HOLOGIC

Actim® PROM

Testing and Implementation Guide

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Test Instructions

Objective

The Actim PROM test is a rapid qualitative immunochromatographic test for the *in vitro* detection of amniotic fluid in vaginal secretions of pregnant women. Actim PROM detects IGFBP-1, a protein produced by the decidual cells and fetal liver throughout pregnancy. IGFBP-1 is present in amniotic fluid and serves as a marker of the presence of amniotic fluid in vaginal secretions.

Key Considerations

- Detecting rupture of membranes (ROM) with Actim PROM does not require a speculum examination.
- Healthcare professionals who perform this test, including doctors, nurses, and midwives, must be trained and certified in the use of the test.
- Actim PROM is intended for use in patients at 29 weeks or greater gestational age.
- Analysis has shown that common contaminants, including blood, urine, semen, hygiene products, common vaginal infections and medications do not affect this test's performance.
- There is no mandatory waiting period between the use of hygiene products or medications and the administration of this test.

Testing Principles

The Actim PROM test delivers results through the principles of immunochromatography. Two murine monoclonal antibodies to human IGFBP-1 are used in this test. One of these antibodies, designated the detecting antibody, is bound to blue latex particles. The other antibody, designated as the capture antibody, is immobilized in the test strip membrane as a test line.

The test strip is composed of a sample/conjugate area, a membrane containing the test and control lines, and an absorbent pad mounted between two plastic films. Placing the sample area of the test strip in an extracted sample causes the sample to be drawn through the absorbent pad toward the test and control lines.

If a sample contains IGFBP-1, the detecting antibody will bind to the protein. If the detecting antibody is bound to IGFBP-1, it will, in turn, bind to the capture antibody that is immobilized on the test line as the liquid flows past. The blue latex bound to the detecting antibody will be visible as a blue line in the test line area if IGFBP-1 in the sample exceeds the test's detection limit. The liquid will continue to flow to the control line area, registering as a blue control line that confirms the correct operation of the test.

Components of the Actim PROM Test

One (1) tube containing 0.5 mL of specimen extraction solution: a phosphate-buffered solution containing bovine serum albumin (BSA), protease inhibitors, and preservatives.

One (1) test strip in a sealed pouch containing a desiccant.

One (1) sterile polyester swab for specimen collection.

Storage Requirements

- Test kits should be stored between 2°C and 25°C (36°F–77°F).
- When stored unopened and within the recommended temperature range, each test component can be used until the “Use By” date marked on that component.
- Test kits can be stored for up to two (2) months at temperatures of up to 30°C (86°F), provided the “Use By” date has not expired.

Required Supplies

- Timer
- Patient Test Report Sheet

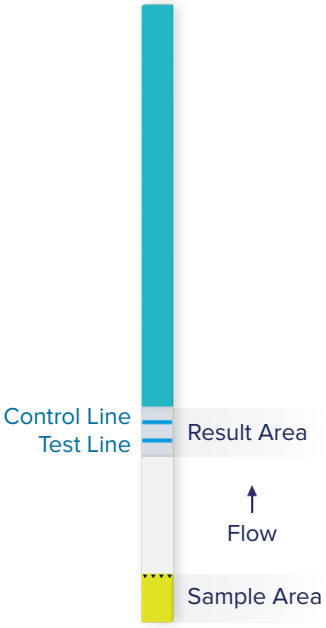
Specimen Collection & Preparation

1. Carefully separate the labia and insert the tip of the swab into the vagina, moving toward the posterior fornix until resistance is met.
2. Leave the swab in the vagina for approximately 10–15 seconds to allow it to absorb a vaginal fluid specimen.
3. Open the tube containing the specimen extraction solution and place it in a vertical position.
4. Immediately swirl the swab vigorously in the specimen extraction solution for 10-15 seconds to extract the specimen.
5. Discard the swab.

Test Procedure

1. Ideally, specimens should be tested immediately after extraction; however, extracted specimens may be stored at room temperature for up to four (4) hours prior to testing. If a specimen cannot be tested within four (4) hours, it should be frozen at or below -20°C (-4°F).
2. Set a timer for five (5) minutes.
3. Remove a test strip from its foil pouch. Take care not to touch the yellow sample area at one end of the test strip.
4. Submerge only the yellow sample area at the lower end of the test strip in the extracted specimen solution and keep it there until the liquid front has reached the result area.

Structure of the Actim PROM Test Strip



5. Remove the test strip from the extracted specimen solution and place it on a clean, non-absorbent, flat surface.
6. Start the timer.
7. A positive result is registered as soon as two blue lines become visible in the result area.
8. A negative result is registered if no blue test line has formed at five (5) minutes.
9. Do not interpret results after five (5) minutes.
10. Record the test results on the patient test report sheet. All patient results must be documented in the patient's chart, accompanied by the internal quality control (QC) results, the date and time of testing, and the operator's initials.

Result Interpretation

Verify that a blue line is present in the control line area when five (5) minutes have elapsed. This indicates that the test is functioning properly.

Positive for Ruptured Membranes

Two blue lines are visible, one in the control line area and one in the test line area. The test is positive even if the blue test line is faint.

Negative for Ruptured Membranes

One blue line is visible in the control line area. No line is visible in the test line area.

Invalid Test

Either no blue lines are visible in the results area, OR a blue line fails to appear in the control line area (regardless of the appearance of the test line).

Notes and Precautions

1. Accurate interpretation of results depends on operators following all directions carefully.
2. The Actim PROM test is only intended for professional *in vitro* diagnostic use.
3. Proper test performance requires approximately 150 µL of extracted specimen.
4. Do not use tests after the “Use By” date printed on each kit component.
5. Use only the swab provided in the test kit for specimen collection.
6. Do not reuse test kit components.
7. Do not remove the test strip from its pouch until just before use.
8. Do not bend or fold the test strip or the pouch that contains the test strip.
9. Do not use a test strip if the pouch is not sealed and intact.
10. Use care when placing the test strip in the specimen extraction solution tube. Only the yellow sample area should make contact with the specimen extraction solution; the upper part of the strip must stay dry.
11. Do not use a test strip that has become wet before testing.
12. Improper sample collection may lead to a false result.
13. Take care to keep the test strip sample area submerged in the specimen until the liquid front has reached the result area.
14. A positive Actim PROM test result indicates the presence of amniotic fluid in the sample. It cannot locate the site of the rupture.

Quality Control Test Instructions

Objective

The Actim PROM controls provide external quality control samples for use with the Actim PROM test. These quality control samples can be used in place of patient samples to verify the Actim PROM test and evaluate operator performance.

Components of the Actim PROM Controls

1. Actim PROM Negative Control (0 µg/L)
2. Actim PROM Low-Positive Control (~40 µg/L)
3. Actim PROM High-Positive Control (~250 µg/L)
4. Actim Reconstitution Solution
5. Instructions for Use

Required Supplies

1. Actim PROM Test Kit
2. Pipettes (capable of measuring 500 µL)
3. Timer

Internal Quality Control

1. The Actim PROM test was designed with a built-in reagent and procedural control in the form of a control line.
2. When performing the test, a blue control line indicates that sufficient capillary flow has occurred and the functional integrity of the dipstick was maintained.

Frequency of External Quality Control

External Quality Control must be performed for each new LOT number received or for each new shipment, even if it uses the same LOT number as previous shipments.

Quality Control Test Material & Storage

1. The positive controls contain purified human IGFBP-1 in a buffered protein solution with BSA and preservatives. The Negative Control contains only the buffered protein solution and preservatives.
2. Components must be stored between 2°C and 25°C (36°F–77°F).
3. Unopened, each component can be used until the “Use By” date printed on each component.
4. After reconstitution, the controls can be stored for 24 hours at 18°C to 30°C (64°F–86°F) or for up to 7 days at 2°C to 8°C (36°F–46°F).

Quality Control Procedure

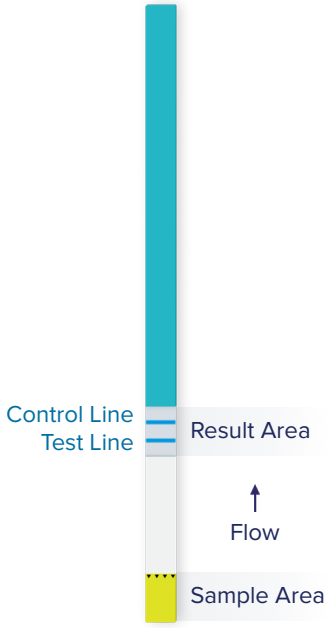
Reconstitution of Negative, Low-Positive, and High-Positive Control Tests

1. Unscrew the caps. Carefully open the vials by removing the gray stoppers.
2. Use a pipette to add 500 µL of reconstitution solution to each vial. Change pipettes or tips after each addition to reduce the risk of contamination.
3. Close the stoppers and let the vials sit for at least 15 minutes.
4. Ensure the lyophilized material in each vial is completely dissolved before use.

Testing

1. Set a timer for five (5) minutes.
2. Each Actim PROM test requires approximately 150 µL of sample. Before placing the test strip in a control vial, ensure sufficient volume is present.
3. Remove a test strip from its foil pouch. Take care not to touch the yellow sample area at one end of the test strip. The test strip must be used as soon as possible after removal from its pouch.
4. Submerge only the yellow sample area at the lower end of the test strip in the control solution vial and keep it there until the liquid front has reached the result area.
5. Remove the test strip from the extracted specimen solution and place it on a clean, non-absorbent, flat surface.
6. Start the timer.

Structure of the Actim PROM Test Strip



Result Interpretation

Verify that a blue line is present in the control line when five (5) minutes have elapsed. This indicates that the test is functioning properly.

Low-Positive Control

The low-positive control solution should yield a positive result, consisting of two visible blue lines, one in the control line area and one in the test line area. The blue line in the test line area should be faint.

High-Positive Control

The high-positive control solution should yield a positive result, consisting of two visible blue lines, one in the control line area and one in the test line area. The blue line in the test line area should be clearly visible.

Negative Control

The negative control solution should yield a negative result, consisting of one visible blue line in the control line area. No line should be visible in the test line area.

Invalid Test

Either no blue lines are visible in the result area, OR a blue line fails to appear in the control line area (regardless of the appearance of the test line).

Levels of Responsibility, Authority, and Accountability as Described by CAP POC.03550

The laboratory will:

1. Order Actim PROM kits as needed.
2. QC new shipments or new LOTS of Actim PROM test Kits.
3. Prepare external QC materials.
4. Prepare proficiency testing materials and coordinate with the birth suites.
5. Train designated staff in the birth suites.
6. Recertify designated staff in the birth suites.

Birth suites will:

1. Designate staff to be trained and perform Actim PROM testing.
2. Ensure that only trained staff perform Actim PROM testing.
3. Ensure that testing is performed in compliance with the procedures and requirements.
4. Coordinate with the laboratory to train new employees.
5. Coordinate with the laboratory to recertify operators.
6. Contact the laboratory when test kits are in short supply.
7. Perform proficiency testing (PT) three times per year for each Actim PROM operator.

Documentation

All Actim PROM patient results must be documented on the Actim PROM Test Report Sheet and accompanied by the two one-minute timings, the internal quality control, the date and time of testing, and the operator's initials.

References

1. Actim PROM Test Kit Instructions for Use (30831ETUS-IFU Rev. A Nov. 2014)
2. Actim PROM Controls Instructions for Use (30800ETUS-IFU Rev. A Nov. 2014)
3. Actim PROM 510(k) K123986
4. CAP POC Checklist

Actim PROM Quick Reference Guide

Test Procedure

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

2. Place the swab in the specimen extraction solution and swirl vigorously for 10 to 15 seconds.

3. Submerge the yellow sample area at the end of the test strip into the prepared specimen extraction solution. Hold the test strip in the solution until the liquid front reaches the result area.

4. Remove the test strip from the extraction solution when the liquid front reaches the result area.

5. Interpret results at five (5) minutes.

Result Interpretation

Verify that a blue line is present in the control line area when five (5) minutes have elapsed. This indicates that the test is functioning properly.

Positive for Ruptured Membranes

Two blue lines are visible, one in the control line area and one in the test line area. The test is positive even if the blue test line is faint.

Negative for Ruptured Membranes

One blue line is visible in the control line area. No line is visible in the test line area.

Invalid Test

Either no blue lines are visible in the results area, OR a blue line fails to appear in the control line area (regardless of the appearance of the test line).

Frequently Asked Questions

Storage & Sample Handling

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

A: Test kits should be stored at 2°C–25°C (36°F–77°F). Tests can be stored for up to two (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 to administer the Actim PROM test?

A: Administering the Actim PROM test does not require a speculum exam or other equipment.

Interpreting the Test Results

Q: Is the Actim PROM test affected by medications or bath products?

A: No. Testing shows that many substances do not affect the test results. These substances include baby oils, baby powder, feminine deodorant suppositories, and RepHresh Vaginal Gel, to name a few. Refer to the Actim PROM Test Kit Instructions For Use for a full list of drugs, substances, and pathogens found not to affect test performance.

Q: Is the Actim PROM test affected by blood?

A: The Actim PROM test was designed with a detection limit optimized to make blood contamination highly unlikely. From the Actim PROM Test Kit Instructions For Use: “Whole blood with concentrations corresponding to typical pregnancy levels of IGFBP-1 was tested and did not affect Actim PROM test performance.” However it should be noted, “in cases of heavy bleeding the locally may have a higher concentration of IGFBP-1 protein. In these cases, a positive result should be interpreted with caution.”

Q: Can the test strip be left in the specimen solution to develop?

A: No. The test strip must be removed from the specimen solution as soon as the liquid front reaches the results area.

Q: Can samples be stored for subsequent testing?

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

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

A: A test can be interpreted as positive as soon as two blue lines appear, one in the test line position and one in the control line position. A negative result must be read at five (5) minutes. Disregard any lines seen after five (5) minutes.

Q: Does the test line need to appear as blue as the control line?

A: A positive result is indicated by two blue lines appearing, one in the test line area and one in the control line area. No attention should be paid to the intensity of the blue lines at either position.

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

A: The appearance of a blue control line confirms the test is performing correctly. If the control line does not appear, the test is invalid and should be repeated with a new test strip.

Actim® PROM