Rapid Test For Rupture of Fetal Membranes
Objectives

• Complete this education
• Understand procedure
• Complete quiz
• Complete quiz yearly
Point of Care Testing (POCT)

Requirements of Accreditation Canada indicate:

• All healthcare professionals who perform POCT require an education session, quiz and yearly review

• POCT performed at a bedside with the result leading to possible change in the care of the patient requires the hospital to monitor this practice
INTENDED USE

PRO·Mcomplete™ is a point-of-care test intended to aid in the detection of the rupture of fetal membranes in pregnant women reporting signs and/or symptoms of possible membrane rupture.
PRO·Mcomplete™ proposes an alternative tool to aid in the diagnosis of PROM by identification of Insulin-Like Growth Factor Binding Protein-1 (IGFBP-1) and Alpha-Fetoprotein (AFP). The addition of AFP increases the sensitivity of PRO·Mcomplete™ over testing IGFBP-1 alone.
Materials required

• PRO·Mcomplete™ Test Kit

• A Standard Laboratory Timer
Test procedure

The test kit components and samples should be tested at room temperature.
Step: 1

» Check the **expiry date** on the back of the packaging.
Step: 2

» Open the PRO·Mcomplete™ test kit
Step:3

» Open the package containing the cassette

» Place it on a flat surface
Step:4

» Open the extraction buffer vial by twisting off the black cap and stand it vertically.
Step: 5

» Open the swab package.
   (The tip of the swab should not touch anything prior to its insertion.)

» Place the swab into the vagina approximately 5 cm deep for at least 15 seconds

*No Speculum required.*
Step 6:

» Dip the swab containing the vaginal secretions into the extraction buffer vial and rotate for 10 seconds

» Press the swab against the vial walls in order to expel as much liquid as possible from the swab and then discard the swab

» Close the vial by twisting on the black cap

(Note the sample can be stored for up to 6 hours at room temperature prior to proceeding with the next step.)
Step 7:

» Shake the extraction buffer vial to mix the content

» Tap the base to ensure the liquid is in the bottom of the vial
Step 8:

a) Twist off the clear dropper cap from the extraction vial

b) Hold it vertically above the sample well (S) on the cassette
Dispense 3 drops of the extracted sample by applying gentle pressure to the walls of the vial.
Step 9:

» Read the result after 10 minutes. Some samples may be obviously positive before 10 minutes.

Note: Do not interpret the test result after 15 minutes have elapsed. Dispose of the components of the test and the sample according to procedures for potentially infectious waste.
Interpretations of Results

• The test result is considered to be positive if either the IFGBP-1 (B) or the AFP (A) band or both are present.
• Even weakly intense bands should be considered as a positive result.
• The control band line (C), must be present in order for the test to be valid.

Note: Line colour may vary from red to purple depending on the sample.
Interpretations of Results

• The test result is considered to be negative if neither the IFGBP-1 (B) or the AFP (A) band are present

• If the Control Band Line (C) is not present then the test is considered to be invalid and you must repeat

Note: Line colour may vary from red to purple depending on the sample.
Limitations of the Procedure

• Test results should be used in conjunction with clinical indications of membrane rupture.

• Presence of significant amounts of blood in the sample can lead to false positive results.

• False negative results may appear when the test is performed more than 12 hours after appearance of symptoms.

• The vaginal secretions sample swab must be placed in the extraction vial immediately after collection of the sample to prevent proteolytic breakdown of the markers being tested.
Record Result

Final Step:

• On the Obstetrical Assessment Record OAU/Triage record:
• Name of person completing test, lot number, and result (+ or -)
Reference

• Product Codes: PL.950-1/PL.950-5/PL.950-10
• Health Canada Approved Instructions For Use:
• Retrieved November 1, 2018
• From: www.pro-lab.com
QUIZ

• Answer the next 7 questions
• Must obtain 80% to pass
• If you do not pass – please see Clinical Educator for further direction
Question 1

Q: When obtaining the test for use, what important piece of information should be inspected beforehand?

• The color of the packaging
• The expiry date on back of the pouch
• The company’s logo
• The company’s phone number
Q: The test kit components and samples should be tested at room temperature?

• A: Yes
• B: No
Question 3

Q: How long should the swab remain in the vagina?

- A: 1 second
- B: 5 seconds
- C: 15 seconds
- D: 30 seconds
Question 4

Q: Which statement is correct?

• A: Read the results after 10 minutes. Do not interpret results after 15 minutes have elapsed.

• B: Read the results after 20 minutes. Do not interpret results after 30 minutes have elapsed.
Question 5

Q: After 10 minutes the cassette shows this result. What does that mean?

• A: positive (+) result
• B: negative (-) result
• C: cassette was damaged. Test should be repeated.
• D: none of the above
Question 6

Q: What should you do if no control band appears on the cassette after 10 minutes?

• A: Interpret the results
• B: Repeat the test
• C: Wait 10 more minutes and then interpret the results
• D: None of the above
Q: When the Obstetrical Assessment Record is being completed, what information must be included?

- A: Your name, result, time
- B: Your name, lot number, time
- C: Your name, date, time
- D: Your name, lot number, result
Congratulations!

You have completed the quiz!