Wake Forest Baptist Medical Center	Amnisure ® ROM Test CL-H23	Dept:	Clinical Core Lab-Hematology Section
		Effective Date:	06/17/19
		Revised Date:	
		Contact:	Clinical Core Lab-Hematology Management
Name & Title: Gregory J. Pomper, MD Medical Director of Pathology Laboratories		Date:	6/14/19
Signature: G Pomper			

PRINCIPLE

The AmniSure® ROM Test is a rapid, self-contained, qualitative immunochromatographic test for the *in vitro* detection of amniotic fluid in vaginal secretions of pregnant women. AmniSure® detects PAMG-1 protein marker of the amniotic fluid in vaginal secretions. A sample of amniotic fluid (acquired via vaginal swab) is diluted into a vial containing solvent. The solvent extracts the sample from the swab. The AmniSure® Test strip, a lateral flow device, is then dipped into the vial. The sample substance flows from the Pad Region of the strip to the Test Region. The test result is indicated visually over the next 5-10 minutes by the presence of one or two lines. One line indicates no membranes ruptured, two lines indicates there is a rupture.

SCOPE

The timely and accurate diagnosis of rupture of [fetal] membranes (ROM) is crucial since failure to identify patients can result in failure to intervene appropriately. Conversely, the false diagnosis of ROM can lead to inappropriate interventions (e.g., hospitalization or induction of labor). Therefore the correct and timely diagnosis of ROM is of crucial importance for the clinician.

Responsible Department/Party/Parties:

- **a.** Procedure owner: Clinical Core Laboratory Management-Hematology Section
- **b.** Procedure prepared by: Heather Lawson
- **c.** Supervision: Clinical Core Laboratory Management-Hematology Section
- **d.** Implementation: Clinical Core Laboratory Hematology Section

SPECIMEN

1. **Specimen Collection – To be performed by Clinic/Floor RN**
   a. Solvent Vial Prep
      1) Take solvent vial, and shake well to make sure all liquid in the vial has dropped on the bottom.
      2) Place patient chart label or accession label on the vial. (Note: During downtime, hand write name, MR# and date on vial.
      3) Open the vial and place in a vertical position.
   b. Collect sample
      1) Remove the sterile swab from package. Do not touch swab tip to anything prior to insertion into vagina.
      2) Hold the swab in the middle of the stick and while a patient is lying flat on her back, carefully insert the swab tip into the vagina until the fingers contact the skin. Insert no more than 2-3 inches.
      3) Allow tip to remain in place for 1 minute.

c. Inoculate the solvent vial

1) Place the swab tip into the solvent vial and rinse the swab by rotating the swab for 1 minute.
2) After 1 minute, remove and dispose of the swab.
3) Cap the specimen tightly and **write the time of collection on the label.**

d. Send the sample to the Lab immediately
   1) If sample is not sent within 30 minutes, tightly close the sample vial and place it in a refrigerator at 4-8°C for up to 6 hours.

2. **Specimen Rejection**
   a. This specimen does not qualify as a non-retrievable sample.
   b. Specimens will be rejected for the following reasons and will require recollection:
      1) Unlabeled or mislabeled specimen
      2) Collection time of greater than 30 minutes prior to receipt without refrigeration.
      3) Specimens without a collection time written on the sample.

      NOTE: Order times are not acceptable, the time must be written on the sample immediately following collection.

SAFETY

- The required personal protective equipment for this procedure includes:
  - Gloves
  - Impermeable lab coats, worn closed
  - Shield
  - Approved Protective eyewear
- Gloves and lab coats should be worn at all times during analysis of the samples.
- Sample caps must be removed behind a safety shield.

REAGENTS AND MATERIALS

1. Qiagen Amnisure® ROM Test kit
   - AmniSure® Test Strip (lateral flow device) in foil pouch with desiccant.
   - Sterile polyester vaginal swab
   - Plastic vial with water solvent.

   Storage/Stability
   a. Store the kit in a dry place at room temperature. DO NOT FREEZE.
   b. When stored in the foil pouch at the recommended temperature, the test is stable until the "Use By" date on the foil pouch.
   c. AmniSure® test should be used within six (6) hours after removing from foil pouch.
   d. Do not mix kit supplies within lot numbers.

Special Handling Note: Each pouch in the kit will have the foil test strip removed and stored in the lab. The pouches containing only the swab and the plastic vial will be supplied to the L&D unit in a prepared box, one 25 test kit at a time. Floor staff should call the lab at ext 6-2859 for re-supply.

2. Qiagen Amnisure® ROM Test Positive/Negative Control Pack
   - 1 Positive Control Vial
   - 1 Negative Control Vial
   - 1 Amnisure Solvent Vials

Storage/Stability

a. Store Negative and Positive Control (PAMG-1) at 2 to 25°C until the "Exp." date indicated on the vial packaging.

b. After reconstituting the control material, the obtained solutions can be stored under refrigeration at 4-8°C.for up to 24 hours. This same vial can be divided into 0.2mL aliquots allowing for 2 – 5 test strips to be run if multiple kits must be QC'd at the same time.

3. Timer

CLIA COMPLEXITY: Moderate

MAINTENANCE: N/A

CALIBRATION: N/A

QUALITY CONTROL

1. External Controls
   a. Perform with each New Lot/Shipment and every 28 days.
      Prepare controls:
      1) Take the vial containing PAMG-1 protein and add the 1 ml of AmniSure® Solvent Solution.
      2) Take the vial containing the Negative Control and add the 1 ml of AmniSure® Solvent Solution.
      3) Vortex or shake solution vigorously.
      4) If you will be testing multiple kits in parallel, divide control into 2-5 test tubes for testing.
         Note: Reconstituted control expires in 24 hours when stored at 4-8°C.
      5) Perform QC testing as outlined under "PROCEDURE" below.
      6) **Do not perform any patient testing if QC is unacceptable, troubleshooting required.**
      7) For a new kit lot number, record the internal and external QC results on the New Lot/Shipment QC Test Log.
2. Internal Controls
   a. Built in test strip.
   b. The appearance of the *control line* assures the following:
      1) Adequate sample volume was present
      2) Adequate capillary migration of the sample has occurred
      3) Presence of antibodies on the test strip.
      4) Proper assembly of the test strip.
   c. Interpret and record results as outlined under "Reporting".

TESTING PROCEDURE

1. Assure specimen acceptability by reviewing rejection criteria outlined above.

   a. Vortex Vial
   b. Place vial in holder.
   c. Tear open the foil pouch and remove AmniSure® test strip. Do not bend or fold the test strip or the aluminum foil pouch with the test strip in it
   d. Dip the white end of the test strip (marked with arrows) into the vial with solvent.
   e. Start timer for 10 minutes
   f. Immediately remove the test strip after 10 minutes.
   g. Read the results by placing the test on a clean, dry, flat surface.
2. Do not read or interpret the results after 15 minutes. Repeat testing required.

3. Interpretation of Results.
    a. Positive Result
        i. If both control and test lines are visible the test result is **positive.**
    b. Negative Result
        i. If only a control line is visible
    c. Invalid Result
        i. If no control lines are visible, the test result is **invalid**
            1. Repeat testing required.

REPORTING

1. For patient resulting, select the patient from the WC FLUIDS Outstanding List. Manually result utilizing the drop down box, select the result option; Positive or Negative.
2. Manually result the Internal QC field by choosing the appropriate option from the drop down box.
3. To release the results, select Verify, perform a final result review and select Final Verify.

REFERENCE RANGE: Negative

CRITICAL VALUE: N/A

LIMITATIONS

- Sensitivity is 5 ng/mL
- Vaginal infections, sperm or urine do not interfere with the results.
- AmniSure® test will still function properly with trace amounts of blood on the swab

REFERENCES

Current AmniSure® ROM Test package insert.

Review/Revision/Implementation:

a. Review Cycle: 2 years
b. Office of Record: Department of Clinical Core Laboratory-Hematology
c. All new procedures and procedures that have major revisions must be signed by the Laboratory Director.
d. All reviewed procedures and procedures with minor revisions can be signed by the designated section medical director.

Attachments: Amnisure ROM Kit Worksheet

Revision Dates:

Review Date	Revision Date		Signature
13 Jun 2019			

Amnisure ROM Worksheet

Kit Lot# _____Kit Exp_____Kit QC Date_____

(External QC to be done with each new kit lot and every 28 days - record QC results as you would patient below)

DATE	PATIENT	Internal Control	RESULT	TECH INIT.

DATE	PATIENT	Internal Control	RESULT	TECH INIT.