laboratory testing process.

Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.

PERFORMANCE CHARACTERISTICS

High Dose Effect

Normal urine that were spiked with hCG concentrations of 62,500, 125,000, 250,000, 500,000, 1,000,000, and 2,000,000 mIU/ml were used to study the high dose hook effect on One Step hCG Pregnancy Test. It was noticed that both color bands at the test band region and the control region were visible. However, when hCG levels were over 500,000 mIu/mL, the higher the hCG concentration became, the lighter the band at test region became.

Accuracy

An external clinical evaluation was conducted comparing the results obtained using One Step hCG Pregnancy Test to another commercially available One Step hCG Pregnancy Test. The study included 200 positive or negative urine samples. The results demonstrated 98% agreement when trained technicians performed comparison testing on the tests. The results are shown in Table 1.

Table 1: Comparison between Cortez Diagnostic, Inc. vs. Predicate Strip Format – urine Samples

		Predicate		Subtotal
		+	-	
DAI	+	122	0	122
	-	2	76	78
Subtotal		124	76	200

Percent Accuracy = 99%
Discrepant Results = 1%

Sensitivity

One Step hCG Pregnancy test detects urine hCG concentrations greater than 20 mIU/ml as indicated by the appearance of a color band at the test region. Additionally, samples containing less than 20 mIU/mL hCG may also produce a positive result. To evaluate the sensitivity of One Step hCG Pregnancy test at low levels of hCG the following experiments were carried out. Urine samples from 100 known non-pregnant subjects were spiked with hCG to the concentrations of 0, 10, 20, 40, 100 mIU/ml. A total of twenty samples at each concentration were performed and blindly labeled and tested. The results are summarized in Table 2.

Table 2: Sensitivity of One Step hCG Pregnancy Test – urine Samples

hCG	0	10	15	20	40	100
# of Samples	20	20	20	20	20	20
Negative	20	19	17	0	0	0
Positive	0	1	3	20	20	20

Specificity:

The cross reactivity of the One Step hCG Pregnancy was evaluated using hCG homologous hormones. Homologous hormones FSH and TSH were added to urine samples containing hCG at concentration of 0, 20 or 100 mIU/mL. No cross reactivity was observed. The results are shown in Table 3.

Table 3: Specificity of One Step hCG Pregnancy Test

hCG conc. in sample (mIU/mL)	Unspiked urine samples	Urine samples spiked with homologous hormones	
		FSH	TSH
		1000 mIU/ml	1000 µIU/ml
0	-	-	-

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	-	-	-
	-	-	-
20	+	+	+
	+	+	+
	+	+	+
100	+	+	+
	+	+	+
	+	+	+

Interfering substances

The One-Step hCG Pregnancy test was checked for possible interference from visibly hemolyzed, lipemic and icteric samples. Human hemoglobin, bilirubin or albumin was spiked into urine samples with different concentration of hCG and tested using un-spiked samples as controls. No significant interference was observed in 20 sample testing results that were either positive or negative for hCG. The results, which have been pooled together due to little variance are shown in Table 4.

Table 4: Non-Specific Interference on hCG Pregnancy Test

Sample No	Unspiked samples	Urine samples spiked with (mg/mL)			
		Hemoglobin		Bilirubin	Albumin
		10	1	0.06	100
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-
5	-	-	-	-	-
6	-	-	-	-	-
7	-	-	-	-	-
8	-	-	-	-	-
9	-	-	-	-	-
10	-	-	-	-	-
11	+	+	+	+	+
12	+	+	+	+	+
13	+	+	+	+	+
14	+	+	+	+	+
15	+	+	+	+	+
16	+	+	+	+	+
17	+	+	+	+	+
18	+	+	+	+	+
19	+	+	+	+	+
20	+	+	+	+	+

The following commonly used drugs and biological substances were added into hCG free and 50 mIU/mL hCG urine samples. No interference was observed.

Acetaminophen	20 mg/mL	Caffeine	20 mg/mL
Acetylsalicyclic Acid	20 mg/mL	Gentisic Acid	20 mg/mL
Ascorbic Acid	20 mg/mL	Glucose	2 g/dL
Atropine	20 mg/mL	Hemoglobin	1 mg/dL

LIMITATIONS OF PROCEDURE

1. 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 should be collected 48 hours later and tested.
2. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
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. Very low levels of hCG (less then 50mIU/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 teat is weakly positive should be confirmed by retesting with a first morning urine collected 48 hours later.
5. 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.
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 be evaluated

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. The test kit can be stored at temperatures between 2 to 30ºC in the sealed pouch to the date of expiration.
5. The test kit should be kept away from direct sunlight, moisture and heat.

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