

October monthly news!

Actim Partus Test is here!



New Study starts in mid October 2012!

This study is a prospective, multi-center study designed to evaluate the clinical test performance characteristics-i.e., the negative diagnostic likelihood ratio, as well as the positive diagnostic likelihood ratio, sensitivity and specificity, positive predictive value and negative predictive value- of the Actim Partus test in cervical secretions of pregnant women between week 21+6 and week 35+6 gestation presenting with intact fetal membranes, minimal cervical dilation (<3cm) and signs and/or symptoms suggestive of and whereby the clinician suspects preterm labor.

The test is intended for use in assessing the risk of delivery in ≤ 7 or ≤ 14 days from time of cervical sample collection. A negative test result indicates that the patient is at low risk of delivering within the next 7-14 days. The results of the study are intended to generate sufficient clinical data to support regulatory filings in the United States.

SCREENING CRITERIA:

1. Pregnant woman presenting for unplanned obstetrical care with signs and/or symptoms suggestive of preterm labor:
 - Uterine contractions (with or without pain)
 - Intermittent lower abdominal pain, dull backache, pelvic pressure
 - Vaginal bleeding during the second or third trimester
 - Menstrual-like intestinal cramping (with or without diarrhea)
 - Change in vaginal discharge (amount, color, consistency)
 - Vague sense of discomfort characterized as "not feeling right"
2. Singleton Pregnancy, and GA 21+6 and week 35+6 @ time of enrollment
3. Subject has not participated in the study before
4. Intact amniotic membranes by clinical evaluation of ROM (2 or more of the following present: Nitrazine test, ferning, pooling/visible leaking of amniotic fluid)
5. Cervical dilation < 3 centimeters
6. **No evidence of any of the following:**
 - Rupture of membranes
 - Amniotic membranes bulging through cervix
 - Cervical cerclage

Dr Miller's Quote of the Month

"I have this theory that if one person can go out of their way to show compassion, then it will start a chain reaction of the same. People will never know how far a little kindness can go."



Dr. Hugh Miller

Rachel Joy Scott

- Suspected placenta previa
- Digital exam or transvaginal ultrasound during previous 24 hours
- Heavy (bright red or clotting) vaginal bleeding. Light, serous bleeding acceptable
- Subject is enrolled in any clinical trial evaluating investigational drug

Step 2

Extract Specimen



Place the swab in the specimen extraction solution and stir. 10-15 sec

Step 3

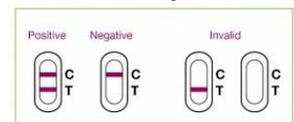
Activate Test



Insert dipstick into the solution until liquid reaches the result area.

Step 4

Result Interpretation



Positive Negative
Two lines can be interpreted immediately.

To confirm a negative, read results at 5 minutes.

Convenient and Easy Testing Process by the Bedside

The testing process is simple, with results in just 5 minutes:

Step 1

Collect Sample



Collect cervical secretion sample from the cervical os.

Comparison of the clinical performance of Actim® Partus to FFN

Mr Ifaturoti, Consultant Obstetrics and Gynaecology
 Dimple D'Costa, Trust SHO Obstetrics and Gynaecology
 Julie Aldred, Advanced Midwifery Practitioner

University Hospital of South Manchester NHS Foundation Trust

Introduction

In 2011 the University Hospital of South Manchester Maternity Unit undertook an assessment to compare Actim Partus to FFN in the clinical setting.

Methods

Women with suspected PTL were tested with both the Actim Partus test and the FFN test (Hologic). Clinical history and observations were taken for these women and recorded. The Actim Partus and the FFN test results were compared to one another and to clinical outcomes i.e. delivery at the 2 week follow up.

Results

Patient	Examination date	Gestation	Actim Partus	FFN	2 weeks follow up
1	12/09/2011	30+3 weeks	Positive	Positive 499ng/ml	Delivered (15/09/2011)
2	30/08/2011	29+2 weeks	Negative	Negative	Not delivered
3	13/09/2011	24 weeks	Negative	Negative	Not delivered
4	22/08/2011	33 weeks	Negative	Negative	Not delivered
5	17/09/2011	32 weeks	Negative	Negative	Not delivered
6	08/09/2011	31+5 weeks	Negative	Negative	Not delivered
7	14/09/2011	35+5 weeks	Negative	Negative	Not delivered
8	06/09/2011	34+1 weeks	Negative	Positive 137ng/ml	Not delivered
9	09/09/2011	24 weeks	Negative	Negative	Not delivered

Table 1: Nine women who presented with suspected PTL were tested with the Actim Partus test. The test result was then compared to the clinical outcome (delivery at 2 week follow up). Patient 8 was admitted due to a positive FFN test and steroids were administered.

Table 1 shows that the Actim Partus test correlated well with clinical outcome. The Actim Partus test was shown to correctly identify as negative all the cases that did not deliver within 2 weeks. The Actim Partus test also correctly identified the one woman who delivered within the 2 weeks. The FFN test was shown to falsely identify one woman as positive (Patient 8). This woman was admitted and given steroids but remain undelivered at the 2 week follow up. In this sample set the Actim Partus test did not have any false negatives or positives.

Feedback

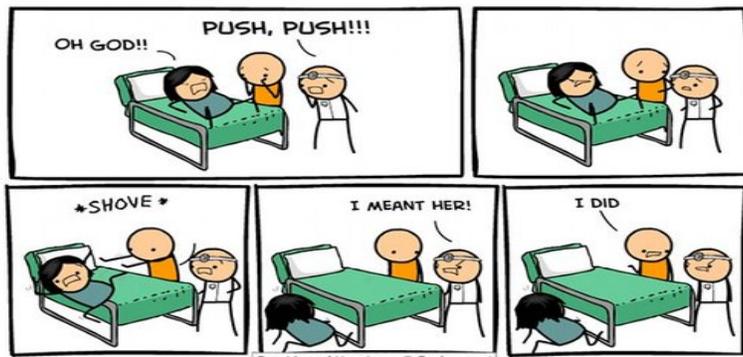
The Actim Partus test was preferred over the FFN test as it was easier to use and interpret and the time to result was significantly faster. Also the test could be performed at the bedside and read without the need for a reader. From a clinical standpoint the advantage of the Actim Partus test is that KY jelly does not interfere with the test, the test can also be used in women whom have had intercourse and those with mild bleeding.

Conclusion

The above shows that the Actim Partus can effectively rule-out PTL in the clinical setting and is at least as reliable as FFN with additional clinical and practical benefits.

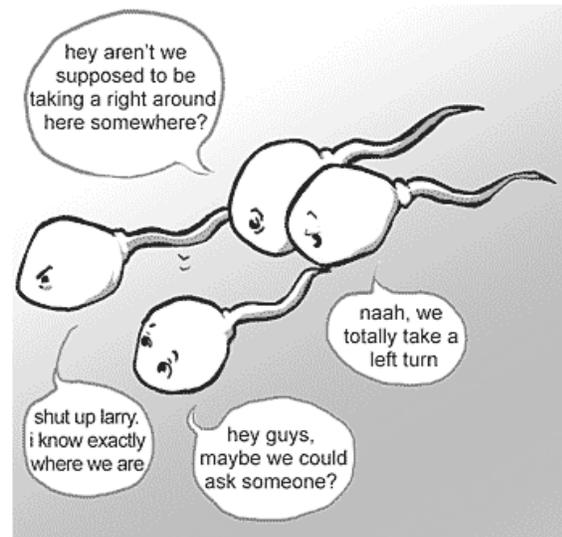
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Fun Facts "A Doctors Advice" (Not actual questions just jokes)

- Q. What's the difference between a nine-month pregnant woman and a model?
 A. Nothing, if the pregnant woman's husband knows what's good for him.
- Q. My childbirth instructor says it's not pain I'll feel during labor, but pressure. Is she right?
 A. Yes, in the same way that a tornado might be called an air current.
- Q. Our baby was born last week. When will my wife begin to feel and act normal again?
 A. When the kids are in college.
- Q. Should I have a baby after 35?
 A. No, 35 children is enough.



why it can take over 100 million sperm to fertilize one egg

Current Studies Enrolling

In-Patient

- 17 PPROM weekly Makena Progesterone injection vs Placebo for patients who have ruptured their membranes between 23w0d and 31w6d at time of enrollment
- Removal vs Retention of Cerclage in PPROM between 22w-32w 6/7 GA, Cerclage in place ≥ 1 week. ACTIVE labor is excluded

Out-Patient

- Makena 17P weekly progesterone injection vs Placebo for patients with a history of preterm delivery at < 37 weeks GA
- Family Alliance Study, Smoking Intervention for pregnant smokers with a viable GA ≥ 14 weeks – 28w 6/7. Must be fluent in English

Contact W.O.M.B with any questions or comments:



Watching Over Mothers and Babies

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