INSTRUCTIONS FOR USE
ONE STEP hCG URINE / SERUM PREGNANCY STRIP TEST

TOYO DIAGNOSTICS

Only for professional *in vitro* diagnostic use

Product Code: THCG09
Rapid one step test for the qualitative detection for human chorionic gonadotropin (hCG) in urine / serum.

BACKGROUND INFORMATION

Human Chorionic Gonadotrophin (hCG) is a sialoglycoprotein with a molecular weight of approximately 46.000 daltons. hCG is initially secreted by the trophoblastic cells of the placenta shortly after implantation of the fertilized ovum into the uterine wall. As hCG appears shortly after conception both in serum and urine and the increase in concentration during the early stages of pregnancy provides this hormone as a perfect marker for the early determination of pregnancy.

INTENDED USE

Qualitative detection of human chorionic gonadotropin (hCG) in human urine / serum to indicate pregnancy for professional use.

REAGENTS

Mouse monoclonal anti-hCG antibody, goat anti-mouse IgG polyclonal antibody, colloidal gold conjugate of monoclonal anti-hCG antibody.

METHOD

The hCG test uses immunochromatographic technology for the qualitative detection of hCG in urine / serum. The test is a two-site immunometric assay in which a combination of monoclonal and polyclonal antibodies is used to selectively detect hCG in samples with a high degree of sensitivity. Mouse monoclonal anti-hCG antibody was immobilized on the test area "T" and goat anti-mouse IgG polyclonal antibody was immobilized on the control area "C" of the nitrocellulose membrane. Monoclonal anti-hCG antibody conjugated with colloidal gold particles, was dried on a conjugate pad. Sample is introduced from sampling pad. If there is hCG in the sample, hCG binds to the mobile monoclonal anti-hCG antibodies conjugated with colloidal gold particles. Together they move to the test area "T". hCG-molecules bind to the immobilized mouse monoclonal anti-hCG antibody and as a result of this, hCG molecules that are already bound to mobile monoclonal anti-hCG antibodies (conjugated with colloidal gold particles) become immobilized in the test area "T" thus creating a visible colored signal due to the accumulation of colloidal gold particles in the test area "T" (a colored test line), indicating positive test result. If there is no hCG in the sample then sample moves to the test area "T" together with unbound (free) monoclonal anti-hCG antibodies conjugated with colloidal gold particles. Immobilized mouse monoclonal anti-hCG antibodies cannot bind to mobilized monoclonal anti-hCG antibodies conjugated with colloidal gold particles, therefore no visible colored signal can be obtained (no colored test line) indicating negative test result. Regardless of hCG content of the liquid sample, mobile monoclonal anti-hCG antibodies conjugated with colloidal gold particles bind immobilized goat anti-mouse IgG polyclonal antibodies while liquid sample is passing through the control area "C". Therefore accumulation of colloidal gold particles produces a visible colored signal in the control area "C" (a colored control line) indicating a valid test result. Colored line should be visible in the control area "C" in every cases; if no visible colored line in control area "C", test result should be indicated as invalid.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
6. Drugs containing hCG can affect the results of the test.
7. Very dilute urine samples, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be collected 48 hours later and tested.
8. This test may produce false positive results in such 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 or serum samples should not be used to diagnose pregnancy unless these conditions have been ruled out.
9. This test may produce false negative results. False negative results may occur when the levels of hCG are below the sensitivity level of this test. When pregnancy is still suspected, a first morning urine or serum samples should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, perform further tests.
10. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the sample. Samples from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such samples may cause false negative or false positive results.
11. This test will indicate only the presence or absence of hCG hormone in the sample, and should not be used as the only basis for the detection of pregnancy.
As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened

Kit components : Test devices and instructions for use.
Additional materials required but not provided : Sample collection container, centrifuge and timer.
Additional materials recommended but not provided : Negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION

The test can be performed using fresh human urine or serum.

For Urine Samples: No special preparations are required for urine samples. Sample must be collected in a clean, dry container that does not contain any preservatives or chemical compounds. The urine sample collected at any time of day is used; however the first morning urine that generally contains highest levels of hCG is preferred. Urine samples that contain visible precipitants should be centrifuged and filtered or should stand by in order to obtain a limpid supernatant for the test. Urine samples can be kept for maximum of 2 hours at 2 - 8 °C before testing. Urine containing excessive amount of bacterial contamination should not be used as leading to inaccurate results.

For Serum Samples: Blood sample can be collected at any time of day, to obtain serum sample. Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum. Do not use turbid, hemolyzed samples. If the sample cannot be tested on the day of collection, store the serum samples in a refrigerator or freezer. Do not freeze and thaw the serum samples repeatedly. Bring the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Turbid test samples should be centrifuged. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.

TEST PROCEDURE

1. Take the test device out of its pouch. Bring the tests and urine / serum samples to room temperature.
2. Place the strip into the urine / serum as far as the line (shown by arrow) and leave for 5 seconds then take out immediately.
3. Depending on the hCG concentration in the sample, the test can react even in 5 minutes. Results should be read within 10 minutes as shown below. Do not interpret results beyond 20 minutes, results forming after 20 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

* C area appears on the upper part of strip near with blue handling part.
* * T area appears on the lower part of strip introduced sample.
(Please refer to figure 1 for the C and T areas location)

Negative : Only one colored line is visible in "C" area, indicating that hCG hormone does not exist; **NOT PREGNANT.**
Positive : Two colored lines are visible in "C" and "T" areas, indicating that hCG hormone exists; **PREGNANT.**
Low concentration of hCG may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid : No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.

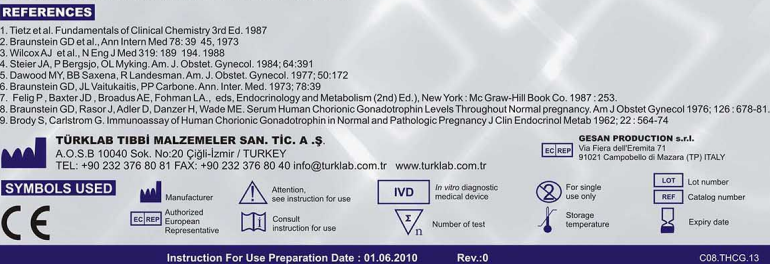

Figure 1

QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

Cut off: 10 IU hCG/L

Sensitivity : 99,4%
Specificity : 99,9%
+ Predictive value : 99,9%
- Predictive value : 98,4%

		Reference	
		+ Result	- Result
Test	+ Result	491	0
	- Result	3	190

The test has been standardized to WHO International Standard.
There is no Hook Effect (Measurement range up to 200.000 IU hCG/L)
Varying sample pH within the range of 4 and 9 has no significant effect on the assay results.
Varying sample specific gravity within the range of 1.003 1.040 has no significant effect on the assay results.

Cross Reactivity : Cross reactivity has been tested with hormones as hFSH, hLH, hTSH. The addition of LH (500 IU/L), FSH (1000 IU/L), TSH (1000 IU/L) to negative and positive samples showed no cross reactivity with the hCG Pregnancy Rapid Test.

Interferences : Following potentially interferences substances were added to hCG positive and negative samples.

h Albumin	10 mg/L	h Haptoglobin	10 mg/L	h Myoglobin	10 mg/L
Cow milk	100 mg/L	Ascorbic acid	2 g/L	Salicylic acid	1 g/L
Fruit acid	4 g/L	Alcohol	5 ml/L	Cellulose	5 g/L
Peroxides	100 mg/L	Bovine serum	100 mg/L	Caffeine	20 mg/dl
Glucose	2000 mg/dl	Hemoglobin	1 mg/dl	Protein	2000 mg/dl
Gentisic Acid	20 mg/dl	Atropine	20 mg/dl		

None of the substances at the concentrations tested interfered in the assay.
Hemolytic samples should not be used since they can cause to invalid or false results. The test is designed for urine / serum samples. Using whole blood samples may cause invalid or false results.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy man. Healthy pregnant women have hCG present in their urine and serum samples. The amount of hCG will very greatly with gestational age and between individuals. One step hCG test has a susceptibility of 10 IU/L for urine / serum. The test is capable of detecting pregnancy within the 7 days before expected menstruation period.

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SYMBOLS USED

CE
Manufacturer
EC REP Authorized European Representative
Attention, see instruction for use
Consult instruction for use
IVD *In vitro* diagnostic medical device
Σ n Number of test
For single use only
Storage temperature
LOT Lot number
REF Catalog number
Expiry date