



**ARROWHEAD REGIONAL MEDICAL CENTER**  
**Department of Ambulatory Care Services**  
**Primary Care Clinics Policies and Procedures**

**Policy No. 567.00 Issue 1**

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**SECTION: PATIENT CARE**

**SUBSECTION: DIAGNOSTIC TESTS AND POINT OF CARE**

**SUBJECT: MANUAL URINE PREGNANCY TESTING AND QUALITY CONTROL**

**APPROVED BY:** \_\_\_\_\_

Clinical Director, Ambulatory Services

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**POLICY**

The human chorionic gonadotropin (hCG) Pregnancy Test Cassette is for the qualitative detection of hCG in urine to aid in the early detection of pregnancy. This test provides onsite pregnancy results to the Practitioners making timely treatment decisions.

The Clinic Staff of the Primary Care Clinics (PCCs) perform urine pregnancy testing. Clinic staff trained in performing manual urine pregnancy testing include: the Medical Assistant (MA), Licensed Vocational Nurse (LVN), and the Registered Nurse (RN).

Quality Control (QC) is conducted on all tests performed in the PCCs on any reagents or equipment used for tests in accordance with Department and Arrowhead Regional Medical Center (ARMC) policy. The results are kept in the Point of Care Testing (POCT) Log.

**PROCEDURES**

I. Precautions

- A. For professional in vitro diagnostic use only.
- B. Test cassettes should remain in the sealed pouch until use.
- C. DO NOT use after Expiration Date.
- D. Test cassettes should be discarded in a proper receptacle by ARMC protocol and or policy.
- E. The test cassette is for single use only.

II. Storage and Stability

- A. Store as packaged in the sealed pouch at temperature per manufacturer guidelines
- B. The test cassette is stable through the expiration date printed on the sealed pouch if stored per manufacturer guidelines
- C. The test cassette must remain in the sealed pouch until use.

- D. Do Not Freeze.
- E. Do not use items beyond the expiration date.

### III. Specimen Collection and Preparation

- A. A urine specimen must be collected in a clean and dry container.
- B. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG.
- C. Urine specimens collected at any time of the day may be used.
- D. Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.
- E. Specimen Storage
  - 1. Urine specimens may be stored at 36- 46 °F (2-8 °C) for up to 48 hours prior to testing.

### IV. Materials

- A. Materials Provided
  - 1. Test cassettes
  - 2. Disposable pipettes
  - 3. Manufacturer Product insert
- B. Materials Required but Not Provided
  - 1. Specimen collection container
  - 2. Timer

### V. Directions for Use

- A. If specimen sample or test cassette was refrigerated, allow to reach room temperature prior to testing.
- B. Remove test cassette from the sealed pouch and use it as soon as possible.
- C. Place the test cassette on a clean and level surface.
- D. Hold the pipette vertically and transfer the specified amount of urine per manufacturer to the specimen well of the test cassette and start the timer.
- E. Wait for the red line (s) to appear.
- F. Read the result at the time specified by the manufacturer. Do Not Read Results after the appropriate read time.
- G. It is important that the test cassette background is clear before the test is read.

VI. Documentation of Results

A. Positive

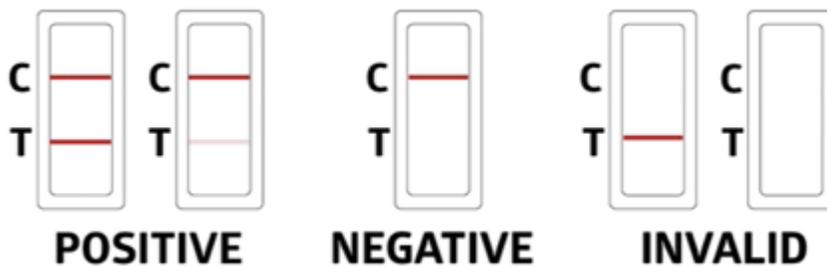
1. Positive results appear as per the manufacturer package insert

B. Negative

1. Negative results appear as per the manufacturer package insert

C. Invalid

1. Invalid results appear as per the manufacturer insert
  - a. Insufficient specimen volume or incorrect procedure techniques are the most likely reasons for test failure.
2. Review the procedure and repeat the test with a new test cassette.



VII. Quality Control

A. Internal Procedural Controls

1. Internal procedural controls are included in the test cassette per manufacturer instructions.

B. External Quality Control Testing

1. It is recommended that a positive hCG control and a negative hCG control be evaluated to verify proper test performance with:
  - a. Each new lot
  - b. Every 30 days as a check on storage
  - c. Each new untrained operator.
  - d. It is recommended that federal, state, and local guidelines be followed.
2. Quality Control (QC) log includes positive control solution lot number, negative control lot number, test cassette lot number, the date the QC performed, and signature of person performing QC.

- a. QC logs are maintained in the PCCs for 3 years.
3. Quality Control Solutions
    - a. The human chorionic gonadotropin (hCG) urine control solution control kit contains two vials of testing reagents.
    - b. The vials used in each PCC for quality control testing include negative control and positive control.
    - c. Universal precautions must be taken when using hCG Control Solutions as they contain human urine.
    - d. The hCG urine control solutions must be kept refrigerated when not in use.
    - e. The hCG urine control solutions are not to be used if there is any evidence of precipitation.
    - f. The hCG urine control solutions are not to be used beyond 90 days after opening. Expiration date is documented in the box and each vial of solution.
      - 1) The hCG urine control solutions are dated with the expiration date when they are opened and not used after expiration date.
      - 2) Recognize the expiration date that comes first: The manufacturer expiration date or 90-days after opening.
  4. Remove control solutions from refrigerator
    - a. Allow refrigerated Control Solutions to reach room temperature before use.
    - b. Gently invert them to mix.
  5. Obtain two hCG urine test cassettes.
  6. Place hCG urine test cassettes on paper towel on flat surface.
  7. Place three drops of hCG urine Positive Control Solution into the Sample Well of one test cassette.
    - a. Read test result at time specified by manufacturer guidelines and record result on the Quality Control Log.
  8. Place three drops of hCG urine Negative Control Solution into the Sample Well of one test cassette.
    - a. Read test result at time specified by manufacturer guidelines and record result on Quality Control Log.
  9. Information to be recorded in the POCT Log for both Positive and Negative control solutions will include:
    - a. Lot number and expiration date of control solutions.
    - b. Lot number and expiration date of hCG urine test cassette.
    - c. Signature and title of the clinical staff completing QC.
    - d. Results obtained.
    - e. QC logs are maintained in PCCs for 3 years.

- f. If quality control results obtained are not within expected values as specified by manufacturer, the following corrective action should be taken:
  - 1) Review technique.
  - 2) Check expiration dates of control solutions and test cassette.
  - 3) Repeat test if indicated.

C. Remedial Actions

1. If unexpected results are seen when running the controls, review the Directions for Use, Interpretation of Results and Limitations sections and repeat the test with another test cassette.
2. Follow manufacturer guidelines and refer to package insert.

REFERENCES: Current manufacturer package insert

DEFINITIONS: Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception making it a marker for early detection of pregnancy.

ATTACHMENTS: N/A

APPROVAL DATE: 7/23/2025 **Kristy Byers, Clinical Director II**  
Department/Service Director, Manager or Supervisor

8/7/2025 **Ambulatory Work Group Committee**  
Applicable Administrator, Hospital or Medical Committee

9/16/2025 **Nursing Standards Committee**  
Applicable Administrator, Hospital or Medical Committee

10/22/2025 **Patient Safety and Quality Committee**  
Applicable Administrator, Hospital or Medical Committee

11/6/2025 **Quality Management Committee**  
Applicable Administrator, Hospital or Medical Committee

11/20/2025 **Medical Executive Committee**  
Applicable Administrator, Hospital or Medical Committee

3/10/2026 **Board of Supervisors**  
Approved by the Governing Body

REPLACES: PCC Policy 565.00 v7 Manual Urine Pregnancy Test  
PCC Policy 566.00 v6 Manual Urine Pregnancy Test – Quality Control

EFFECTIVE: 6/8/1999

REVISED: N/A

REVIEWED: N/A