HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Parasitology)		
Document:	Internal Policy and Procedure		
Title:	Urine Pregnancy Test		
Applies To:	All Laboratory Staff		
Preparation Date:	January 02, 2025	**Index No:**	LB-IPP-026
Approval Date:	January 16, 2025	**Version:**	2
Effective Date:	February 16, 2025	**Replacement No:**	LB-IPP-026(1)
Review Date:	February 16, 2028	**No. of Pages:**	04

1. PURPOSE:

1.1 A one-step immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine specimens for the early detection of pregnancy.

2. DEFINITONS:

N/A

3. POLICY:

3.1 The assay is conducted by the addition of a urine specimen into the sample well and observing for the formation of coloured lines in the result area. The specimen migrates via capillary action along the membrane and reacts with the antibody-dye conjugate. Positive hCG specimens form a coloured line in the Test Zone (T) portion of the membrane. Absence of this coloured line suggests a negative result. To serve as a positive procedural control, a coloured line in the Control Zone (C) will always appear regardless of the presence or absence of hCG.

4. PROCEDURE:

4.1 **Specimen:**

4.1.1 Urine specimens should be collected in a clean, dry container such as a urine collection cup.

4.1.2 Specimens may be collected at any time of the day. First morning urine samples are preferred since they normally contain the highest levels of hCG.

4.1.3 If not tested immediately, urine may be stored refrigerated at 36—46oF (2—8oC) for up to 72 hours. Samples must be brought to room temperature 59—86oF (15—30oC) before testing.

4.1.4 If a sample will not be tested until more than 48 hours after collection, it should be stored frozen (-20oC or below) for up to three months. Prior to testing, frozen samples must be completely thawed, thoroughly mixed, and brought to room temperature.

4.1.5 Urine specimens exhibiting visible precipitates should be centrifuges, filtered, or allowed to settle to obtain a clear specimen for testing.

4.1.6 Specimen rejection criteria: Samples of unknown age or in unapproved containers should be rejected, and a fresh sample collected.

4.2 **Storage and Stability:**

4.2.1 The test kit is to be stored at room temperature, 59-86 oF (15-30oC), for the duration of the shelf life. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not use beyond the expiration date.

4.2.2 Do not freeze. The test cassettes must be at room temperature for use.

4.2.3 Do not use the test cassette if the protective pouch has been punctured, if the device appears damaged, or if the membrane appears discoloured or damaged.

4.3 **Method:**

4.3.1 Review specimen collection instructions.

4.3.2 The test device, patient sample, and controls must be brought to room temperature 59-86 °F (15-30 °C) prior to testing.

4.3.3 Remove the test device from its protective pouch. Do not open the foil pouch until ready to perform the test.

4.3.4 Place the device on a clean level surface and label the device with patient or control identification.

4.3.5 Hold the dropper vertically and transfer two (2) full drops of urine (approximately 0.12 mL) to the round sample well of the test device, and then start the timer. Avoid trapping air bubbles in the sample well (S).

4.3.6 Wait for the coloured line(s) to appear in the test result window. Read the result at three (3) minutes and then discard the cassette. It is important to ensure that the background is clear before a result is recorded

4.4 **Results:**

4.4.1 Negative: One coloured line appears in the control zone marked "C". No apparent coloured line appears in the test result region (T). A negative result indicates that the concentration of hCG is below the detection sensitivity of the test and that the patient is not pregnant or it is too soon for the pregnancy to be detected.

4.4.2 Positive: Two coloured lines appear, one in the test result region marked "T" and one in the control result region marked "C". A positive result indicates that hCG has been detected at or above a concentration of 20 mIU/mL in the sample, a strong indicator that the patient is pregnant. The coloured lines may vary in intensity.

4.4.3 Invalid: A coloured line fails to appear in the Control Zone.
An invalid result may be due to deterioration of the test reagents or to improper testing procedure (such as insufficient specimen volume).
Carefully review the procedure and retest the sample with a new cassette.
All failed tests must be documented and the appropriate corrective action must be initiated and documented.

4.5 **Interpretation of Results:**

4.5.1 Positive test results may be interpreted as soon as colour develops on the test result region in the square test window and on the control line region in the round control window. Weak positive results may show a lighter coloured line in the Test Zone than the coloured line appearing in the Control Zone

4.5.2 The intensity of the coloured colour in the test result region will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by a qualitative test.

4.5.3 Weakly reactive positive or negative test results in patients suspected to be pregnant should be confirmed by a fresh early morning sample obtained 48-72 hours later, or by performing a quantitative hCG assay.

4.6 **Limitations of the procedure:**

4.6.1 A number of conditions other than pregnancy can result in a false positive test result. These conditions include trophoblastic disease and certain non-trophoblastic neoplasms and should be considered if appropriate to the clinical evidence. Therefore, the presence of hCG in urine samples should not be used to diagnose pregnancy unless these conditions have been ruled out.

4.6.2 Normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels. Spontaneous miscarriage may also cause confusion in interpreting assay results.

4.6.3 Specimens from clients who have received preparation of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). These specimens may demonstrate either false positive or false negative results when tested with assays which employ mouse monoclonal antibodies.

4.6.4 Do not use test devices which have become wet or which have been left out of the foil pouch for more than 24 hours.

4.6.5 Positive results from early pregnancy may later prove negative due to natural termination of the pregnancy. This is estimated to occur in 22% of clinical unrecognized pregnancies and 31% of pregnancies overall. It is therefore recommended that weak positive results be re-tested 48-72 hours later.

4.6.6 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 should be obtained 48-72 hours later and retested.

4.6.7 As with all pregnancy tests, the final diagnosis should be based on a correlation of test results with typical clinical signs and symptoms.

5. MATERIAL AND EQUIPMENT:

5.1 Test devices
5.2 Disposable specimen droppers
5.3 Specimen collection containers
5.4 Timer or watch that measures minutes and seconds

6. RESPONSIBILITIES:

6.1 The assigned technetium will perform the test

7. APPENDICES:

N/A

8. REFERENCES:

8.1 ATG Biotech One Step Pregnancy Test package insert.
8.2 Stanbio True® One Step Pregancy Test package insert. Stanbio Laboratories, Boerne, TX

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Talal Abdelgawad	Clinical Pathologist		January 02, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 07, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 08, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 12, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 16, 2025