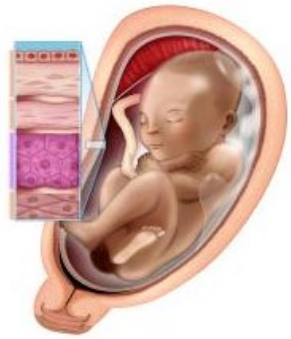
| PROGRAM Standard Operating Procedure – Laboratory Services | |
|---|---|
| Title: POCT Actim Partus Testing Procedure | Policy Number: 15-21-V1 |
| Program Name: Point of Care Testing (POCT) | |
| Applicable Domain: LAB, DI and Pharmacy Services | |
| Additional Domain(s): Hospital Based Clinical Services | |
| Effective Date: 11/10/19 | Next Review Date: 11/10/22 |
| Issuing Authority: Director Health Services | Date Approved: 11/10/19 |
| Accreditation Canada Applicable Standard: Point-of-Care Testing | |

**GUIDING PRINCIPLE:**

Decidual cells synthesize the phosphorylated forms of insulin-like growth factor binding protein-1 (phIGFBP-1) while amniotic fluid contains substantial quantities of non and less phosphorylated forms of IGFBP-1. When delivery is approaching, fetal membranes begin to detach from the decidua parietalis, and small amounts of phIGFBP-1 begin to leak into the cervical secretions.

In the Actim Partus test, a cervical specimen is taken with a sterile polyester swab during sterile speculum examination and extracted into the Specimen Extraction Solution. The presence of phIGFBP-1 is detected using a dipstick.



The test is based on immunochromatography. It involves two monoclonal antibodies to human phIGFBP-1. One is bound to blue latex particles (the detecting label). The other is immobilized on a carrier membrane to catch the complex of antigen and latex-labeled antibody and indicate a positive result.

When the area of the dipstick is placed in the extracted sample, the dipstick absorbs liquid, which starts to flow up the dipstick. If the sample contains phIGFBP-1 it binds to the antibody labeled with latex particles. The particles are carried by the liquid flow and, if phIGFBP-1 is bound to them, they bind to the catching antibody.

A blue line (test line) will appear in the result area if the concentration of phIGFBP-1 in the sample exceeds the detection limit of the test (approximately 10µg/l). A second blue line confirms correct performance of the test.

**PURPOSE/RATIONALE:**

The Actim Partus test is a visually interpreted, qualitative immunochromatographic dipstick test for detecting the presence of phosphorylated IGFBP-1 (insulin-like growth factor binding protein-1) in cervical secretions during pregnancy. The test is intended for professional use to help in predicting the risk of preterm or imminent delivery when fetal membranes are intact. In the appropriate clinical setting, a negative test result strongly supports the conclusion that the patient will not deliver within 7-14 days.

**DEFINITIONS:**

N/A

**SCOPE/APPLICABILITY:**

Health Care Professionals as designated in the Northwest Territories Health and Social Services Authority (NTHSSA) Point of Care Testing (POCT) Policy who have completed training and competency requirements and are limited to the following: Physicians, Nurse Practitioners, Midwives, Medical Residents, Registered Nurses, Medical Laboratory Technologists.

**SAMPLE INFORMATION:**

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| Type | The specimen is cervical secretion extracted into the labeled Specimen Extraction Solution tube provided. |
| Volume | The test requires about 150 µl of extracted sample to ensure proper performance of the test. (10-15 seconds in cervix) |
| Source<br>Stability<br>Storage requirements<br>Criteria for rejection | The sample should be collected prior to performing digital examination and/or trans-vaginal ultrasound. |
| | Patients with moderate or heavy vaginal bleeding should not be tested. It is recommended that a sample be taken when bleeding has stopped, and the extract is essentially blood-free. |
| | Specimens should be tested as soon as possible after extraction but in any case no more than 4 hours after specimen collection and extraction. |
| | If a specimen cannot be tested within 4 hours, it should be frozen. After thawing, the specimen should be mixed prior to testing. |
| | Leaking specimens, mislabeled/unlabeled specimens, and specimens that do not meet the stability and storage requirements listed above will be rejected. |

**REAGENTS and/or MEDIA:**

- Actim Partus Test Kit
  - One sterile polyester swab for specimen collection
  - One tube of Specimen Extraction Solution (0.5 ml). This phosphate-buffered solution contains bovine serum albumin (BSA), protease inhibitors and preservatives.

  - One dipstick in a sealed aluminum foil pouch with desiccant.
- Store the Actim Partus test kit at 2-25°C
- Stored unopened, each component can be used until the expiry date marked on the component.
- Use only the swab provided with the kit.
- Do not use the dipstick if you notice a blue colouring in the result area before testing.
- Do not use the dipstick if its aluminum foil pouch or the seals of the pouch are not intact.
- Do not use a dipstick that has become wet before use, because moisture damages the dipstick.
- Care must be taken when placing the dipstick in the sample tube. The upper part of the dipstick must stay dry.
- When dipping, be careful to hold the dipstick in position (with the dip area in the sample extract) until the sample liquid front reaches the result area.
- Open the foil pouch and remove the dipstick from the pouch just prior to use.

**SUPPLIES:**

- Watch, clock or timer that measures minutes
- Gloves
- Sterile speculum

**SPECIAL SAFETY PRECAUTIONS:**

- See The NWT Infection Prevention and Control Manual 2012
- Follow proper PPE and Hand Hygiene before and after testing
- **Testing materials containing Client ID should be disposed of in biohazard waste**

**QUALITY CONTROL:**

- Performed by the Laboratory
- Ensure Quality Control has been performed on kit before use. There should be a Laboratory Sticker indicating Ready for Use.
- Do not perform patient testing on any box of kits that does not have this indicated.

**PROCEDURE INSTRUCTIONS:**

Ensure the Actim Partus Box has a Ready to Use sticker indicating Quality Control has been performed before removing a testing kit.

Part 1. Extraction of sample

| Step | Action |
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| **Collection and Extraction of Sample** | |
| **1** | Remove a testing kit from the Actim Partus Box. |
| **2** | Label a Specimen Extraction Solution tube with the client identifiers and |

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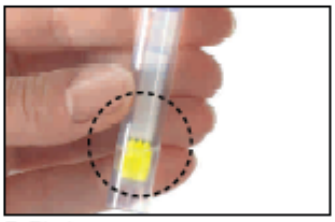
| | put it in a vertical position. |
| **3** | Take care not to touch anything with the swab before taking the sample. |
| **4** | A cervical secretion sample is obtained using a sterile polyester swab (provided in the kit) from the cervix during a sterile speculum examination. |
| **5** | The swab should be left in the cervix for 10-15 seconds to allow it to absorb the secretion specimen. Approximately 150 ul is required. |
| **6** | The specimen is extracted immediately from the swab by swirling the swab vigorously in the extraction solution for approximately 10 seconds.  A. Extraction |
| **6** | Press the swab against the wall of the Specimen Extraction Solution tube to remove any remaining liquid from the swab. |
| **7** | Discard the swab into the garbage. |

Part 2: Testing and Interpretation

| Step | Action |
|---|---|
| **Test Procedure and Interpretation of Results** | |
| **1** | Allow the aluminum foil pouch to reach room temperature. Open the foil pouch containing the dipstick by tearing. **Do not touch the yellow dip area at the lower part of the dipstick.** Client identifiers are to be written on the upper purple part of the dipstick. |
| **3** | Place the yellow dip area (the lower end of the dipstick) into the extracted sample.<br><br>Care must be taken when placing the dipstick in the sample tube. The upper part of the dipstick must stay dry.  B. Dipping |

| | | |
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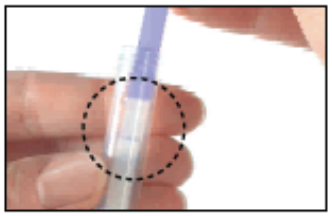
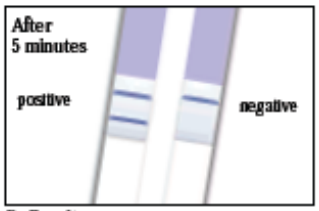
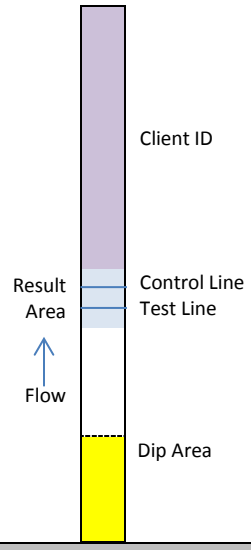
| **4** | Hold the dipstick in the extracted sample until you see the liquid front enter the result area. |  C. Note liquid front |
| **5** | Remove the dipstick from the solution and place it in a horizontal position. Set a timer for 5 minutes. | |
| **6** | The result can be interpreted as positive as soon as two blue lines become visible in the result area. **The negative result should be read at 5 minutes.**<br><br>Do not pay attention to any lines that develop after the 5 minutes. |   D. Result |
| **7** | The test line is in the lower half and the control line is in the upper half of the result area of the dipstick. Appearance of a control line confirms correct performance of the test. |   |

| | **If:** | **Then:** |
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| **8** | **Two blue** lines appear (the test line and the control line) | The test result is **positive** |
| | **One blue line** appears (the control line) | The test result is **negative** |
| | **The control line does not appear** | **The test is invalid.** Repeat the |

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| | | test with a new kit and new sample. |
| **9** | Read and record the result onto the POCT Patient Report form and scan report into patient's EMR or add to chart. Indicate your POCT user ID (Employee ID) in the appropriate area of the report. | |
| **10** | Discard of testing materials into the Biohazard waste. | |

**PERFORMANCE MEASURES:**
N/A

MEASUREMENT UNCERTAINTY/LIMITATIONS:

- The test is intended for in vitro diagnostic use only.
- Before performing an Actim Partus test ensure that the fetal membranes are intact, because with ruptured fetal membranes the Actim Partus test will also give a positive result.
- Patients with moderate or heavy vaginal bleeding should not be tested. It is recommended that a sample be taken when bleeding has stopped, and the extract is essentially blood-free.
- Improper sampling may lead to a false result.
- The test result indicates the risk at the time of sampling and changes in the patient's condition may later affect the final outcome of the pregnancy.
- The test results are qualitative. No quantitative interpretation should be made based on the test results.
- As with all diagnostic tests, results must be interpreted in light of other clinical findings.
- The test requires about 150 ul (obtained by leaving the swab in the cervix for 10-15 seconds) of extracted sample to ensure proper performance of the test.

INTERPRETATION OF RESULTS:

See testing procedure above.

**CROSS REFERENCES:**
N/A

**ATTACHMENTS:**
N/A

**REFERENCES:**

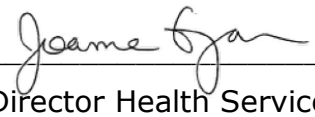
- Medix Biochemica. (2017/03). *Actim Partus Instructions for Use.* Espoo, Finland: Medix Biochemica. OOOOOALCE31931-4
- Medix Biochemica. (n.d.). *Medix Biochemica.* Retrieved July 22, 2019 from Medix Biochemica: www.medixbiochemica.com

**RELATED DOCUMENTS:**

- NTHSSA Client Identification Policy
- POCT Patient Report Actim Partus

**APPROVAL:**

October 11, 2019
Date


Director Health Services

**REVISION HISTORY:**

| REVISION | DATE | Description of Change | REQUESTED BY |
|---|---|---|---|
| | | Initial Release | |
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