PROCEDURE	**COLLECTION AND PROCESSING OF HUMAN AMNIOTIC FLUID**	
PREPARED BY	**GAPPS Staff**	
DATE ADOPTED		
REVIEWED BY	**SIGNATURE**	**REVIEWED DATE**

SUMMARY OF CHANGES TO THIS SOP
Version 1.5 1. 15 ml tube added 2. 6 ml discontinued 3. 20 ml syringe added 4. Safety section added
Version 2.0 1. Added amniotic fluid collection at cesarean section delivery
Version 2.5 1. Added alternate collection technique for amniotic fluid collection at cesarean section delivery

PURPOSE

This Standard Operating Procedure (**SOP**) describes a procedure for the collection and storage of human amniotic fluid during amniocentesis and during a cesarean section surgical procedure.

SCOPE

This procedure is intended for the collection, processing, and storage of amniotic fluid. There are two approved methods of collection (during amniocentesis and during cesarean section surgical procedure). It does not cover shipping, testing or analysis of these specimens.

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 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.

Amniotic Fluid collected during Amniocentesis

Limitations

1. Amniotic fluid is collected only if an OB health care provider is already performing an amniocentesis for clinical purposes AND there is excess fluid available for storage. Participants are not asked to partake in this specimen collection as an additional procedure.
2. Specimen collection and processing must be completed in less than 2 hours.

Supplies

Site Supplied:

1. Pipette

Supplied in Kit:

1. 15 ml tube
2. 20 ml syringe
3. 10 Cryovial, 2ml GAPPS Labeled.

Safety

1. Required Training for processing
   a. Blood borne pathogens
   b. Standard laboratory practices
2. Risks
   a. Sharps hazard
   b. 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.

Amniotic Fluid Collection during Amniocentesis–

Amniotic fluid is collected only if an OB health care provider is already performing an amniocentesis for clinical purposes AND excess fluid (up to 10 ml) is available for storage in the GAPPS repository.

1. Before initiating procedures make sure collection supplies, labels and forms are in the room, ready and within easy reach.
2. After clinical samples of amniotic fluid are completed, the excess fluid (typically in a sterile syringe with needle) is placed into additive free vacutainer or sterile tube
3. Pipette 1ml aliquots of amniotic fluid into separate GAPPS supplied and labeled cryo-vials. Attempt to minimize exposure of amniotic fluid to air to avoid specimen contamination.
4. Record specimen data on lab requisition form.

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.

Amniotic Fluid Collection during Cesarean Section

Limitations

1. Amniotic fluid is collected only if an OB health care provider is performing a cesarean section for clinical reasons.
2. Specimen collection and processing must be completed in less than 2 hours.

Supplies

On Site:

1. 18 gauge IV Angiocath
2. Pipette

Supplied in Kit:

1. 1 15ml conical tube
2. 10 (1.8cc) cryo vials, GAPPS labeled
3. 20cc sterile syringe

Safety

1. Required Training for processing
   a. Blood borne pathogens
   b. Standard laboratory practices
2. Risks
   a. Sharps hazard
   b. Blood and 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

Amniotic Fluid Collection during Cesarean Section –

Amniotic fluid is collected only if an OB health care provider is performing a cesarean section for clinical purposes and fluid (up to 10 ml) is available for storage in the GAPPS repository.

1. Before initiating procedures make sure collection supplies, labels and forms are in the room, ready and within easy reach.
2. After reflecting the bladder flap, manually elevate fetal presenting part.
3. Insert IV angiocath through lower uterine segment avoiding placenta, withdraw the sharp leaving only the plastic tubing in the uterus for fluid collection.
4. Transfer amniotic fluid from the tube into sterile conical tube.
5. Pipette 1ml aliquots of amniotic fluid into separate GAPPS supplied and labeled cryo-vials. Attempt to minimize exposure of amniotic fluid to air to avoid specimen contamination.
6. Record specimen data on lab requisition form.

ALTERNATE Amniotic Fluid Collection during Cesarean Section-

Amniotic fluid is collected only if an OB health care provider is performing a cesarean section for clinical purposes and fluid (up to 10 ml) is available for storage in the GAPPS repository.

1. Before initiating procedures make sure collection supplies, labels and forms are in the room, ready and within easy reach.
2. After hysterotomy, but before amniotomy insert IV angiocath through membranes, withdraw the sharp leaving only the plastic tubing for fluid collection.
3. Transfer amniotic fluid from the tube into sterile conical tube.
4. Pipette 1ml aliquots of amniotic fluid into separate GAPPS supplied and labeled cryo-vials. Attempt to minimize exposure of amniotic fluid to air to avoid specimen contamination.

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.