Center for Cognitive and Neurobiological Imaging
Standard Operating Procedures for
CLIA-Waived, Point of Care, Urine-Based Testing

SCOPE

This is a facilities-based SOP for CLIA-waived point of care (POC) urine-based testing at 450 Serra Mall, Building 420, CNI Facility. This facility is covered by a CLIA-waiver.

- Unless this SOP is amended, POC testing is restricted to bathrooms at the CNI facility only.
- **All testing requires prior approval from the Stanford IRB** and notification of Laima Baltusis.
- Testing is not permitted in any other location in the building.
- This SOP covered requires handling of urine sample, their monitoring, and proper disposal.
- Note that University PPE regulations in addition to POC test manufacturer instructions should always be followed.
- The Study PI or her/his designee is responsible for training study staff in the procedures listed here.
- The Study PI needs to complete documentation stating that their personnel will comply with these procedures.

Each PI is to provide his/her study-specific urine collection cup/kit, testing kits, gloves, timer/clock, testing tray and any other required testing supplies. The CNI does not provide or stock these materials. The proper administration, recording, and validity of POC tests are the responsibility of the PI.

In the case of a spill, wipe the area with Sani-Wipe and dispose in the proper waste receptacle provided in the restroom. In the case of a large splatter spill onto the adjacent areas, post the “Out Of Order” sign on the outside of the restroom door to prevent re-entry and contact Laima Baltusis for urgent request. PIs are responsible for extra cleaning fees.

FACILITIES PROCEDURE

- Trained study personnel enters the restroom and puts down a chux on a flat testing area and places the urine collection cup upon the chux.
- Trained study staff meets with the participant and gives specific instructions regarding urine collection (see Appendix 1 and 2)
- Staff waits outside of the restroom while sample is being collected by the participant.
- When the participant exits the restroom, have the participant wait while you complete the testing process. The sample collected in the restroom should not be left unattended in order to prevent contamination and to maintain test result validity.
- The study personnel wears gloves and completes the testing.
- When testing is completed and the result has been recorded per study protocol, dispose of the urine by pouring it into the toilet and dispose of the collection cup and kit in the foot-pedal operated metal can. **Note:** If you see visible blood in the urine, the urine and cup with cap will be disposed in a biohazard can.
- All supplies must be removed from the restroom after each testing occurrence is complete.
- Check that there is no urine on the tray, toilet seat, or any other unexpected place in the restroom. Wipe down with Sani-wipe if necessary.
- Remove and dispose of gloves before exiting the restroom. **Note:** Gloves should never touch door handles, telephones, card swipes, or any common surfaces.
Appendix 1: Urine Collection Instructions for Female Clinical Research Participants

1. Wash hands thoroughly with soap and water, rinse and dry.
2. Open the collection package but DO NOT TOUCH INSIDE OF CUP OR RIM.
3. Open the package of 3 towelettes. While seated on the toilet spread labia major (outer folds). With the first towelette, wipe one side of the labia minora (inner fold) using a single downward stroke. Discard towelette. With the second towelette repeat the procedure on opposite side using a single downward stroke. Discard towelette. With the third towelette, cleanse meatus (center area) with a single downward stroke. Discard towelette.
4. Remove lid carefully from the collection container, DO NOT TOUCH the inside of the container or rim. Gently grasp the container.
5. Begin to void urine, letting the first 20-25 ml pass into the toilet. Position the cup in the stream of urine until the container is about one-half to two-thirds full. Finish voiding into the toilet.
6. After obtaining the urine specimen, screw the lid on tightly again being careful to avoid touching inside the container or lid.

Appendix 2: Urine Collection Instructions for Male Clinical Research Participants

1. Wash hands thoroughly with soap and water, rinse and dry.
2. Open the collection package but DO NOT TOUCH INSIDE OF CUP OR RIM.
3. Open the package of 3 towelettes. Retract foreskin if present. With the first towelette, cleanse the urinary opening of the penis starting at the center and work outward. Repeat the cleansing in the same manner with the two remaining towelettes.
4. Remove lid carefully from the collection container, DO NOT TOUCH the inside of the container or rim. Gently grasp the container.
5. Begin to void urine, letting the first 20-25 ml pass into the toilet. Position the cup in the stream of urine until the container is about half to two-thirds full. Finish voiding into the toilet.
6. After obtaining the urine specimen, screw the lid on tightly again being careful to avoid touching inside the container or lid.