A. Purpose:
The Cardinal Health hCG rapid cassette pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

Human chorionic gonadotropin is a hormone produced by the placenta shortly after fertilization. Since hCG is present in the serum and urine of pregnant women, it is an excellent marker for confirming pregnancy.

The Cardinal Health hCG rapid pregnancy Test uses a monoclonal and polyclonal antibody specific to the beta subunit of hCG in a single-step technology to accurately detect elevated levels of hCG in urine.

B. Principle:
Urine is added to the Sample Well of the Test Cassette. The sample migrates by capillary action through a pad containing mouse monoclonal anti-hCG and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. If the sample contains hCG, a color complex is formed with the anti-hCG detection reagent. The hCG complex will continue to migrate to the Result Window and be bound by polyclonal anti-hCG spotted on the test line.

If hCG is present in the sample at a level of 25 mlU/mL or greater, a red Test (T) line along with a red procedural Control (C) Line will appear in the result window. If hCG is present at low levels, or not present in the sample, only a red procedural Control Line will appear.

C. Policy:
1. A physician’s or PA’s order is required.
2. LifeBridge Health Trainers will be identified and trained by POCT Team Leader or Technical Specialist.
3. Certification as LifeBridge Health operators will include an in service, completion of a written examination, and will perform a test.
4. Re-certification for operators and trainers will be done yearly.
5. LifeBridge Health Certified Trainers are responsible for implementation and maintenance of certification records.

6. A record of LifeBridge Health Certified Operators and Trainers will be maintained on each nursing unit, in Staff Development, and in Pathology.

7. The Bedside Testing Team Leader/Technical Specialist will supply Nursing Directors with a monthly report identifying problems concerning Point-of-Care Testing.

8. Documentation of follow-up investigation and corrective actions taken will be returned to Pathology to be maintained by the Point-of-Care Team Leader/Technical specialist.

9. Results will be recorded:
   a. For In-Patient Locations:
      Will be entered into the glucose meter and then downloaded to PowerChart. For any problems in entering patient identification or entry of incorrect results, nursing units will notify POCT and corrections will be made.
   b. For Out-Patient Locations:
      Results will be entered in the Patient’s Medical Record or in Cerner using special software available in their location. For any corrections, it is the responsibility of that location to make corrections.

D. Specimen:

1. Specimen Type: Urine

2. Patient Preparation: N/A

3. Handling Conditions: Collect specimen in a clean container. First morning specimens generally contain the highest concentrations of hCG and are recommended for early detection of pregnancy. However, any urine sample is suitable for testing. Urine specimen containing visible precipitates should be allowed to settle to obtain a clear specimen for testing.

4. Storage Requirements: Urine specimens are tested immediately.

5. Rejection Criteria: If patient has heavy vaginal bleeding, blood should be drawn and sent to lab.

E. Equipment and Materials:

1. Equipment: Cardinal Health hCG rapid pregnancy test cassette for urine

2. Materials/Supplies:
   a. Individually wrapped Test Cassettes. Each device contains mouse monoclonal antibody and goat polyclonal antibody to hCG
b. Disposable pipettes (included in each individually wrapped cassette package)
c. Watch with a second hand or timer
d. Sample collection containers

3. Preparation: N/A

4. Performance Parameters: The Cardinal Health hCG rapid pregnancy Test will detect urine hCG concentrations as low as 25 mIU/mL.

5. Storage Requirements: Store kit at room temperature 2-30ºC (36-86°F) out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box carton. Do not freeze.

F. Calibration:

1. Standard Preparation: N/A

2. Calibration Procedure: N/A

G. Quality Control:

1. Materials Used: Cardinal Health hCG rapid pregnancy Test Controls: Alere HCG urine controls

2. Preparation and Handling: When stored refrigerated (2-8°C) controls are stable for 90 days from date of opening or the expiration date, whichever comes first. When stored at room temperature (18-25°C) controls are stable for 31 days or until the expiration date, whichever comes first.

3. Frequency Run: Liquid quality controls using a positive and negative control are performed once per shipment and/or lot numbered when received at hospital and weekly thereafter.

4. Tolerance Limits: The Cardinal Health hCG rapid pregnancy Test contains built-in control features. The development of the Red Procedural Control Line next to the letter “C” is a positive procedural control. If this line does not develop, the test result is invalid. The absence of color within the white background is a negative procedural control. If background color appears in the Result Window it interferes with your ability to read the test result, your result may be invalid.

5. Corrective Action: Contact Alere Technical Assistance at 877-441-7440, option 2 or Point of care staff by vocera (2-1000 for Sinai 5-7500 for Northwest): Point of Care testing.

H. Procedure:
1. Apply gloves.
2. Collect urine sample from patient in unused, plastic, container labeled with patient’s name, date of birth and unit number (patient label).
3. Check expiration date on Cardinal Health hCG rapid pregnancy Test. If beyond expiration, discard test and get a new box of pregnancy kits.
4. Remove the Cardinal Health hCG rapid pregnancy Test from the pouch and place on a clean, dry, level surface.
5. Using the disposable pipettes supplied, in the pouch, add 3 full drops of urine to the round sample well on the test cassette. Do not pick up the cassette. Avoid trapping air bubbles in the specimen well.
6. Wait exactly 3 MINUTES to read results. Read results before the 4 minute mark. Use a watch or timer; **Timing IS Critical**.
7. Record results as stated in Policy related to the location where test was performed.
8. Discard all contaminated materials in appropriate biohazard containers.
9. Notify doctor if necessary.

I. **Expected Values:**
   Specimens containing as low as 25 mIU/mL hCG will yield positive results when tested with the Cardinal Health hCG rapid pregnancy Test. In normal pregnancy, hCG can be detected as early as 7-10 days following conception with concentrations doubling every 32 to 48 hours. Levels of 25 mIU/mL are reportedly present in urine as early as 1 day after the first missed menses.

J. **Interpretation of Results:**
   1. **Positive:**
      The appearance of any red line next to the letter “T” in the result test window, along with a red procedural Control Line next to the letter “C.”
   2. **Negative:**
      The appearance of the red procedural Control Line next to the letter “C” only and no red line next to the letter “T” at 3 minutes.
   3. **No Result:**
      If no red procedural Control Line appears next to the letter “C”, the test is invalid, and the specimen must be retested.

K. **Limitations:**
   The contents of this kit are for use in the **qualitative** detection of hCG in urine only.
   1. While pregnancy is the most likely reason for the presence of hCG in serum and urine, elevated hCG concentrations unrelated to pregnancy have been reported in some patients. hCG may remain detectable for a few days to several weeks after delivery, abortion, or hCG injections. Natural termination occurs in 31% of pregnancies overall and 22% of clinically unrecognized pregnancies. Abnormal pregnancies cannot be diagnosed by qualitative hCG results. The above conditions should be ruled out when diagnosing pregnancy.
2. Very dilute urine specimens, as indicated by low specific gravity, may not contain representative urinary hCG concentrations. If pregnancy is still suspected a first morning urine specimen should be collected 48 hours later and tested.

3. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine or serum specimen should be collected and tested 48 hours later.

4. This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect hCG degradation products and therefore may disagree with the results of this rapid test.

5. A number of conditions other than pregnancy, including trophoblastick disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.

6. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.

7. The presence of hCG in urine as determined by using the Cardinal Health hCG rapid pregnancy Test must always be evaluated in conjunction with other clinical and laboratory data available to the clinician.

L. Calculations: N/A

M. Reporting Results: In Accu-chek Inform II, Powerform or on Point-Of-Care Result Sheet.

N. Procedure Notes:

1. Reference Range: Negative

2. Critical Value: N/A

3. Reporting Format: Positive or negative

4. Hazardous Materials: Urine samples

5. Protective Equipment Requirements: gloves

O. Limitation of Procedure:

1. Linearity: N/A
2. **Interfering Substances**: The following chemical and biological compounds were evaluated using the Cardinal Health hCG rapid pregnancy Test. All compounds were added to hCG positive and negative specimens.

<table>
<thead>
<tr>
<th>Analytes</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Acetone</td>
<td>1,000 mg/dL</td>
</tr>
<tr>
<td>Acetylsalicylic Acid</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Acetoacetic Acid</td>
<td>2,000 mg/dL</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>20 mg/dL</td>
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<tr>
<td>Atropine</td>
<td>20 mg/dL</td>
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<tr>
<td>Albumin</td>
<td>2,000 mg/dL</td>
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<tr>
<td>β-Hydroxybutyrate</td>
<td>2000 mg/dL</td>
</tr>
<tr>
<td>Benzoylecgonine (cocaine metabolite)</td>
<td>10 mg/dL</td>
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<tr>
<td>Brompheniramine</td>
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<tr>
<td>Caffeine</td>
<td>20 mg/dL</td>
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<tr>
<td>Clomiphene</td>
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<tr>
<td>Cocaine</td>
<td>10 mg/dL</td>
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<tr>
<td>Codeine</td>
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<tr>
<td>Cholesterol</td>
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<tr>
<td>Creatinine</td>
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<tr>
<td>Dextromethorphan</td>
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</tr>
<tr>
<td>DMSO</td>
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<tr>
<td>Ephedrine</td>
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<tr>
<td>Estrone 3-sulfate</td>
<td>10 mg/dL</td>
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<tr>
<td>Gentisic Acid</td>
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<tr>
<td>Heroine</td>
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<tr>
<td>Ibuprofen</td>
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<tr>
<td>Methamphetamine</td>
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<td>Morphine</td>
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<tr>
<td>Oxalic Acid</td>
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<tr>
<td>Phenylpropanolamine</td>
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<tr>
<td>Salicyclic Acid</td>
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<tr>
<td>Triglycerides</td>
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<tr>
<td>Theophylline</td>
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<td>Phenothiazine</td>
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<tr>
<td>EDTA</td>
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<td>Cannabinol</td>
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<tr>
<td>Methadone</td>
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<tr>
<td>Ethanol</td>
<td>1.0 %</td>
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<tr>
<td>Methanol</td>
<td>10.0 %</td>
</tr>
<tr>
<td>Urea</td>
<td>2,000 mg/dL</td>
</tr>
</tbody>
</table>
Uric Acid 20 mg/dL

b. Urine Analytes: Concentration:
   Glucose 2000 mg/dL
   Bilirubin 1000 mg/dL
   Hemoglobin 1000 mg/dL

c. Hormones: Concentration:
   Estriol 2 mg/dL
   Pregnanediol 2 mg/dL

P. REFERENCES:

Q. ATTACHMENTS: N/A