Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep hCG Combo Urine / Serum 3.5mm RapiDip™ InstaTest

REF 113032-1-20

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

Sensitivity	20 mIU/ml

INTENDED USE

Cortez Diagnostics, Inc. OneStep hCG Serum/ Urine combo RapiDip™ InstaTest is a test kit for the determination of hCG (Human Chorionic Gonadotropin) in serum / plasma or urine specimens.

TEST PRINCIPLE

There is an appearance of hCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth. This test is used to obtain a visual, qualitative result for the early detection of pregnancy.

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.

Serum / Plasma / Assay

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

Specimen Storage

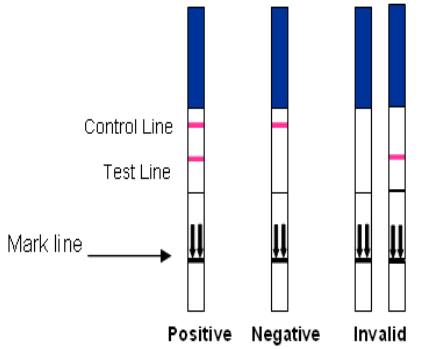
If the specimen cannot be tested on the day of collection, store the specimen in a refrigerator or freezer at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and stirred before testing. Do not freeze and thaw the specimen repeatedly.

ASSAY PROCEDURE

1. 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.
2. Immerse the strip into the urine, serum or plasma sample with the arrow end pointing towards the sample. Do not immerse past the "Mark" Line. Take the strip out after 10 seconds and lay the strip flat on a clean, dry, non- absorbent surface (such as the mouth of the urine container).
3. Wait for 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. Do not read results after more than 30 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.



PERFORMANCE CHARACTERISTICS

Cross Reactivity

The cross reactivity of hCG test kits was evaluated with hCG homologous hormones. Homologous hormones FSH, LH and TSH were added to serum or urine samples containing hCG at concentration of 0, 20 or 100 mIU/mL. No cross reactivity was observed in the study (shown in Table 1).

Non-specific interference

One-Step hCG (Combo) test was checked for possible interference from visibly hemolyzed, lipemic and icteric samples. Human hemoglobin, bilirubin or albumin was spiked into samples with different concentration of hCG (Combo) and tested using un-spiked samples as controls. No significant interference was observed in 20 samples with results that were either positive or negative for interference was observed in 20 samples with results that were either positive or negative for hCG. The results are shown in Table 2.

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Table 1 – Cross-reactivity study of One-Step hCG (Combo) test kit
Urine samples spiked with homologous hormones

hCG conc. In sample (mIU/mL	Unspiked serum or urine samples	FSH 1000mIU/mL	LH 1000mIU/mL	TSH 1000mIU/mL
0	-	-	-	-
	-	-	-	-
	-	-	-	-
20	+	+	+	+
	+	+	+	+
	+	+	+	+
100	+	+	+	+
	+	+	+	+
	+	+	+	+

Table 2 – Non-specificity study of One-Step hCG (Combo) test kits

Sample No	Unspiked Samples	Urine samples spiked with (mg/mL0			
		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	+	+	+	+	+

LIMITATIONS OF PROCEDURE

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 urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in 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. A number of conditions other than pregnancy, including trophoblastic disease and certain non- trophoblastic neoplasms including breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine/ serum/ plasma should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. 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.

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.

ISO 13485
ISO 9001

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EC REP	CEpartner4U , Esdoornlaan 13, 3951DB Maarn. The Netherlands. www.cepartner4u.eu
Revision Date: 2007-05-01	