

LABORATORY COLLECTION MANUAL	FETAL FIBRONECTIN (fFN®) PHYSICIAN SPECIMEN COLLECTION INSTRUCTIONS
Effective Date: 3/2006	Page 1 of 2

I. PURPOSE:

To provide guidelines for the physician to obtain a vaginal swab for fetal fibronectin enzyme immunoassay via sterile speculum examination to assist in assessing the patient's risk for preterm delivery.

II. PATIENT PREPARATION:

- A. Specimens should be obtained prior to digital cervical examination or vaginal probe ultrasound examination as manipulation of the cervix may cause the release of fetal fibronectin.
- B. Patient should not have had sexual intercourse within 24 hours prior to the sampling time because semen and/or sperm present in the sample may increase the possibility of a false positive result.
- C. Care must be taken not to contaminate the swab or cervicovaginal secretions with lubricants, soaps, disinfectants or creams (e.g. K-Y® jelly lubricant, Betadine® disinfectant, Monistat® cream, hexachlorophene). These substances may interfere with absorption of the specimen by the swab or with the antibody-antigen reaction of the test.

III. PROCEDURE:

- A. Specimen must be obtained **PRIOR** to performing a vaginal examination. Criteria for eligibility include:
 1. gestational age between 24 and 34 6/7 weeks.
 2. signs and symptoms of preterm labor, such as:
 - ◆ uterine contractions with or without pain
 - ◆ menstrual - like cramping, dull backache and/or pelvic pressure
 - ◆ vaginal spotting or light bleeding during the second or third trimester
 - ◆ intermittent abdominal pain with or without diarrhea
 - ◆ any change in vaginal discharge (amount, color or consistency)
 3. intact amniotic membranes
- B. Patients who are **not eligible** for fetal fibronectin enzyme immunoassay or for whom the effectiveness of the test has not been established include those who:
 - have ruptured membranes
 - are known to be dilated > 3 cm
 - are experiencing moderate or heavy vaginal bleeding
 - have cancer of the reproductive tract
 - have a cerclage in place
 - have a placenta previa or an abruptio placentae
 - have engaged in sexual intercourse within the past 24 hours
 - have within the past 24 hours experienced manipulation of the cervix, such as a digital cervical examination, a vaginal probe ultrasound, a Pap smear and/or collection of vaginal specimens for culture
 - have within the past 24 hours douched or used other vaginal solutions, **lubricants**, creams or medications
- C. Explain the procedure to the patient. Provide for privacy.
- D. Assemble equipment: sterile speculum and gloves, small sterile basin, saline or water for lubricant, Fetal Fibronectin fFN® collection kit and biohazard bag. Obtain the collection kit from the BRMC Laboratory.

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Effective Date: 3/2006	Page 2 of 2

- E. Wash hands.
- F. Position patient for sterile speculum exam in dorsal lithotomy position with foot of labor bed removed or with buttocks elevated on large folded blanket or inverted bed pan. Drape patient to ensure privacy.
- G. Open the fetal fibronectin collection kit, which contains a sterile dacron swab for specimen collection and a transport tube containing extraction buffer. Open small sterile basin and pour sterile saline or sterile water into it to lubricate the speculum. Open the sterile speculum package, maintaining sterility. Don sterile gloves and lubricate the speculum with sterile saline or sterile water. NOTE: Sterile saline and sterile water are the ONLY lubricants which may be used for specimen collection for fetal fibronectin enzyme immunoassay. A dry speculum may also be used.
- H. Insert the sterile speculum per normal procedure. Visualize the cervix and observe for leakage of amniotic fluid, cervical dilation, and any abnormalities. If there is leakage of amniotic fluid from the cervical os and/or the cervix is obviously dilated > 3 cm., the patient is not a candidate for fetal fibronectin enzyme immunoassay: do not collect the specimen.
- I. There are two sites which may be used for specimen collection: either outside the cervical os or the posterior vaginal fornix. Visualize both sites and select the one to be used prior to inserting the dacron swab for specimen collection to avoid contaminating the swab with mucus and/or blood. Avoid collecting the specimen from a site where blood is present.
- J. Collect the specimen by placing the tip of the dacron swab from the collection kit either on the outside of the cervical os or into the posterior vaginal fornix and lightly rotating it across the cervix or the fornix for 10 seconds to permit absorption of the fetal fibronectin. Use a gentle sweeping and twisting motion, avoid aggressive sampling. If sampling from the cervix, keep the swab on the outside of the cervix; do not place it into the os. The dacron swab from the collection kit is the ONLY swab which may be used for sample collection; any other swab will invalidate the test results.
- K. Remove the dacron swab and place the tip with the vaginal swab in the extraction buffer in the specimen tube from the fetal fibronectin enzyme immunoassay collection kit. Break the shaft of the dacron swab even with the top of the specimen tube (a guide mark indicates the correct place to break the shaft). Align the end of the swab shaft with the hole inside the specimen tube cap and push the cap down tightly to seal the tube.
- L. Remove the speculum, remove gloves and assist the patient to a comfortable position. Wash hands.
- M. Label the specimen tube properly with patient and collector identification, and date and time of collection. According to the physician's order, transport the specimen to the laboratory either for testing (room temperature up to 8 hours) or to be held in the specimen refrigerator for 72 hours.

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APPROVED BY: Martin F. Belli, M.D. DATE: 3-2006

See original policy in the Laboratory for all documented annual reviews.

Reference:

fFN® Specimen Collection Kit package insert, Adeza Biomedical Corporation, December, 2003