

Actim Partus test in prediction of preterm labour

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Key Amendments

Date	Amendments	Approved by

Introduction

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.

The presence of phosphorylated IGFBP-1 during weeks 24-34 of pregnancy, along with symptoms of labour, suggests the possibility of a preterm labour.

The appropriate use of Actim Partus test, should reduce not only the need for tocolysis, but also reduce the number of unnecessary courses of steroids currently used. It will also be beneficial in reducing unnecessary transfers between units.

Patients Covered

Patients eligible for Actim Partus

1. Women are between 24⁺⁰ weeks and 34⁺⁰ /35⁺⁶ weeks' gestation.
2. Women are tightening or contracting and there is no sign of cervical dilatation on speculum.
3. There is no evidence of ruptured membranes.
4. There has been no moderate or heavy bleeding or suspected placental abruption or placenta praevia.
5. No fetal compromise or demise
6. Singleton or twin pregnancy.

Patients NOT eligible for Actim Partus

Women presenting with signs and symptoms of threatened preterm labour between 24⁺⁰ –35⁺⁶ weeks with:

1. Ruptured membranes.
2. Cervical dilatation more than or equal to 1.5 cms or less than or equal to 1 cm long.
3. Moderate or gross vaginal bleeding.
4. Co-existing medical disorder such as severe pre eclampsia.
5. Gestational age <24⁺⁰ weeks or >35⁺⁶ weeks.

The test is kept in the clean utility room on central / delivery suite.

Please note that the key documents are not designed to be printed, but to be used on-line. This is to ensure that the correct and most up-to-date version is being used. If, in exceptional circumstances, you need to print a copy, please note that the information will only be valid for 24 hours and should be read in conjunction with the key document supporting information and/or Key Document intranet page, which will provide approval and review information.

Specimen collection

Step 1: Test should ideally be performed prior to a digital examination. Insert a speculum and visualise the cervical os. Take the cervical secretion sample by the holding the sterile polyester swab at the Cervical Os for 10-15 seconds. This allows the swab to absorb a sufficient amount of specimen. If indicated also take HVS and endocervical swabs.

Step 2: Open the Specimen Extraction solution tube and place the polyester swab in the extraction solution tube and swirl around vigorously for approx. 10 seconds. Press the swab against the wall of the Specimen Extraction Solution tube to remove any remaining liquid from the swab. Discard the swab.

Step 3: Open the foil pouch containing the dipstick by tearing. Do not touch the yellow dip area at the lower part of the dipstick. Patient identification marks may be written on the upper purple part of the dipstick. The dipstick must be used ASAP after its removal from the foil pouch.

Step 4: Place the yellow dip area of the dipstick into the extracted sample and hold it there until you see the liquid front reach the result area. Remove the dipstick from the solution and place it in a horizontal position.

Step 5: A negative result (control line only) should be read at 5 minutes. The results should not be interpreted after this time.

Step 6: A positive test result can be interpreted as soon as two blue lines - a control line and a test line - appear in the result area. If, after five minutes, only the control line has appeared, the test result is negative. Should no control line appear, the test should be discarded and a new test performed.

Negative Result

- A negative result has a negative predictive value of 100% for birth within 48 hours, and 92% for birth within 7 – 14 days.
- If the result is negative the patient should be discharged home unless other obstetric indications require admission.
- All women with a negative test will be given education on the signs and symptoms of preterm labour and reassured that they can come back at any time.
- **NB A negative test is not helpful if there is cervical dilatation present. The patient should then be treated as being in preterm labour. Clinical judgement must always be a part of the assessment – in the presence of a negative test where there is still a high index of suspicion, please discuss the case with the ST 6 -7/ Consultant on call.**

Positive Result

- Once a positive test has been confirmed on a woman who has signs and symptoms of preterm labour the management will be in accordance to the preterm labour guidelines.
- Positive test patient should have steroids administered.
- The use of tocolysis should be considered in line with the preterm labour guideline.
- Neonatal Intensive Care will be notified of admission. If there are no cots available it may be necessary to arrange an intra-uterine transfer, this should always involve discussion with the Consultant Obstetrician on call.

If the woman has not delivered within 7 days, a plan of care will be decided by the obstetric consultant/obstetric team. A further Actim Partus test may be indicated.

Management of Actim Partus test result

If Actim Partus test negative:

- Reassure the patient.
- Prescribe Oral analgesia (if needed).
- Discharge home 2 hours after contractions/pain settles.

- If Actim Partus is negative then the patient should only be considered for transfer to another hospital after review by the Obstetric Consultant. The decision for transfer should then be a consultant to consultant referral with clear documentation as to the indications for transfer.

If Actim Partus test positive:

- Admit for observation.
- Intravenous access.
- Take blood for Group and Save. FBC.
- Send MSU for culture and sensitivity.
- Prescribe Steroids if <34 completed weeks. See WAHT-TP-094 PPRM
- Prescribe Oral analgesia if required.
- Tocolysis - refer to Atosiban guideline D12
- Arrange transfer to hospital with neonatal unit (Worcestershire Royal Hospital or other) as per guideline.
- Request pediatrician to speak to mother

APPENDIX 1

Alere Actim[®] Partus
How to Use Guide

Can be used as indicated below:



Lubricants



Following Intercourse



Mild Bleeding

Actim Partus 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 predict the risk of preterm or imminent delivery when foetal membranes are intact.

Step 1 - Taking the Sample

- The sample should be collected prior to performing digital examination and/or transvaginal ultrasound
- Take cervical secretion sample using the polyester swab
- Leave the swab in the cervical os for 10 - 15 seconds to allow absorption



Step 2 - Extract

- Place the polyester swab in the extraction solution tube
- Swirl the swab vigorously in the solution for 10 - 15 seconds
- Discard the swab



Step 3 - Dip

- Dip yellow area of the dipstick into the extracted sample contained in the tube
- **Hold until the liquid reaches the results area**
- Remove dipstick and place it in a horizontal position



Step 4 - Read Result

- If two blue lines (test line and control line) appear, the test result is positive. A result can be interpreted as positive as soon as these two blue lines become visible in the result area
- If only one blue line (the control line) appears, the test result is negative. A negative result **must** be read at **5 minutes**
- **Do not interpret results after 5 minutes**

(Refer to the Instructions For Use for full information)

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