RapidTech HCG
One Step Urine Pregnancy test

REF ATI-100

INTENDED USE
For the rapid determination of human chorionic gonadotropin (hCG) in urine specimens. This test kit is used to obtain a visual, qualitative result for early detection of pregnancy. This product is for professional use only.

SUMMARY AND EXPLANATION
Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after implantation. hCG can be detected in the urine and serum of pregnant women as early as 6 to 15 days after conception. The concentration of hCG increases to 5-50 IU/L one week post implantation, reaches about 100 IU/L at the time of the first missed menstrual period, and peaks at 100,000-200,000 IU/L at the end of the first trimester[1]. 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.
The RapidTech HCG test kit is a rapid test to detect the presence of hCG in urine specimens in a qualitative format sensitive to 20 IU hCG/L. The test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of hCG in urine. The immunological specificity of the test kit virtually eliminates cross reactivity interferences from the structurally related glycoprotein hormones hFSH, hLH, hTSH at physiological levels.

PRINCIPLE
The RapidTech HCG test is a qualitative, two site sandwich immunoassay for the determination of hCG in urine. The membrane is precoated with monoclonal mouse anti-hCG-α on the test band region and polyclonal goat anti-mouse on the control band region. During the test, the patient urine is allowed to react with the coloured colloidal gold-monoclonal mouse anti-hCG-β conjugate which was predried on the test strip. The mixture then moves across the membrane by capillary action. A pink-purple coloured band with the antibody-antigen complex will form on the membrane at the test band region when the hCG concentration is greater than 20 IU/L. Absence of this coloured band in the test band region suggests a negative result. To serve as a procedural control, a coloured band at control region will always appear regardless of the presence of hCG in the test specimen.

SPECIMEN COLLECTION AND STORAGE
Any urine specimen is appropriate for hCG testing, but the first morning urine is optimal because it generally contains the highest concentration of hCG. Urine specimens may be collected in any clean, dry, disposable container. Do not use reusable containers to avoid carry-over. Specimens may be kept at room temperature for 8 hours or refrigerated at 2°C to 8°C for up to 72 hours. Samples may be frozen at -20°C or below. Mix after thawing. Do not refreeze. Do not add preservatives. Allow specimens to reach room temperature before testing. Centrifuge very turbid urine or filter prior to use. Samples with visible precipitates should be allowed to settle and the clear supernatant used for testing.

REAGENTS AND MATERIALS SUPPLIED
1. Test device with monoclonal mouse anti-hCG-α, polyclonal goat anti-mouse, and coloured colloidal gold monoclonal mouse anti-hCG-β conjugate.
2. Instruction For Use.

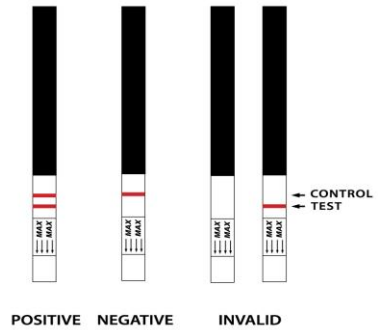
MATERIALS REQUIRED BUT NOT SUPPLIED
1. Specimen collection container.
2. Timer.

PRECAUTIONS
1. For professional in vitro diagnostic use only.
2. Do not use after the expiration date.
3. Use the strip immediately after opening the protective pouch.
4. Do not touch the test result window on the strip.
5. Urine specimens and used strips should be considered potentially hazardous. Handle in the same manner as an infectious agent. Dispose according to local regulations.
6. Do not use haemolysed urine for testing.
7. For single use only. Do not reuse.

STORAGE AND STABILITY
Store at a temperature between 2°C and 30°C. Keep away from heat, moisture, and direct sunlight. Sealed tests are stable until the expiry date printed on the pouch.

TEST PROCEDURE
Bring test strips, patient samples, controls and reference materials to room temperature 20°C to 30°C prior to testing.
1. Tear open the sealed pouch and remove test strip. Label the strip with patient or control identification.
2. Immerse the strip into the urine with the arrow end pointing towards the urine. Do not immerse pass the MAX (maximum) line. You may leave the strip in the urine or you may take the strip out after a minimum of 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface (e.g. mouth of the urine container).
3. Coloured band(s) will appear. Depending on the concentration of hCG in the test specimen, positive results may be observed as soon as 10-30 seconds. However, confirm negative results, the complete reaction time of 5 minutes is required. **Do not interpret results after 10 minutes.**

INTERPRETATION OF RESULTS
Positive: Distinct colour bands appear at the control and at the test region. Colour intensity of the test bands may vary. Any colour in the test region indicates a positive result.
Negative: Only one colour band appears at the control region. No visible band appears at the test region.
Invalid: No visible bands appear at all, or no visible band shows at the control region even if there is colour at the test region. Repeat the test.



QUALITY CONTROL
An internal procedural control is included in the test. The colour band appearing at the control region of the test window indicates proper performance and reactive reagents.
Good laboratory practice suggests the use of external controls to ensure proper procedure and performance. Negative and positive controls containing hCG at various concentrations are available at Innovatek Medical Inc.

LIMITATIONS
1. A number of conditions other than pregnancy, including trophoblastic disease and certain nontrophoblastic neoplasms, cause elevated levels of hCG. These diagnosis should be considered if appropriate to the clinical evidence.
2. Certain heterophile antibodies may cause false-positive reactions.
3. If the urine specimen is too dilute (i.e. low specific gravity) it may not contain representative level of hCG. If pregnancy is still suspected, a first morning urine should be obtained from the patient 48-72 hours later and tested.
4. 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 clinical and laboratory findings have been evaluated.
5. False negative reaction may occur when the HCG level in the urine specimen is extremely high. This typically occurs when the patient's HCG levels peaks at 12-16 week pregnancy. If this is suspected, the user can dilute one drop of urine with 50 drops of saline and retest the diluted urine using a fresh test strip. If the diluted specimen gives a positive result, the pregnancy test can be read as positive.
6. The red colour of haemolysed urine may mask the colour of weak positive test result.

PERFORMANCE CHARACTERISTICS
Specificity
RapidTech hCG urine test device was evaluated in an experiment to determine the cross reactivity of structurally related hormones: human luteinizing hormone (hLH), human follicle stimulating hormone (hFSH), and human thyroid stimulating hormone (hTSH). hFSH, hLH or hTSH were added to urine samples containing hCG at concentration of 0, 20 or 100 IU/L. No cross reactivity was observed in the study.

Sensitivity
The sensitivity of the test is ≥ 20 IU/L of hCG in urine.
A clinical evaluation was carried out for the clinical performance of RapidTech hCG test. Total 400 samples were recruited and tested by ELISA which identified 187 positive samples, 213 negative samples. RapidTech hCG test could detect correctly all the 187 positive samples and 209 negative samples from the total 213 negative samples confirmed by ELISA. The results are demonstrated below and specificity and sensitivity were calculated:

Commercial EIA Assay	RapidTech HCG test		Total
	POS	NEG	
POS	187	0	187
NEG	4	209	213
Total	191	209	400

Diagnostic Sensitivity: 187/ 187×100% = 100%
Diagnostic Specificity: 209/(4+209)×100% = 98.1%
Overall Agreement: (187+209)/400×100% = 99.0%

Standardization
The RapidTech HCG test has been standardized to World Health Organization Third International Standard (WHO 3rd IS 75/589).

Interference Testing
The following conditions were found not to interfere with RapidTech hCG test:

Acetaminophen	20 mg/dL	Acetylsalicylic acid	20 mg/dL
Albumin	2 g/dL	Ascorbic acid	20 mg/dL
Atropine	20 mg/dL	Benzoylecgonine	10 mg/dL
Bilirubin	1 mg/dL	Caffeine	20 mg/dL
Cannabinol	10 mg/dL	EDTA	80 mg/dL
Ethanol	1 %	Gentesic acid	20 mg/dL
Glucose	2 g/dL	Haemoglobin	1 mg/dL
Methanol	1 %	Phenylpropanolamine	20 mg/dL
Salicyclic acid	20 mg/dL	Urine pH	5-6, 8-9

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