



DRG® One Step HCG Pregnancy Test (RAP-2818)



IVD

Revised 22 July, 2008

INTENDED USE

The DRG® One Step HCG Pregnancy Test is an in vitro diagnostic test for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The test is a two-site immunoassay employing monoclonal and polyclonal antibodies and is designed to reliably produce a visually detectable pink to purple test line in the presence of hCG at a concentration of 25 mIU/ml or greater (WHO 1st IRP, 75/537) in five minutes of sample application.

SUMMARY AND EXPLANATION

Human Chorionic Gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. In a normal pregnancy, hCG can be detected in serum as early as 7 days following conception¹⁻⁴, doubling every 1.3 to 2 days. At the time of the first missed menstrual period, hCG concentration is about 100 mIU/ml, and peak levels of 100,000 to 200,000 mIU/ml are seen at the end of the first trimester. The appearance of hCG soon after conception and its subsequent rise in concentration during early gestational growth make it an excellent marker for the early detection of pregnancy. Elevated serum hCG levels comparable to those observed in early pregnancy may also be associated with trophoblastic or non trophoblastic neoplasms⁶⁻⁷ such as hydatidiform mole and choriocarcinoma; therefore, the possibility of such diseases should be ruled out before a positive hCG result is considered diagnostic for pregnancy. The DRG Quickstick™ One Step HCG Pregnancy Test is a rapid, visual, and easily read test to qualitatively detect the presence of hCG in urine specimens at concentrations as low as 25 mIU/ml. The immunological specificity of the test kit virtually eliminates cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH, and hTSH at physiological levels.

PRINCIPLES OF THE PROCEDURE

The DRG® One Step HCG Pregnancy Test employs the basic immunochemical sandwich assay principle, relying on the recognition and formation of specific antibody / hCG / antibody complexes. The membrane is coated with goat anti-hCG on the test band region and goat anti-mouse on the control band region. During the test, urine is allowed to react with colored conjugate (mouse anti-hCG monoclonal antibody - colloidal gold conjugate), which is pre-dried on the test strip. As urine migrates chromatographically across the membrane, it carries the colored conjugate with it. If hCG is present, a specific antibody / hCG / colored antibody complex is formed on the membrane. The absence of this colored band suggests a negative result. To serve as a procedural control, a colored band will always appear in the control region regardless of the presence of hCG in the test specimen. In the assay procedure, the test device is inserted into the urine specimen, which is absorbed into the device by capillary action. The sample mixes with the antibody-dye conjugate and flows across the pre-coated membrane from the sample pad through the label pad to the membrane test area. As stated previously, if hCG is present in the urine sample, a specific antibody / hCG / colored antibody complex is formed. The test result is read in 5 minutes. The presence of two color bands within the test region of the device indicates a positive result.

REAGENTS AND MATERIALS PROVIDED



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1. 25 individually pouched test devices. Each pouch also contains a desiccant packet to absorb moisture.
2. Test Instructions

MATERIALS REQUIRED, BUT NOT PROVIDED

1. Clock or timer
2. Sample collection containers

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. For testing human urine only.
3. Urine specimens may be potentially infectious; properly handle and dispose of all specimens and used reaction devices according to Universal Precautions for biohazardous materials.
4. Do not use kit beyond the expiration date.
5. Do not reuse the test device.

STORAGE

Store the test kit between 2 and 28 °C until the expiration date on the pouch or kit box.

SAMPLE COLLECTION AND PREPARATION

Collect a urine sample in clean, dry container, either plastic or glass, without any preservatives. Samples may be refrigerated (2 - 8 °C) and stored up to 48 hours. For longer storage, freeze samples (-20 °C or below).

ASSAY PROCEDURE

PREPARATION

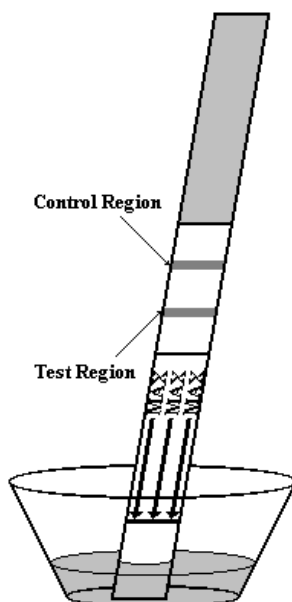
1. Bring the test device and sample to room temperature (15 - 28 °C) before testing.
2. Do not break the seal on the foil pouch until ready to perform the test.

TESTING

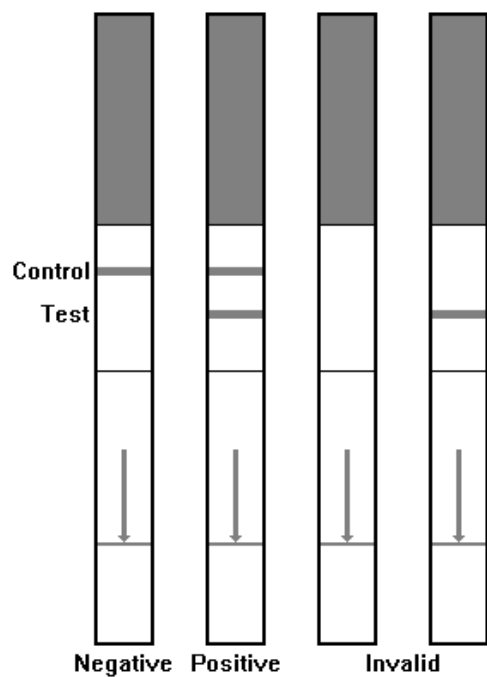
1. Open the foil pouch at the notch and remove the test device, taking care not to touch the exposed membrane. Verify that the test device is within its expiration dating.
2. Insert the sample end of the dipstick into the urine specimen no deeper than the maximum level indicated by the line on the label.
3. Within 5 minutes a colored band will appear at the top of the test area to show that the test is complete.
4. Read test results immediately at 5 minutes. Results read after 15 minutes have elapsed should be considered invalid.



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INTERPRETATION OF RESULTS





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Negative

A rose-pink colored band appears in the Control Reaction Zone “C” but not in the Test Reaction Zone “T”. This is a negative result and indicates the hCG level is below the detection sensitivity of 25 mIU/ml.

Positive

Two horizontal rose-pink color bands appear, one in the Control Reaction Zone “C” and one in the Test Reaction Zone “T”. This is a positive result and indicates the hCG level is at or above the detection sensitivity of 25 mIU/ml.

Invalid

If no bands appear, or a Test Band appears without a Control Band, the device reagents may have deteriorated or the test may not have been performed properly. The presence of a Control Band is necessary to validate test performance. Retest the sample with a new test device.

QUALITY CONTROL

An internal procedural control has been incorporated into the test to ensure proper kit performance and reliability. The development of the rose pink Control Band demonstrates antibody recognition, verifies that the reagents are chemically active, and confirms that the test was performed correctly. The use of external controls is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing facility. Assay controls in same method as urine specimens.

LIMITATIONS OF THE PROCEDURE

1. This method has been tested using urine only. Other fluids have not been evaluated.
2. Positive results, as evidenced by the appearance of rose-pink Test and Control bands, may be apparent in as little as 1 minute. However, to confirm negative results the full 5-minute assay time should be allowed to elapse.
3. If a urine specimen is too dilute (i.e., low specific gravity), it may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be obtained from the patient and tested.
4. Occasionally, samples containing hCG levels below the cutoff sensitivity for the test may produce positive results.
5. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms, cause elevated levels of hCG. These diagnoses should be considered if appropriate to the clinical evidence.
6. The test is a qualitative screening assay and is not for determining quantitative concentration levels.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.



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EXPECTED VALUES

Healthy males and healthy non-pregnant females do not have detectable hCG with the Phamatech DRG® One Step HCG Pregnancy Test. HCG levels of 25 mIU/ml can be reached by the day of the first missed menstrual period. HCG levels peak about 8 weeks after the last menstrual period and then decline to lower values for the remainder of the pregnancy. Following delivery, hCG levels rapidly decrease and usually return to normal within days after parturition.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

A normal male urine pool was spiked with hCG to 0, 25, and 600 mIU/ml, then aliquoted, randomized, and coded. Technicians tested each coded aliquot with the DRG® One Step HCG in a random order for a total of 10 replicates of each hCG level. The coded results were visually interpreted as positive or negative by four Phamatech technicians (10 replicates of each level x 4 reads = 40 test results per hCG level) upon assay completion. Visual interpretation of the DRG® One Step HCG Pregnancy Test resulted in the correct identification of 100% of all samples \geq 25 mIU/ml hCG. At 25 mIU/ml, the assay sensitivity, 100% of the samples were correctly identified as positive.

ACCURACY

A total of 118 female urine samples were collected from clinical sites from normal females who suspected they were pregnant. Testing was performed at Phamatech. Immediately upon completion of the assays, results were visually scored as “negative” (absence of hCG) or “positive” (presence of hCG) by the technician. Quality Assurance personnel then verified all results. Overall, the Quickstick™ One Step HCG Pregnancy Test obtained an overall accuracy compared to the RapidVue™ and the Be Sure™ Pregnancy Test and the of 100% (236/236). The DRG® test correctly detected 90 of 90 (100%) positive samples and 28 of 28 (100%) negative samples. These results are presented below.

	<u>Competitive Assays</u>	
	(-)	(+)
<u>Quickstick™</u> (-)	28	0
<u>HCG Test</u> (+)	0	90

Based on these results, the DRG® One Step HCG Pregnancy Test is substantially equivalent in clinical performance to commercially available pregnancy tests for the qualitative detection of hCG when performed according to direction.

SPECIFICITY

Various concentrations of hLH, hTSH and hFSH were spiked into a normal male urine pool which was previously spiked with 0, 25 or 100 mIU/ml hCG. Each sample was tested in triplicate using the DRG® test in accordance with the package insert procedure. The expected results were observed each time, demonstrating that the DRG® One Step HCG Pregnancy Test has no cross-reactivity with hLH, hTSH or hFSH.



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INTERFERENCE

The following substances were added to hCG-free and 25 mIU/ml hCG-spiked urine samples and tested with the DRG® One Step HCG Pregnancy Test. No interference with the expected results was observed from any of the substances at the indicated concentrations.

Acetaminophen	20 mg/dl	Caffeine	20 mg/dl
Acetylsalicylic Acid	20 mg/dl	Gentisic Acid	20 mg/dl
Ascorbic Acid	20 mg/dl	Glucose	2 g/dl
Atropine	20 mg/dl	Hemoglobin	1 mg/dl

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