Clinical and Translational Research Center **TraCS Institute**	**Approved by:** Director of Nursing
SOP Title and #: Guidelines for Urine Dipstick Testing in the CTRC	**Revisions:** 3/23/2022
Effective Date: 6/12/2017	**Page 1 of 2**

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

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

III. **Applicability**: Participating in research studies may require POC urine dipstick testing to be performed prior to study entry, performance of a study procedure or at different time points throughout the duration of a study. Urine dipstick testing performed in the CTRC facilitates the start of a study visit and can potentially decrease a subject's length of stay on the unit.

The intended use of the Clinitek Status Connect® test system is for semi-quantitative detection of urinary protein, blood, leukocytes (esterase), nitrite, glucose, ketone (acetoacetic acid), pH, specific gravity, bilirubin, and urobilinogen.

IV. **Requirements:** All CTRC staff will be trained on the proper POC urine dipstick testing procedure as outlined in the "POC Urine Dipstick Testing Using the Siemens Clinitek Status® Connect System" policy which can be accessed at UNC Medical Center Intranet Policy Stat site. Annual competency testing will be provided via the Learning Management System (LMS) website or in person by a member of the Point-Of-Care Committee to assure all CTRC nursing staff can competently and accurately perform POC urine dipstick testing.

V. **Responsible Parties**: Principal Investigator, study staff and the CTRC nursing staff that are trained in the procedure of POC urine dipstick testing and quality assurance who will be using the hospital provided equipment and as outlined in the "POC Urine Dipstick Testing Using the Siemens Clinitek Status® Connect System" policy which can be accessed at UNC Medical Center Intranet Policy Stat site.

VI. **Procedures**:

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

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

C. CTRC nursing staff will perform POC urine dipstick testing using hospital approved equipment (Clinitek Status Connect®) 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.

D. The Clinitek Status Connect® urine dipstick test strips will have quality control (QC) testing performed only on the days the test is ordered using the hospital provided urine controls for testing. The nurse performing the ordered POC urine dipstick testing will be responsible for the QC testing prior to the actual participant test. The expiration date of the reagent strips and the expiration dates of the level 1 and level 2 urine controls will be checked at time of QC testing.

E. For information regarding the actual performance of POC urine dipstick testing, QC requirements and the limitations of the procedure; review the "POC Urine Dipstick Testing Using the Siemens Clinitek Status® Connect System" policy which can be accessed at UNC Medical Center Intranet Policy Stat site.

F. Study staff requiring POC urine dipstick testing 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 "**Urine Dipstick (POC Urinalysis – RN Obtain (Nur389)**." The study will not be billed by UNC Hospitals for this procedure if it is ordered correctly.

G. When requesting a point of care (POC) urine dipstick test in the CTRC outpatient unit, the study staff must indicate the request on the dry erase board in the Nurses' Suite. Study staff will indicate whether the remainder of the sample should be saved for study purposes or disposed of upon completion of urine dipstick 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. A signed order must be present in Epic prior to the test being performed.

H. Due to the nature of bedside testing, the printout results will be given directly to the study team. Additionally, the test results will automatically be uploaded into the participant's chart in Epic immediately after testing is performed if the test is ordered correctly. Results from POC urine dipstick testing will also be documented by the nurse who performed the testing on the study specific flow sheet (if applicable).

I. CLIA License – POC testing carried out by CTRC staff is performed under McLendon Labs' CLIA license. The outpatient unit in Burnett-Womack is attached by a wall or walkway to UNC Hospitals and as such the CLIA license remains the same. Additional CLIA information can be found on the Mclendon Lab's website at http://www.uncmedicalcenter.org/mclendon-clinical-laboratories/accreditation/.

VII. **Related Documents**:

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