PROGRAM Standard Operating Procedure – Laboratory Services	
Title: POCT Actim Partus Quality Control Procedure	Policy Number: 15-22-V1
Program Name: Point of Care Testing (POCT)	
Applicable Domain: LAB, DI and Pharmacy Services	
Additional Domain(s):	
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:

The test is based on immunochromatography. It involves two monoclonal antibodies to human IGFBP-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 IGFBP-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 controls are intended to be used with the Actim Partus test for external quality control to ensure the components of the kit are working properly.

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, Combined Laboratory and X-Ray Technicians.

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 of the kit can be used until the expiry date marked on the component.
- Open the foil pouch and remove the dipstick from the pouch just prior to use.
- Do not use a 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.
- Use only the swab provided with the kit.
- 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.

- Actim Partus Control Kit
  - Actim Partus Negative Control
  - Actim Partus Positive Control, Low
  - Actim Partus Positive Control, High
  - Actim Reconstitution Solution
- Do not use a control if the vial is damaged.
- Controls are for use with the Actim Partus test kit only

SUPPLIES:

- Watch, clock or timer that measures minutes
- Gloves
- Calibrated Pipette capable of measuring 500 ul.
- Disposable pipette tips

SPECIAL SAFETY PRECAUTIONS:

- See The NWT Infection Prevention and Control Manual 2012
- Follow proper PPE and Hand Hygiene before and after testing.
- Controls should be treated as potentially infectious and hazardous.

QUALITY CONTROL:

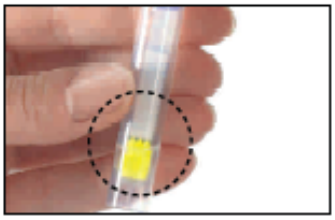
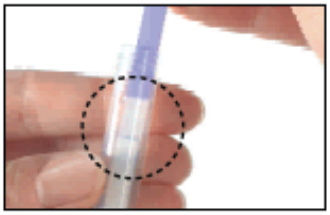
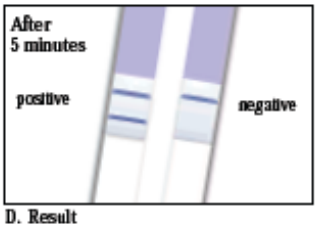
- Controls are run with **each new box** of Actim Partus testing kits.
- Actim Partus Negative Control
- Actim Partus Positive Control, Low

- Actim Partus Positive Control, High
- Controls are reconstituted with 500 ul of Actim Reconstitution solution
- The positive controls consist of purified human phlGFBP-1 in a buffered protein solution with BSA and Thimerosal as preservative. The negative control consists of the same matrix without added antigen.
- Stored unopened at 2-25^0 C, each component can be used until the expiry date marked on each component.
- After reconstitution, the controls are stable for 24 hours at room temperature, 7 days at 2-8^0 C, and 24 months frozen at -20^0 C.
- Do not refreeze after thawing.
- Do not use the controls before they have been completely reconstituted.

PROCEDURE INSTRUCTIONS:

Follow the steps in the table below

Step	Action
Control Testing Procedure and Interpretation of Results	
Bring Controls to room temperature for 15 minutes if stored in the fridge. If using frozen reconstituted Controls, thaw at room temperature and mix before using. Proceed to Step 4.	
1	Unscrew the cap and open the Quality Control vials by carefully removing the grey stopper.
2	Reconstitute the Controls by adding 500 ul of the reconstitution solution to the vials. Change the pipette tip after adding solution to each vial.
3	Recap the Controls and allow to reconstitute for at least 15 minutes. After 15 minutes ensure material is dissolved and mix before use.
4	Label three tubes with Positive-Low, Positive-High and Negative, for corresponding Control Solution. Transfer 250 ul of control materials to corresponding labeled tubes.
5	Write date and time of reconstitution and 24 month expiry on remaining Vials of Quality Control and freeze. (Skip this step if using frozen QC)
6	Remove three testing strips from the Actim Partus Testing kits, and label for the corresponding Quality Control. Discard the remaining components of the testing kits.

7	Place the yellow dip area (the lower end of the dipstick) into the Labeled tubes for each level of Control. Care must be taken when placing the dipstick in the sample tube. The upper part of the dipstick must stay dry.	 B. Dipping
8	Hold the dipstick in the tube until you see the liquid front enter the result area.	 C. Note liquid front
9	Remove the dipstick from the solution and place the tube in a horizontal position. Set a timer for 5 minutes.	
10	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.** Do not pay attention to any lines that develop after the 5 minutes.	 D. Result

11	**If:**	**Then:**
	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 test using a new kit. If the test is still invalid, notify Supervisor or POCT Specialist.
12	Record results on the Actim Partus Quality Control Log.	
13	Place a Ready for Use sticker on the Actim Partus testing kit box for Obstetrics use only if all three levels of QC pass.	

14	Discard of testing materials into the Biohazard waste.

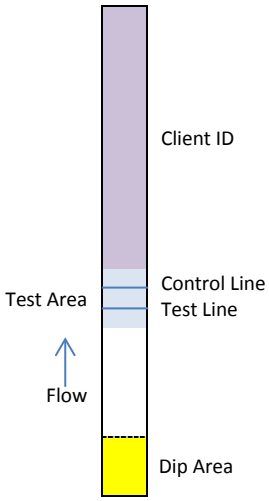
PERFROMANCE MEASURES:
N/A

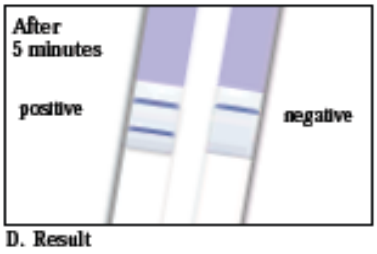
MEASUREMENT UNCERTAINTY/LIMITATIONS:

- The test is intended for in vitro diagnostic use only.
- Improper sampling may lead to a false result.
- The test results are qualitative. No quantitative interpretation should be made based on the test results.
- The test requires about 150 ul of Control material to ensure proper performance of the test.

INTERPRETATION OF RESULTS:

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.





D. Result

If the control line does not appear, the test is invalid, and should be repeated 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.

At five minutes the appearance of any faint-to-dark blue test line along with a control line indicates a positive result. However, do not pay attention to any lines appearing after 5 minutes.

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:
- POCT Actim Partus Quality Control Log

APPROVAL:

October 11, 2019
Date

Director Health Services

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
		Initial Release	