

POLICIES AND PROCEDURES

SECTION: Research and Compliance			NUMBER: CLN-28.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/4/2009	REV. B: 8/30/2010	REV. C:
TITLE: Obtaining a Urine Sample			Page 1 of 2	

1. PURPOSE

To standardize the procedure for collecting urine samples.

2. SCOPE

Applies to all personnel involved in the review and implementation of clinical research investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for the training of the SCs and other designated site personnel for the collection and at least the initial processing of laboratory samples, including urine samples.

4. BACKGROUND

The collection of urine specimens as required by the study protocol should be consistent between sessions.

Clear record keeping is essential when documenting urine samples, including serial collections, as in a pharmacokinetic (PK) study and 24-hour urine sampling.

5. PROCEDURE

5.1. Collecting Urine Samples from Adults

- 5.1.1. Subjects/patients will be asked to provide a urine sample in a collection cup.
- 5.1.2. When samples are taken in containers that have a temperature indicator, the temperature of the sample must be recorded along with the volume and other information required by the protocol.
- 5.1.3. If the purpose of the urine sample is for the determination of the drugs of abuse, and if the presence of such drugs will exclude an SP from participating in a given study, the PI and clinical research staff must be very careful that the sample given to them is indeed from the SP
- 5.1.4. The SC will pour the urine into appropriate vial or container, using acceptable infection control techniques, for processing.
- 5.1.5. The samples will be delivered/shipped to the designated laboratory, as specified by the protocol.

5.2. Collecting Urine Samples from Infants and Toddlers

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- 5.2.1. Thoroughly wash the area around the urethra. Clean from the front to the back on the female patient, and from the tip of the penis on a male patient.
- 5.2.2. Open a urine collection bag (a plastic bag with an adhesive paper on one end), and place it on the infant. For males, place the entire penis in the bag and attach the adhesive to the skin. For females, place the bag over the labia.
- 5.2.3. Put a diaper securely over the bag. Check the bag placement often and remove the bag after the infant has urinated into it. This procedure may take several attempts as infants and toddlers can displace the bag.
- 5.2.4. Drain the urine into a urine collection container for testing, as specified by the study protocol.

6. TERMS & ABBREVIATIONS

PI	Principal Investigator
PK	Pharmacokinetics
SP	Study Participant

7. REFERENCES

None

8. ATTACHMENTS

None