

PROCEDURE	Infant Urine and Meconium Collection	
PREPARED BY	GAPPS Staff	
DATE ADOPTED		
REVIEWED BY	SIGNATURE	REVIEWED DATE

SUMMARY OF CHANGES TO THIS SOP
<p>Version 1.5</p> <ol style="list-style-type: none"> 1. Discontinue use of non-absorbent pad 2. Addition of 72 hour max, post birth collection 3. Addition of multiple urine collections, if possible
<p>Version 2.0</p> <ol style="list-style-type: none"> 1. Safety section added.
<p>Version 2.1</p> <ol style="list-style-type: none"> 1. Change meconium processing window from 2 hrs to 12 hrs 2. Clarification of urine window 3. Addition of OB pads in kits
<p>Version 2.2</p> <ol style="list-style-type: none"> 1. Change cotton balls to sponges. 2. Added instructions for trimming unsaturated sponge before urine expression.
<p>Version 2.3</p> <ol style="list-style-type: none"> 1. Added two more tongue depressors
<p>Version 2.4</p> <ol style="list-style-type: none"> 1. Added a swab and vial for meconium swab collection. 2. Change urine processing window from 2 to 12 hrs

PURPOSE

This Standard Operating Procedure (**SOP**) describes a procedure for collection of infant urine and meconium from one of the baby’s first diaper changes while still in the hospital.

SCOPE

This procedure covers the collection, processing, temporary and long-term storage of infant urine and meconium. It is important to track labels, specimens and documents of individual participants while processing.

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's PI and Coordinator 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:

1. Infant diaper

Supplied in Kit:

1. Sterile cotton balls or OB pads
2. 4 Sticks (infant tongue depressors)
3. Sterile collection cup
4. 2 Cryovials, 2 ml, GAPPS labeled
5. 2 polyester swabs
6. 12 Cryovials, 5 ml, GAPPS labeled.
7. 20 ml syringe without needle.

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.

Please collect from the earliest possible diaper change. 72 hours post-delivery is the outer limits of collection for this sample. If possible at your site, multiple diaper collections preferred.

Urine and meconium collection-

1. Collecting meconium and urine in diaper

- a. Wearing gloves, clinical staff should place sponges in gender appropriate area of a clean diaper.
- b. Clinical staff should place the diaper, with sponges for urine, onto baby.
- c. During routine diaper change, the diaper should then be given to, or set aside for, GAPPS research coordinator instead of being discarded.
- d. If permissible, multiple diapers should be used as urine should not be collected from diapers containing meconium.

2. Transferring urine

- a. Trim off any unsaturated portions of the sponge with alcohol wiped scissors. Pack wet sponges into sterile 20 mL syringe (without needle).
- b. Express urine into a sterile specimen cup.
- c. Pipette 5mL of urine into GAPPS supplied and labeled 5-mL cryo-vials; up to four aliquots may be stored.
- d. Record specimen data on lab requisition forms and in specimen tracking data base.
- e. Specimen collection, processing and storage should be completed in less than 12 hours. If that is not possible, please specify on the lab requisition form when it was collected and processed.

3. Transferring meconium

- a. Scrape meconium from diaper with provided spatula/stick into GAPPS supplied and labeled 5-mL cryovials, up to four aliquots may be stored.
- b. Collect a swab of meconium from the diaper, transfer the swab to the GAPPS supplied and labeled 2-mL cryovial. Snap the head of the swab off in the vial and cap. Repeat with the 2nd 2-ml vial.
- c. Record specimen data on lab requisition forms and in specimen tracking data base.
- d. Specimen collection, processing and storage must be completed in less than 12 hours.

4. Specimen Storage

- a. Storage at -20°C is acceptable for short term of < 30 days; -80°C is preferred for immediate and long term storage.
- b. Consult "Shipping SOP" when specimens are ready to be shipped.