Test-it™ PREGNANCY Lateral Flow Assay
Immunoassay for Human Chorionic Gonadotropin (HCG) in Human Urine

Product Codes
HCG001

Intended Use
Life Assay manufactures the Test-it™ range of lateral flow assays for serodiagnosis of diseases and conditions in humans. The Test-it™ Pregnancy test is designed for the detection of Human Chorionic Gonadotropin (HCG) in urine with a high degree of accuracy.

Introduction and Test Principle
Human chorionic gonadotropin is a hormone normally produced by the placenta. Since hCG is present in the serum and urine of pregnant women, it is an excellent marker for confirming pregnancy. The Test-it™ Pregnancy lateral flow assay is a simple and rapid assay. It does not require special training, equipment, or electricity. Results are obtained in 3 minutes. The test is a lateral-flow test using a monoclonal antibody specific to the beta subunit of hCG to accurately detect hCG as early as 2 or 3 days before the expected menses. To perform the test, a serum or urine sample is collected and added to the Sample window of the device. If the sample contains hCG, a pink/red vertical line forms in the Test zone. This pink vertical line indicates a positive result. If hCG is not present in the sample, no line will form in the Test zone. As the sample continues to move through the test, a pink/red line in the Control zone becomes visible. This indicates that the test is functionally active and is also evidence that the test has been performed correctly. The test assays can be stored at +4°C to +28°C.

COLLECTION
Collect urine specimens in a clean container. Urine collected anytime during the day can be used. For optimal results, it is best to test the first urine voided in the morning because it contains the greatest concentration of hCG. Samples can be stored for 8 hours at room temperature (15–30°C) or up to 72 hours refrigerated (2–8°C). DO NOT freeze the urine sample. No special patient preparation is necessary. A whole blood specimen should be obtained by standard medical procedures. After clotting has occurred, the separated serum should be used for testing. Serum specimens may be stored refrigerated (2–8°C) for up to 48 hours prior to assay. If testing will be delayed for more than 48 hours, the sample may be frozen once at -20°C or below. If frozen, mix after thawing. Do not re-freeze. Do not chemically modify the serum in any way.

Standard Assay Procedure - CASSETTE
1. Remove a Test-it™ HCG lateral flow assay device from the packaging and place flat with the test window facing upwards.
2. Immediately check if desiccant is still orange in colour. If desiccant has turned green, the test has been exposed to moisture and the test must be discarded.
3. Using a plastic pipette or micropipette, add 100 µl (4 drops) of urine or 75µl of serum to the round sample port.
4. You will see the reagent moving across the test and control zones. This shows that the test is working.
5. Read results at 3 minutes for urine and 5 minutes for serum. Note: Some positive results may appear sooner.

INTERPRETATION OF TEST RESULTS
Positive Result: Indicated by the presence of a line at the test zone (T) and a line at the control zone (C). Note: The intensity of the control line (C) can vary and a weak control line does not indicate a poor test (T) result.

Negative Result: Indicated by absence of a line at the test zone (T) and presence of a line at the control zone (C).
Standard Assay Procedure - DIPSTICK

1. Remove a test strip from foil pouch
2. Dip in urine up to arrow mark for 3 seconds
3. Remove, lay flat, read result in 5 minutes

INTERPRETATION OF TEST RESULTS

Positive Result: Indicated by the presence of 2 red lines
Negative Result: Indicated by the forming of one red line only.

LIMITATIONS

The contents of this kit are for use in the qualitative detection of hCG in serum or urine. Test results must always be evaluated with other data available to the physician. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Very low levels of hCG are present in serum and in urine shortly after implantation. Positive test results from very early pregnancy may later prove negative due to natural termination of pregnancy. This is estimated to occur in up to 50% of all conceptions. If a very low, faint positive serum result is obtained, another sample should be obtained in 48 hours and retested. If waiting 48 hours is not medically advisable, the test result should be confirmed with a quantitative hCG test. Patients with trophoblastic and nontrophoblastic disease may have elevated hCG levels, therefore, the possibility of hCG secreting neoplasms should be eliminated prior to the diagnosis of pregnancy. If a urine sample is too dilute, it may not contain a representative urinary hCG concentration. If a negative result is obtained and pregnancy is still suspected, a first morning sample should be obtained and tested.

Sensitivity of the test

20 MIU/ml in urine; 10-20 MIU/ml in serum
In normal pregnancy, hCG levels in urine can reach 20 mIU/ml as early as 7 days post conception, and continue to increase exponentially to reach a maximum concentration in excess of 200,000 mIU/ml at the end of the first trimester.