QuickStep™ Plus
One Step Urine Pregnancy Test

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.

SUMMARY AND EXPLANATION OF PROCEDURE

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 increased to 5-50 mIU/mL one week post implantation, reaches about 100mIU/mL at the time of the first missed menstrual period, and peaks at 100,000-200,000 mIU/mL at the end of the first trimester[1].

The appearance of hCG soon after conception and its subsequent rise in concentration during early gestation growth make it an excellent marker for the early detection of pregnancy.

The ***QuickStep Plus*** test kit is a rapid test to detect the presence of hCG in urine specimens in a qualitative format sensitive to 20 mIU hCG/mL. The test utilises a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated level of hCG in urine. The immunological specificity of the test kit virtually eliminates cross reactivity interferences form the structurally related glycoprotein hormones hFSH, hLH, hTSH at physiological levels.

PRINCIPLE

The ***QuickStep Plus*** test is a qualitative, two site sandwich immunoassay for the determination of hCG in urine. The membrane was precoated with goat anti-hCG on the test band region and goat anti-mouse on the control band region. During the test, the patient urine is allowed to react with the coloured colloidal gold-monoclonal anti-hCG conjugate which was predried on the test device. The mixture then moves upward on the membrane by the capillary action. For a positive result, a colour band with the specific antibody-hCG-coloured conjugate complex will form on the membrane. Absence of this coloured band in the test band region suggest a negative result. To serve as a procedural control, a coloured band at control region will always appear regardless the presence of hCG in test specimen.

REAGENTS AND MATERIALS SUPPLIED

Test device: Containing membrane coated with goat anti-hCG and coloured colloidal gold-monoclonal mouse anti-hCG conjugated predried in pad.

STORAGE AND STABILITY

The test kit can be stored at normal room temperature (2-30°C) in the desiccated pack up to the expiration date. The packs should be kept from direct sunlight, moisture and heat.

The test kit must be used immediately once the desiccated pack is opened.

PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.

SPECIMEN COLLECTION

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, plastic or glass container. If specimens cannot be assayed immediately, they may be stored in the refrigerator (2-8°C) for up to 72 hours prior to assay. Preservatives are not required.

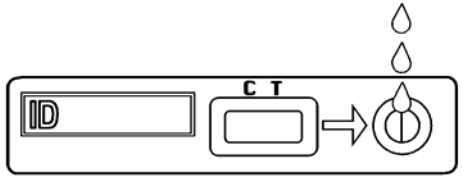
Specimen should be allowed to reach room temperature before testing. Very turbid urine specimen should be centrifuged or filtered prior to use. Samples with visible precipitates should be allowed to settle and the clear supernatant used for testing.

ASSAY PROCEDURE

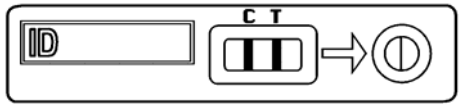
1. Review Specimen Collection instructions. Test device, patient's sample, or control should be brought to room temperature (18-30°C) prior to testing.
2. Remove the test device from the desiccated pack (bring the device to room temperature before opening to avoid condensation of moisture on the membrane). Label the device with patient or control identification.
3. Add 3 drops of urine into the samples well. Hold the pipette in a straight up and down position - not at an angle. For each sample or control, use a separate pipette and test device.
4. Wait for coloured bands to appear. Depending on the concentration of hCG in the test specimen, positive results may be observed in as short as 20 seconds. However, to confirm negative results, the complete reaction time of 5 minutes is required. **Do not interpret results after 10 minutes.**

INTERPRETATION OF RESULTS

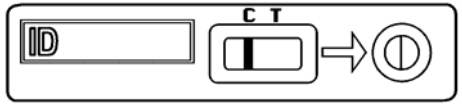
1. **Negative:** Only one colour band appears on the Control region. No apparent band on the Test region.
2. **Positive**: Distinct colour bands appear on the Control and Test regions. Colour intensity of the bands may vary.
3. **Invalid**: No visible band at all or no visible band at the Control region. Repeat test.



Add specimen



Positive



Negative

QUALITY CONTROL

The procedural control is included in the test. A colour band appearing on the control region of the device indicates proper performance and reactive reagents.

Good laboratory practices include the use of control specimens to ensure proper kit performance. Negative and positive controls containing hCG at various concentrations are available commercially.

PROCEDURE LIMITATION

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. 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.
3. 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity:

The ***QuickStep Plus*** detects urine hCG concentrations greater than 20 mIU/mL as indicated by the appearance of a colour band at the test region.

Specificity of the ***QuickStep Plus*** test was determined from cross reaction studies with known amounts of luteinizing hormone (hLH), follicle stimulating hormone (hFSH), and thyroid stimulating hormone (hTSH). 300 mIU hLH/mL, 1,000 mIU hFSH/mL and 1,000 µIU hTSH/mL all gave negative results.

Standardisation

The ***QuickStep Plus*** test has been standardised to World Health Organisation First International Reference Preparation (WHO 1st IRP 75/537).

Interference Testing

The following substances were added in hCG free and 50 mIU hCG/mL spiked urine samples. None of the substances at concentration tested interfered in assay.

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	2 g/dL
Haemoglobin	1 mg/dL

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