

<b>PROCEDURE</b>	<b>Urine Collection</b>	
<b>PREPARED BY</b>	GAPPS Staff	
<b>DATE ADOPTED</b>		
<b>REVIEWED BY</b>	<b>SIGNATURE</b>	<b>REVIEWED DATE</b>

<b>SUMMARY OF CHANGES TO THIS SOP</b>
<p><b>Version 2.0</b></p> <ol style="list-style-type: none"> <li>1. Increased Urine aliquot from 4ml to 5ml.</li> <li>2. Specimen collection, processing and storage must be completed in less than 2 hours rather than 8 hours.</li> </ol>
<p><b>Version 2.5</b></p> <ol style="list-style-type: none"> <li>1. Safety section added.</li> </ol>
<p><b>Version 3.0</b></p> <ol style="list-style-type: none"> <li>1. Increased number of Urine aliquots from 1 to 4.</li> <li>2. Added 2 more towelettes to meet clinical standards of clean catch.</li> </ol>

**PURPOSE**

This Standard Operating Procedure (**SOP**) describes a procedure for collection of urine from Primary participants.

**SCOPE**

This procedure covers the collection, processing and storage of urine from participants. It does not describe any analysis of specimens collected.

### **Authority and Responsibility for SOP's**

1. The GAPPS Medical Director (or his/her designee) and Laboratory Manager have the authority to establish this procedure.
2. The GAPPS Laboratory and the QA monitors are responsible for the implementation of SOP documentation at participating sites.
3. The site PI (or his/her designee) is responsible for the implementation of this procedure at their site and for ensuring that all appropriate personnel are trained and sign "Acknowledgement of Understanding" document for this SOP.
4. All health care providers and technicians who implement this SOP at study sites are responsible for reading and understanding this SOP prior to performing the procedures described.
5. All health care providers and technicians are expected to be trained and follow the procedures described in any of the GAPPS SOPs and have their signature on file at the collection site.

### **Supplies**

#### On Site:

n/a

#### Supplied in Kit:

1. Urine collection cup
2. 4 Cryovials, 5ml, GAPPS labeled
3. Sanitary towelette

### **Safety**

1. Required Training for processing
  - a) Blood borne pathogens
  - b) Standard laboratory practices
2. Risks
  - a) Biofluid exposure
3. Required safety equipment
  - a) Lab coats/scrubs
  - b) Face shield/safety goggles
  - c) Closed toed shoes
  - d) Gloves

All health care providers and technicians are expected to be trained and follow universal precautions when handling biological or hazardous materials when performing the any procedures described in any of the GAPPS SOPs.

**NOTE:** Specimen collection, processing and storage must be completed in less than 2 hours.

### **Urine Collection**

1. Urine will be collected from primary participants using the "clean catch" method at specified time points designated in the GAPPS project. Urine may also be collected from catheter bags by pouring into the specified collection cups.
2. Place urine "Clinic" label on urine collection cup prior to handing it to Participant.
3. When participant is providing a clinical urine sample by "Clean Catch" method, they will be given a separate urine collection cup labeled for GAPPS specimen collection along

with their Clinical urine collection cup. Do not transfer or decant urine from the clinical specimen collection cup into the GAPPS collection cup.

4. Instruct participants to collect urine for their clinical visit first; then they should collect urine in the GAPPS urine collection cup second.
5. Per institutional approval, urine can be collected for GAPPS independent of clinical collection.
6. A minimum of 5 ml of urine is needed. It is sometimes helpful to mark on the cup with a sharpie a minimum collection line on the collection cup to help define a minimum volume.
7. If participants are not given specific instructions by the clinical staff about collecting a “clean catch” urine sample please use the “Clean Catch” instructions below.

### **Clean Catch Urine Collection – (Participant Procedures)**

1. A clean-catch specimen is also referred to as a midstream specimen collection.
2. The participant should be given a cleansing towelette with the urine collection cup.
3. After washing her hands, the participant opens the sterile cup(s) making sure to avoid touching the inside of the lids and containers to prevent contamination. Set the lid(s) down with the inside of the lid(s) facing up beside the matching cup.
4. Make sure the cups are within easy reach of toilet or urine collection container.
5. Using one hand the patient should separate the folds of the urinary opening. Using the first towelette, the patient should wipe one side of the inner fold front to back and discard towelette. Using the second towelette, the patient should wipe the opposite side, front to back, and discard. Using the third towelette, the patient should wipe down the center, front to back and discard.
6. The initial part of the urine stream should be voided into the toilet or another container.
7. At approximately the middle of the urine flow, the first container should be positioned to capture urine, the first cup set down in a secure location while the second cup is positioned to collect more urine. The remainder of the urine should be voided into the toilette or container.
8. The specimen cups and lids should be re-capped tightly, and any splashed urine wiped from the outside of the cup.
9. Participant should then present collected urine specimen to study coordinator at specified location. The date and time of collection should be recorded.

### **Urine Processing**

1. Specimen cup with urine and completed lab requisition forms should be placed into the specimen bag compartments and maintained at room temperature until processed.
2. Pipette 5 ml of urine into pre-labeled 5 ml cryo-vial x 4.
3. Record specimen data on lab requisition forms and in specimen tracking data base.

### **Specimen Storage**

1. Store aliquots at a minimum of -20°C for short-term storage (< 30 days), and preferably at -80°C until shipped to the core repository.
2. Consult “Shipping SOP” when specimens are ready to be shipped.