CE 0088

Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

# OneStep hCG Urine 2.5 mm RapiDip™ InstaTest

**For Self Testing**
REF **113042ST-1-20**

IVD | 2°C 30°C | Σ 1 Test

| Sensitivity | 20 mIU/ml |
|---|---|

## INTENDED USE

Cortez Diagnostics, Inc. OneStep hCG Urine RapiDip™ InstaTest is a rapid chromatrographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine at a concentration level from 20mIU/ml or greater to aid in the early detection of pregnancy. The test is designed for over-the–counter use.

## SUMMARY

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.

OneStep hCG Urine RapiDip™ InstaTest 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, OneStep hCG Urine RapiDip™ InstaTest shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH and hTSH at high physiological levels.

## PRINCIPLE

OneStep hCG Urine RapiDip™ InstaTest 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.

## MATERILAS AND REAGENTS

**Materials povided**
- OneStep hCG Urine RapiDip™ InstaTest
- insert

**Materials needed but not provided**
- Clean glass or plastic container for specimens collection
- Timer

**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

## PRECAUTION

1. For in vitro diagnostic and OTC use only.
2. Do not use test kit beyond the expiry date.
3. The test device should not be reused.
4. Urine specimens may be infectious; insure proper handling and dispose of all used reaction devices into a biohazard container.

## SPECIMEN COLLECTION AND PREPARATION

A fresh urine specimen should be used, no special pre-treatment is necessary. Specimens should be collected in a clean glass or plastic container.
The specimen may be refrigerated (2-8°C) and stored up to 2 days. For longer storage, freeze samples at -20°C or below. Refrigerated samples should be allowed to come to room temperature and mixed thoroughly before assaying. Frozen samples should be thawed completely allowed to come to room temperature, and mixed thoroughly before assaying.

## ASSAY PROCEDURE

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

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 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.
3. 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.

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 30 minutes.

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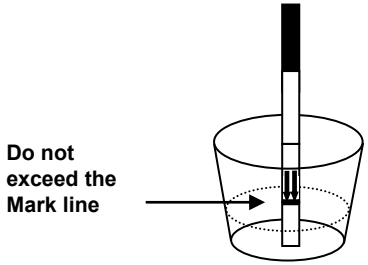
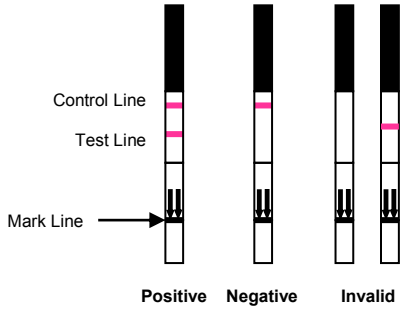



## RESULTS

**Negative:** Only one pink colored band appears on the control region. No apparent band on the test region.

**Positive:** Distinct pink color bands appear on the control and test regions. The color intensity of the test bands may vary since different stages of pregnancy have different concentrations of hCG hormone.

**Invalid:** No line appears in the control zone "C", the test should be voided since an improper test procedure may have been performed or deterioration of reagents may have occurred. This is due to the internal control built in which a distinct control region (C) line should always appears. Repeat the test using a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.




## PERFORMANCE CHARACTERISTICS

**Comparison study**

Other commercially available qualitative test kits were used to compare with OneStep hCG Urine RapiDip™ InstaTest for relative sensitivity and specificity in 200 urine samples. Only 2 samples were discordant, the agreement is 99%.

| Strip Format | | Predicate Device | | Subtotal |
|---|---|---|---|---|
| | | + | - | |
| Cortez | + | 122 | 0 | 122 |
| | - | 2 | 76 | 78 |
| Subtotal | | 124 | 76 | 200 |

Comparable Results: 99%; Discrepant Results: 1%

**Cross reactivity**
The following substances were added in hCG free, 20 mIU/mL and 50 mIU/mL spiked urine samples.

| | |
|---|---|
| Acetaminophen | 20 mg/mL |
| Acetylsalicylic acid | 20 mg/mL |
| Ascorbic acid | 20 mg/mL |
| Atropine | 20 mg/mL |
| Caffeine | 20 mg/mL |
| Gentesic acid | 20 mg/mL |
| Glucose | 2g/dL |
| Hemoglobin | 1mg/dL |

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

## STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat. The expiration dating was established under these storage conditions.

## 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.

## 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.

## REFERENCES

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ISO 13485
ISO 9001

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| **Date Adopted** | **2017-08-22** |
| REF **113042ST-1-20** | **CORTEZ- OneStep hCG Urine 2. 5mm RapiDip™ InstaTest** |
| EC REP | **CEpartner4U , Esdoornlaan 13, 3951DB Maarn. The Netherlands.** www.cepartner4u.eu |
| Revision Date: **2014-12-01** | |