Wishaw General Hospital
Women's Services Directorate

GUIDELINE FOR THE USE OF THE FETAL FIBRONECTIN TEST

Background

Fetal fibronectin (fFN) is a protein which is found at the interface between the fetal membranes and the uterine decidua. fFN is virtually never found in the cervico-vaginal secretions between 22 and 35 weeks gestation, and so its presence aids in the diagnosis of preterm labour.

A negative fFN test result has a negative predictive value of 99.2% for birth within 14 days of the test and 92% for delivery before 37 weeks. Therefore a negative result is very reassuring for the expectant parents, medical and midwifery staff that the risk of preterm birth is low. This also helps avoid unnecessary hospital admissions, medical interventions and transfers to other hospitals for neonatal facilities.

If the test is positive, 16.7% of women will deliver within 14 days of the test. While this is less reliable in predicting the onset of labour, it allows staff to increase surveillance of the pregnancy and target the use of tocolysis. In addition, administration of magnesium sulphate can be considered for women at high risk of delivering early. MgSO4 provides a neuro-protective effect on newborn babies by reducing the risk of cerebral palsy (RR 0.68; 95% CI 0.54 to 0.87) and gross motor dysfunction (RR 0.61; 95% CI 0.44 to 0.85) 5-9. The magnitude of this effect is likely to be largest at gestations less than 30 weeks.

Indications for Use

- Consider for all pregnant women between 24 and 34 weeks gestation, with painful uterine contractions occurring 2 in 10 minutes or more often.
- The membranes should be intact.
- The test may be inaccurate if the patient has had sexual intercourse, digital vaginal examination or a speculum examination within the preceding 24 hours.
- Any patient with 'show' or light bleeding and symptoms suggestive of preterm labour can be tested if necessary, but there should be no blood on the swab.
- If painful uterine contractions persist, the fFN test can be repeated 24 hours later.
- Cervix < 3cm dilated

Contraindications to the test

- Gestation <24 or >34 weeks

- Spontaneous rupture of the membranes
- Systemic infections
- Moderate-to-severe antepartum haemorrhage
- Fetal distress
- Sexual intercourse or digital examination within 24 hours
- Any contra-indication to tocolysis

Necessary Equipment

- Specimen collection kit
- Speculum
- **Water should be used as a lubricant**
- fFN testing machine analyser/printer – should be calibrated daily and kept plugged in and switched on
- fFN cassette kit – when a new batch of cassettes arrives the machine analyser should be recalibrated and retested

The specimen collection kits, machine analyser and cassettes will be kept in Triage.

Taking the Swab

The pregnant woman will be admitted to Triage, and the test performed there. The swab will be taken by the on call registrar and the test will be performed by the triage midwives who have been trained to use the analyser.

- The correct specimen collection kit must be used – no other swab can be used to take the test. Extra swabs are provided.
- Do a **speculum examination first**
- Use **water as a lubricant for the speculum examination**
- Care must be taken to avoid contaminating the cervico-vaginal fluid with topical agents such as KY jelly, other lubricants, soap, disinfectant or cream
- Rotate the swab from the specimen collection kit across the posterior fornix for 10 seconds
- Remove the swab and immerse the tip in the buffer solution
- Mix the swab in the buffer solution for 10-15 seconds
- Leave the swab in the tube, break the shaft of the swab by snapping at the score, in line with the top of the tube
- Align the shaft with the hole inside the tube cap and push down tightly over the shaft, sealing the tube for transfer to the analyser. If the shaft is not aligned properly, the tube will leak and the test will not be reliable.
- The sample should be labelled with the patient's name and number
- Then perform a vaginal examination. If the cervix is 3 cm or more dilated, the swab is discarded and the test abandoned.
- There is no cost for the swab therefore if in any doubt, take the swab then discuss need for the swab to be analysed with a senior registrar or consultant on call.

Performing the Analysis

- From the main menu select 1 – TEST PATIENT
- Enter your user ID (this can be any combination of numbers and letters – record your name and user ID in the diary beside the machine so that there is a record of who is operating the machine) and press ENTER
- Enter the last 2 digits of the cassette lot (on cassette pouch) and press ENTER
- Enter the patient's CHI number and press ENTER
- Insert the fFN cassette into the analyser and follow the on screen instructions to run the test
- Draw up 200uL (0.2ml) sample into the well of the fFN cassette using a 1ml syringe or the 0.2ml pipettes.
- Keep the labelled tube in the box next to the machine, in case you have to repeat the test
- The analyser will begin a 7-minute incubation countdown and then analyse the cassette.
- The analyser will generate a printout of the results.
- Press enter to get a second printout
- One result label should be placed in the patient's notes
- The second result label should be placed in the diary next to the machine

Interpreting the Results

FFN VALUE ng/ml	% who will deliver within 2 weeks	% who will deliver at <34/40 weeks	MANAGEMENT
0 – 9	< 2	< 2	Discharge with routine MW F-U
10 – 49	< 2	5 – 15	Discharge with Consultant F-U
50 – 199	5 – 15	10 – 15	• Admit • Steroids • F-U with Consultant 2/52 • Consider repeating FFN
200 – 499	30	30	• Admit • Steroids • Tocolysis • MgSO4 if in labour and <30wks • If discharged, F-U with consultant 1/52 and repeat FFN
>500	50	75	• Admit • Steroids • Tocolysis • MgSO4 if in labour and <30wks • If discharged, F-U with consultant 1/52 and repeat FFN

References

Honest H, Bacjmann LM, Gupta JK et al. Accuracy of cervico-vaginal fetal fibronectin test in predicting risk of spontaneous preterm birth: systematic review. BMJ 2002; 325:301-304.

Abenhaim H, Morin L, Benjamin A, Maharaj S. Does availability of fetal fibronectin testing in the management of threatened preterm labour affect the utilization of hospital resources. JOGC 2005; July: 889-894.

Goldenberg RL et al. The preterm prediction study: patterns of cervico-vaginal fetal fibronectin as predictors of spontaneous preterm delivery. AM J Obstet Gynecol 1997; 177: 8.

Goldernberg RL, Iams JD, Mercer BM et al. The preterm prediction study: the value of new vs standard risk factors in predicting early and all spontaneous preterm births. Am J Public Health 1998; 88: 233-238.

Anderson HF. Use of fetal fibronectin in women at risk for preterm delivery. Clinical Obstet Gynecol 2000; 43: 746-758

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