Clinical and Translational Research Center **TraCS Institute**	**Approved by:** Medical Director and Director of Nursing
SOP Title and #: Guidelines for Urine Pregnancy Testing in the CTRC	**Revisions:** 02/18/2015, 8/9/2015, 8/06/2016, 03/23/2022
Effective Date: 4/1/2009	**Page 1 of 3**

I. **Purpose**: This Standard Operating Procedure (SOP) describes the activities and identifies the individuals responsible for urine pregnancy testing at the Clinical and Translational Research Center (CTRC).

II. **Scope**: This SOP applies to the procedures for urine pregnancy testing and the documentation of the findings.

III. **Applicability**: Female subjects of childbearing age, participating in research studies are frequently required to have pregnancy testing performed prior to study entry, performance of a study procedure, or medication administration. Urine pregnancy testing performed in the CTRC facilitates the start of a study visit and could decrease a subject's length of stay on the unit. Accurate specimen collection and proper handling of such specimens is imperative for all research studies in order to avoid any errors or protocol deviations. Serum beta hCG testing through McLendon Laboratory is available if required by sponsor or for verification of a positive urine pregnancy test.

All CTRC nursing staff will be trained on the proper urine testing procedure as outlined in the "**POC Urine Pregnancy Testing Using the Siemens Clinitek Status® Connect System."** This policy can be accessed at the UNC Medical Center Intranet Policy Stat site. Annual competency testing will be provided by UNC Hospital's Point-of-Care Committee or via the LMS website to assure all CTRC nursing staff can competently and accurately perform POC urine pregnancy testing.

IV. **Responsible Parties**: Principal Investigator, study staff and CTRC nursing staff that are trained in the procedure of urine pregnancy testing and quality assurance will be using the hospital provided equipment and follow UNC Hospital's policy and procedure guidelines.

V. **Procedures**:

A. The requirements of each study in regard to pregnancy testing can vary depending on the sponsor of the research and the nature of the study. Frequency of pregnancy testing will be detailed in the IRB approved study. The Principal Investigator assumes responsibility for ensuring pregnancy testing is ordered as outlined per protocol.

B. Industry sponsored studies providing their own urine pregnancy kits should be performed by the study staff. Only study staff will be allowed to perform urine pregnancy testing using sponsor provided kits. The CTRC staff cannot perform any urine pregnancy testing by kits which are not approved by McLendon Laboratory.

C. When a CTRC staff member is required to perform a procedure or administer a medication that may include risk to a fetus, women of childbearing potential must have a urine pregnancy test performed by CTRC nursing staff or a pregnancy test performed by UNC Hospitals McLendon Laboratories. Results must be confirmed as negative prior to having a procedure performed. Such procedures include, but are not limited to, DXA scans and study drug administration.

D. CTRC nursing staff will only perform urine pregnancy testing using hospital approved equipment (Clinitek Status Plus) and needed supplies from Central Distribution. Therefore, study staff must get sponsor permission to use hospital supplied testing materials if CTRC staff are to perform the test.

E. The Clinitek Status Plus urine pregnancy equipment will have daily quality control (QC) testing performed using the hospital provided urine controls. QC findings will be automatically transmitted from the machine to the Point-of-Care Committee. The 7 AM nurse or Charge Nurse will be responsible for daily QC testing. The expiration date of the test cartridge and the expiration dates of the level 1 and level 2 urine controls will be checked at time of QC testing. The cartridge expiration dates must be checked prior to each subject test. A member of the Point-of-Care committee will routinely monitor to ensure the equipment receives QC testing as outlined in the hospital policy.

F. For information regarding the actual performance of a POC urine pregnancy test, review the policy "**POC Urine Pregnancy Testing Using the Siemens Clinitek Status® Connect System,"** available the UNC Medical Center Intranet Policy Stat site.

G. Study staff requiring POC urine pregnancy testing (POC) must indicate this by pending an order then requesting the licensed provider to sign the order in Epic. A signed order in Epic must be present prior to CTRC nursing staff performing the test. The required test name in Epic is "**POC Pregnancy, Urine – RN Obtain (Nur1009)**." The study will not be billed by UNC Hospitals for this procedure if it is ordered correctly. However, if a serum beta hCG pregnancy test is required to confirm results, the study or subject must pay for this additional test.

H. When requesting a point of care (POC) urine pregnancy test in the outpatient unit, the study staff must indicate the request on the dry erase board in the Nurse's Suite. Study staff will indicate whether or not the remainder of the urine sample should be saved for study purposes or disposed of upon completion of pregnancy testing. The specimen container is required to have an Epic label with the current CSN number as well as the date, time and initial of the collector. The label must be placed vertically on the specimen cup so that the barcode can be read by the scanner. The sample should then be placed in the designated location in the Serial Processing room. An order in Epic must be signed before the test will be performed.

I. On the inpatient unit, urine for an ordered POC urine pregnancy test will be collected by nursing staff. Study staff will indicate on the flowsheet whether or not the remainder of the sample should be saved for study purposes or disposed of upon completion of pregnancy testing. The nursing staff collecting the specimen should ensure the container has the required Epic label with the current CSN number as well as the date, time and initial of the collector. The label must be placed vertically on the specimen cup so that the barcode can be read by the scanner.

J. POC urine pregnancy test results will automatically be uploaded into the subject's chart in Epic immediately after testing is performed if the test is ordered correctly. Results from POC urine pregnancy testing will also be documented by the nurse who performed the testing on the study specific flow sheet (if applicable). A machine printout may be given to the study staff if requested. A positive result will be communicated to the study staff immediately and all further testing (e.g., DXA scan, XRAY) or drug administration will be held until result is confirmed by a serum beta HCG test.

K. A positive urine pregnancy test may be confirmed with a serum beta hCG using the UNC Hospitals McLendon Laboratory at the request of the study physician. The principal investigator or designated physician will be required to place an order for serum beta hCG test in Epic. CTRC nursing staff or an RN study coordinator may take a verbal order for serum beta hCG test if the study physician is unable to order the test in Epic. A positive result will be communicated to the physician and all further procedures will be held.

L. CLIA License:

1. POC testing (urine and glucose) carried out by CTRC staff is performed under McLendon Labs' CLIA license as both units are attached by a wall or walkway to the hospital and as such the CLIA remains the same.
2. The CLIA license can be found at McLendon Labs' website at http://www.uncmedicalcenter.org/uncmc/professional-education-services/mclendon-clinical-laboratories/accreditation/.

VI. **Related documents:**

A. SOP titled "Guidelines for Specimen Processing and Use of Centrifuges"