Clinical Research Center Urine Pregnancy Point of Care Testing	CR-505
Clinical Research Standard Practices	**Effective Date:** September 2024

SCOPE AND PURPOSE This document is applicable to the following roles within Penn State College of Medicine and Penn State Health entities engaged in clinical research:

X	Principal Investigator		Regulatory Specialists
X	Sub-Investigators	X	Key Study Ancillary Personnel
X	Study Coordinators/Associates		Financial Analyst/Contract Management Accountants
	Data Specialist		Central Research Office Personnel

This standard operating procedure (SOP) describes how human chorionic gonadotropin (hCG) Point of Care Testing (POCT) will occur in the Clinical Research Center (CRC) unit of Penn State Health Milton S. Hershey Medical Center. The hCG Cassette Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of hCG in urine to aid in the early detection of pregnancy.

This test is used as a screening assay to detect pregnancy in individuals of childbearing potential whose pregnancy status is unknown, prior to prescribing medications and/or performing procedures that may cause harm to a fetus.

Due to variability in manufacturers' specifications, it is recommended that the enclosed instructions be reviewed before using a new manufacturer's kits.

This SOP may be shared with Sponsors and/or CROs upon request.

POLICY AND PROCEDURE STATEMENTS

1. Quality Control:
    a. Reagents/Supplies:
        i. CRC stock of a hCG Cassette Rapid Test cassette, individually packaged, with disposable specimen dropper. The hCG Cassette Test Kit is stored in room H4515H which is temperature controlled and monitored.
        ii. Urinalysis Dipstick Control, Level 1 and Level 2 which are stored in the Lab fridge (room H4515H), which is temperature controlled and monitored. The controls are stable until the expiration date printed on the vial.
    b. Internal procedural controls are included in each test.

        i. The appearance of a red line in the control (C) region is an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique. A red control line must be present for a valid patient test.

ii. A clear background is an internal negative procedural control. If the test is functioning properly, the background in the result area should be white to light pink and should not interfere with the ability to read the test result.

c. A positive and negative external quality control must be performed with each new lot number, each new shipment, and monthly as a check on storage conditions.
   i. Remove quality control solutions from refrigerator and allow to reach room temperature (15-30°C), at least 15 minutes.
   ii. Remove test cassette from sealed pouch. Use the cassette as soon as possible.
   iii. Place the test cassette on a clean and level surface. Transfer three (3) full drops of Level 1 quality control solution into the specimen well (S) of the test cassette. Avoid trapping air bubbles in the specimen well.
   iv. Start a timer, and wait for the red line(s) to appear.
   v. Read the results at the designated time point. It is important that the background is clear before the result is read.
      - Interpret the result:
         A. **Positive**: Two distinct red lines, one in the Control region and one in the Test region.
         B. **Negative**: One red line in the Control region. No apparent red line in the Test region.
         C. **Invalid**: Red line in the Control region fails to appear or no lines in either the Control or Test regions.
   vi. Repeat procedure with Level 2 control.

2. PATIENT TEST PROCEDURE
   a. Collect reagents/supplies.
   b. Perform hand hygiene. Universal precautions are required for all patient care. Nonsterile gloves must be worn when performing this procedure.
   c. Perform testing according to procedure outlined below:
      i. Verify expiration date.
      ii. Remove the test cassette from the sealed pouch. Use the cassette as soon as possible.
      iii. Place the test cassette on a clean and level surface. Holding the dropper vertically, transfer the appropriate number of full drops of urine into the specimen well of the test cassette based on the manufacturer's instructions.
      iv. Start a timer based on the manufacturer's instructions and wait for the red line(s) to appear.
      v. Read the results at designated. It is important that the background is clear before the result is read.
         - Interpret the result:
            A. **Positive**: Two distinct red lines, one in the Control region and one in the Test region.
            B. **Negative**: One red line in the Control region. No apparent red line in the Test region.
            C. **Invalid**: Red line in the Control region fails to appear or no lines in either the Control or Test regions.

- Document results on the Urine Pregnancy Testing Quality Control Log.

vi. Do not use "+/-" symbols for documentation of results.

RELATED POLICIES AND REFERENCES
Manufacturer's instructions for use

APPROVALS

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