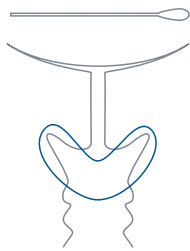
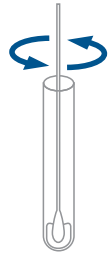




Step-by-Step Instructions



1. Hold the swab in the vaginal fornix for 10 to 15 seconds.



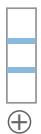
2. Place the swab in the Specimen Extraction Solution and swirl around vigorously for 10 to 15 seconds.



3. Dip the yellow area of the dipstick into the Specimen Extraction Solution and hold it there until the liquid front reaches the result area.



4. Remove the dipstick from the Specimen Extraction Solution as soon as the liquid front reaches the result area.



POSITIVE RESULT:

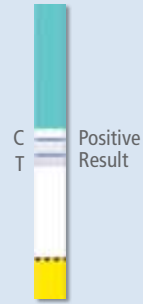
- A positive result can be read as soon as it becomes visible.
- Two blue lines = Membranes are ruptured.



NEGATIVE RESULT:

- A negative result should be confirmed at 5 minutes.
- One blue line = Membranes are intact.

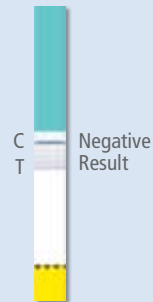
INTERPRETING THE RESULTS



Positive Test Result: Membranes Have Ruptured

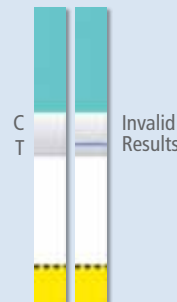
- Two blue lines appear.
- One line should be in the test line area (T) and the other in the control line area (C).

Note: The intensity of the line in the test line area (T) may vary. **Any test line appearing at or before the 5 minute read time can be considered a positive result, assuming a control line is also present.** Disregard any lines seen after 5 minutes.



Negative Test Result: Membranes Are Intact

- One blue line appears in the control line area (C).
- A negative result should be confirmed at 5 minutes.



Invalid Test Result

- The control line fails to appear.

Repeat the test using another dipstick. If the test result cannot be interpreted clearly (e.g., if the lines are blotched or uneven) it is recommended that the test be repeated. If the problem persists, discontinue using the test kit and contact Technical Support.

For more information, call 800.243.2974 or 203.601.5200 or visit www.coopersurgical.com. Also, see us on YouTube at YouTube.com/CooperSurgical.

Frequently Asked Questions



STORAGE & SAMPLE HANDLING

Q: How should the Actim PROM test kit be stored?

A: Store the test kit at 2°–25°C (36°–77°F). The test kit and the test packs can be stored for 2 months at temperatures up to 30°C (86°F) as long as the expiration date is not exceeded.

Q: Is a speculum exam required?

A: Actim PROM does not require a speculum exam, or other equipment.

Q: Can the dipstick be left in the sample to develop?

A: **No.** The dipstick should be removed from the sample as soon as the liquid front becomes visible in the result window. The appearance of the liquid front in the result window indicates that enough sample has been absorbed by the dipstick.

Q: Can samples be stored for subsequent testing?

A: Whenever possible, the Actim PROM test should be performed immediately after sample collection. Extracted samples may be stored at room temperature for up to 4 hours. If a specimen cannot be tested within this time, it should be frozen at or below -20°C.

Product	Order Number
Actim PROM 10 test kit	30831ETUS
Actim PROM Control test kit	30800ETUS

INTERPRETING THE TEST RESULTS

Q: Is the Actim PROM test affected by medications, lubricants, or shower products?

A: No. Several substances have been tested and demonstrated not to affect the test result. These include personal lubricants, baby oils and powder, feminine deodorant suppositories, and RepHresh Vaginal Gel, to name a few. Please refer to the Actim PROM 510(k) K123986 for a full list of drugs, shower and bath products, odor control products and vaginal pathogens that were tested with Actim PROM and found not to affect test performance.

Q: Is the Actim PROM test affected by blood?

A: Actim PROM's detection limit has been optimized to a level at which blood contamination is highly unlikely to affect the test result. From the Actim PROM 510(k): "Whole blood with concentrations corresponding to typical pregnancy levels of IGFBP-I was tested and did not affect Actim PROM test performance."

Q: Do the results need to be read exactly at 5 minutes?

A: A positive result can be interpreted as soon as two blue lines become visible in the result window. A negative test **must** be confirmed at 5 minutes.

Q: Should the intensity of the test line be compared to the intensity of the control line?

A: The result is interpreted by counting the number of lines in the result area. No attention should be paid to the relative intensities of the control and test lines.

Q: What should be done if no control line appears?

A: The control line confirms correct performance of the test. If the control line does not appear, the test result is invalid and should be repeated with another dipstick.