Saratoga Hospital Laboratory

211 Church St., Saratoga Springs, N.Y. 12866

**Procedure for ROM Plus® Rupture of [fetal] Membranes (ROM) Test**

**Principle**

The ROM Plus (Rupture of [fetal] Membranes) Test is a rapid, non-instrumented qualitative immunochromatographic test for the *in vitro* detection of amniotic fluid in vaginal secretions of pregnant women. ROM Plus detects the following amniotic fluid markers, found in vaginal secretions.

* PP12 (also known as Insulin-like Growth Factor Binding Protein-1/IGFBP-1)
* AFP (Alpha-fetoprotein)

**Clinical Significance**

The timely and accurate diagnosis of rupture of fetal membranes (ROM) is crucial since the ROM may be associated with serious neonatal and maternal consequences. Failure to identify patients with ROM can result in the failure to intervene appropriately. Conversely, the false diagnosis of ROM can lead to inappropriate interventions (e.g., hospitalization or induction of labor).

\*\*WARNING\*\*

● Results should be used in conjunction with other clinical information.

● Bleeding, placenta previa, and performing digital exams prior to sample collection

can lead to inaccurate test results.

**Test Precautions & Limitations**

* ROM diagnoses should not be based solely on ROM Plus test results.

***Additional methods that will be used to determine rupture of membrane include, but are not limited to, evaluation of dilation, effacement, station, presentation, position, membrane status, as well as, the absence or presence of bloody show. Membrane status is further determined by fluid leaking from the vagina, a sudden gush of fluid, or a slow trickle of fluid.***

* Test performance in patients without signs or symptoms of ROM is unknown.
* Failure to detect membrane rupture does not assure the absence of membrane rupture.
* Women may labor spontaneously despite a negative test result.
* False negative results and delay in diagnosis of rupture of membranes can increase the risk of chorioamnionitis, oligoydramnios and fetal umbilical cord accident.
* **Presence of significant blood, collected with the swab, can lead to false positive results.**
* ROM Plus results are qualitative. No quantitative interpretations should be made.
* Elevated fetal serum, urine, cord blood, and amniotic fluid as well as maternal serum levels of AFP have been reported in various development disorders such as neural-tube defects, hypothyroidism, autoimmune states, congenital heart defects, cystic fibrosis, etc. ROM Plus has not been evaluated for the potential interference in these conditions.

***Note: For specifics regarding method performance, please see the ROM Plus test package insert.***

**Specimen Type & Stability**

* Use the sterile polyester swab provided to obtain a sample from the surface of the vagina.
* Use the ROM Plus specimen within six (6) hours of collecting and placing swab into the buffer vial.

##### Specimen Rejection Criteria

* Specimen not labeled appropriately according to Administrative Policy II-68: Specimen Labeling.
* Specimen not collected in the provided collection/transport system or container.
* Reject swabs that have been delayed for more than six (6) hours.
* Reject significantly bloody specimens.

**Equipment and Materials**

* ROM Plus test card (lateral flow device).
* Sterile polyester vaginal swab.
* Plastic vial with buffer solution.
* Certified electronic timer.

**Equipment Storage and Stability**

* Store the kit in a dry place at 4˚ to 24˚C (40˚ to 75˚F)

***Note: Always bring card pouch to Room Temperature before use.***

* When stored in foil pouch at recommended temperature, the test is stable until the “Expiration” date on the pouch.
* Use ROM Plus within six (6) hours after opening foil pouch.
* Daily Minimum and Maximum temperature must be recorded on *Attachment 1: Temperature Log.*

**Quality Control**

***NOTE: External Quality Controls must be entered into the ACCU-CHEK Inform II meter. Internal Quality Control is entered into the meter when the patient test is resulted.***

***Internal Control****:*

Each ROM Plus test cartridge contains a built-in procedural control to verify the integrity of the test procedure. The appearance of the control line (C) ensures that an adequate volume of sample has been applied, as well as proper assembly of the test strip by manufacturer.

* Presence of the control line (C) between five (5) and twenty (20) minutes indicates a valid test.

***Note: If the control line (C) does not appear between (5) and twenty (20) minutes the test is invalid and results must not be reported. A new ROM Plus card should be used to repeat the test.***

***External Control****:*

The lyophilized positive and negative controls can be stored in a dry place at room temperature until the expiration date.

**External Quality Controls (positive & negative) are run each day of patient testing.**

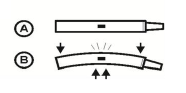
* **The test performer will log the date and time the External Quality Control was run on *Attachment 2: External Quality Control Log*, after control testing is complete.**

**External Control Procedure:**

1. Check *Attachment 2: External Quality Control Log.* If External Quality Control has been performed, proceed to the patient testing procedure.
2. Prepare two (2) ROM Plus test cassettes, one for the Positive Control and one for the Negative Control. Since this is a quality control test and no human sample is required, the polyester vaginal swab and standard dropper vial should not be used.
3. Tear open the Positive Control Vial foil pouch and remove the vial. Gently bend or squeeze the Positive Control vial, breaking the glass ampoule inside. Mix the buffer with the lyophilized positive sample for **45 seconds**. Be careful not to let the sample drip out of the vial.



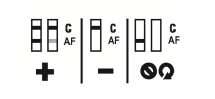
1. Gently bend or squeeze the Negative Control vial, breaking the glass ampoule inside. Be careful not to let the sample drip out of the vial.



1. Add 4-6 drops of the Positive Control solution to one ROM Plus test cassette. Add 4-6 drops of the Negative Control solution to the other ROM Plus cassette. Start the electronic timer for both 5 minutes and 20 minutes. Wait 5-20 minutes for test results to manifest in the test window.



1. Read the test results from 5 to 20 minutes. A positive test result may be visible as early as 5 minutes or take the full 20 minutes. A negative result will take the full 20 minutes.



1. Enter results into the Nova StatStrip meter.
   1. Sign into the meter by scanning your employee ID badge.
   2. Select “Manual”
   3. Select “Manual QC” and Accept
   4. Select either “ROM NEG QC” or “ROM POS QC”
   5. Enter the Lot printed on the test kit pouch and Accept
   6. Enter the QC Lot printed on the QC kit pouch and Accept
   7. Select QC result, either “Negative” or “Positive” and Accept.
   8. Select Internal Control Bar result, either “Valid” or “Invalid” and Accept.
   9. Review your entered results and select “Accept” to accept results.

**Patient Testing Procedure**

1. Check *Attachment 2: External Quality Control Log.* If External Quality Control has not been performed yet for the day, proceed to the External Quality Control Procedure section of this procedure.
2. Remove the ROM Plus contents from the packaging. Holding the buffer vial in the upright position, remove the shipping cap and set the vial aside.
3. Remove the sterile swab from its package to collect a sample from the surface of the vagina. The tip of the swab should not touch anything prior to insertion. Insert the swab tip into the vagina 2-3 inches (5-7cm) deep. Withdraw the swab after a **minimum of 15 seconds**.



1. Place the swab into the vial and mix the swab in the buffer solution for **at least 15 seconds**. Break off the swab tip at the scored mark and leave the tip in the vial. Label vial with a barcoded chart label.



1. Place the drop dispenser cap on the buffer vial and dispose of the remaining swab stick.
2. Tear open the foil pouch and remove the ROM Plus cassette and add 4-6 (or more) drops of the sample/buffer solution to the sample well of the cassette.



1. Start the certified electronic timer for both 5 minutes and 20 minutes.
2. Wait 5-20 minutes for test results to manifest in the test window. A positive test result may be visible as early as 5 minutes or take the full 20 minutes. A negative result will take the full 20 minutes.
3. **Darkness of the stripes may vary**, however the test is valid even if the stripes are faint. Do not interpret test results based on darkness of the stripes. Very high concentrations of proteins may result in a light test line.



1. Enter results into the Nova StatStrip meter.
   1. Sign into the meter by scanning your employee ID badge.
   2. Select “Manual”
   3. Select “Manual Patient” and Accept
   4. Select “ROM+”
   5. Enter the Lot printed on the test kit pouch and Accept
   6. Enter the patient ID by scanning the chart label used to label vial and Accept
   7. Select Patient result, either “Negative” or “Positive” and Accept.
   8. Select Internal Control Bar result, either “Valid” or “Invalid” and Accept.
   9. Review your entered results and select “Accept” to accept results.
2. Discard the single use ROM Plus test kit and do not attempt to reuse.
3. If a positive result is obtained refer to Nursing Practice Policy: *Nursing Management of Patients in Labor and Deliver*

**Interpreting Results:**

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| If only a control line (C) is seen, the test is **negative,** no membrane rupture. | | If both the control line (C) and test line (AF) are seen, the test is **positive,** membranes are ruptured. | | If no lines are visible, or just the test line (AF) is visible, the test result is **invalid** and should be repeated. | |
|  | **Negative** |  | **Positive** |  | **Invalid** |

**References:**

*ROM Plus Fetal Membranes Rupture Test Instructions For Use*. Murray, UT: Clinical Innovations, LLC, n.d. PDF.

*ROM Plus Fetal Membranes Rupture Test*. Murray, UT: Clinical Innovations, LLC, n.d. DOCX.

Clinical Innovations, LLC*. Analysis of ROM Plus to Detect Rupture of Membranes*. In: ClinicalTrials.gov [Internet]. Bethesda (MD):

National Library of Medicine (US). 2000- [Cited 2014 Sept 23]. Available from: <http://clinicaltrials.gov/show/NCT01366443> NLM Identifier: NCT0166443.

**Attachments:**

Attachment 1: Temperature Log

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| --- | --- | --- | --- | --- |
| Date of origin: | 09/23/14 |  | Prepared By: | Harvey Hveem |
| Revised: | 04/07/15 |  | By: | Harvey Hveem |
| Revised: | 04/20/15 |  | By: | Teri Baldwin |
|  | |  |  | |
| **Date Placed in Service:** | |  |  | |

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| **Approved by:** |  |  |  |  |  |  | |  | |
|  | Point of Care Supervisor  Teri Baldwin |  | Date |  | Saratoga Hospital Laboratory Medical Director  William E. Field II, MD | |  | | Date |
|  |  |  |  |  |  |  | |  | |
|  |  |  |  |  |  |  | |  | |
|  | Laboratory Administrative Director  Richard Vandell |  | Date |  | Maternity Services Administrative Director  Carrie Inglee |  | | Date | |

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| **Attachment 1** | **Temperature Log (min/max)** | | | | | | | |  | | Location: | | | | |  | | | | | | | Range: | | | | | 4 - 24º C | | | | |
| **Month** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** | **25** | **26** | **27** | **28** | **29** | **30** | **31** |
| **January** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **February** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **March** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **April** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **May** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **June** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **July** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **August** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **September** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **October** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **November** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **December** |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Notes:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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**Attachment 2: External Quality Control Log**

*Please enter the Date & Time external quality control was performed.*

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| --- | --- | --- | --- | --- |
| Date | Time (circle am or pm) |  | Date | Time (circle am or pm) |
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