fFN Rapid Test Cassette (Vaginal secretion)
Package Insert

REF FFF-502 English

For professional in vitro diagnostic use only.

【INTENDED USE】

The fetal fibronectin (fFN) rapid test (vaginal secretion) is a visually interpreted, qualitative immunochromatographic test device for detection of fFN in vaginal secretions during pregnancy, which is a special protein that literally holds your baby in place in the womb. The test is intended for professional use to help diagnose if the preterm delivery is likely to occur in pregnant women. The test may be run on patients between 24 and 34 weeks gestation.

【SUMMARY】

Fetal fibronectin (fFN), an isoform of fibronectin, is a complex adhesive glycoprotein with a molecular weight of approximately 500,000 daltons.[1, 2]

Fetal fibronectin is elevated in cervicovaginal secretions during the first 24 weeks of pregnancy but is diminished between 24 and 34 weeks in normal pregnancies.Detection of fFN in cervicovaginal secretions between 24 and 34 completed weeks gestation is reported to be associated with preterm delivery in symptomatic[3, 4, 5] and asymptomatic pregnant women[6, 7].

【PRINCIPLE】

The fFN (vaginal secretion) has been designed to detect fFN through visual interpretation of color development. Anti-fFN antibodies are immobilized on the test region of the membrane in the test unit. During the test, the specimen is allowed to react with colored anti-fFN antibodies conjugated colloidal gold, which were impregnated on the sample pad of the test. The mixture then moves on the membrane by a capillary action and interacts with reagents on the membrane. If fFN is available above detectable limits in specimens, a colored band will form at the T region of the membrane. Presence of colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

【MATERIALS】

Materials Provided

- Test cassettes
- Package insert
- Specimens dilution tubes with buffer (0.1 M PBS)

Materials Required But Not Provided

- Timer
- Specimens collection swabs

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Do not use test if pouch is damaged.

【STORAGE AND STABILITY】

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

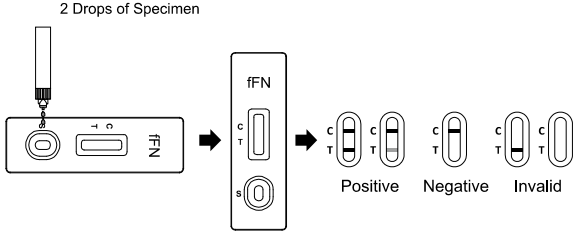
【SPECIMEN COLLECTION AND STORAGE】

- The Fetal fibronectin (fFN) Rapid Test Cassette (vaginal secretion) is intended only for use with cervicovaginal secretions.
- The specimen is cervicovaginal secretion that is extracted into the Specimen Extraction Solution provided. A cervicovaginal secretion is obtained using a sterile polyester swab from the posterior fomix of the vagina during a sterile speculum examination or, if no vaginal fluid is visible, the sample may be taken from the cervix. Take care not to touch anything with the swab before taking the sample. The swab should be in the vagina or cervix for approximately 10~15 seconds to allow it to absorb the secretion samples.
- Open the Specimen Extraction Solution tube and put it in a vertical position. The specimen is extracted immediately from the swab by swirling the swab vigorously in the extraction solution for approximately 10 seconds. Specimens should be tested as soon as possible after extraction but in any case no more than 4 hours after specimen collection and extraction. If a specimen can not be tested within this time it should be frozen. After thawing, the specimens should immediately be tested as fresh sample, bringing it to room temperature as with a fresh sample.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours.
- Bring specimens to room temperature prior to testing.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

【PROCEDURE】

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. To obtain a best result, the assay should be performed within one hour.
- Add 2 drops (80µl) of the extracted buffer into the sample well. As the test begins to work, you will see color move across the membrane.
- Wait for the colored band to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

POSITIVE RESULT: * A colored band appears in the control band region (C) and another colored band appears in the T band region.

NEGATIVE RESULT: One colored band appears in the control band region (C). No band appears in the test band region (T).

INVALID RESULT: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS OF THE TEST】

1. The Fetal fibronectin (fFN) Rapid Test Cassette (vaginal secretion) is for in vitro diagnostic use only. This test should be used for the qualitative detection of fFN only. Neither the quantitative value nor the rate of increase in fFN concentration can be determined by this qualitative test.
2. This test will only indicate the presence of fFN in specimens Performance with specimens other than female cervical swabs has not been assessed.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
5. Excessive blood on the swab may cause false positive results.

【EXPECTED VALUES】

The fFN Rapid Test Cassette (Vaginal secretion) has been compared with a leading commercial fFN test. The correlation between these two systems is 98.4%.

【PERFORMANCE CHRACTERISTICS】

Sensitivity and Specificity

The fFN Rapid Test Cassette (vaginal secretion) has been tested with a leading commercial fFN Rapid Test using clinical specimens.

Method		Other fFN Rapid Test		Total Results
fFN Rapid Test Cassette	Results	Positive	Negative	
	Positive	101	2	103
	Negative	2	148	150
Total Results		103	150	253

Relative Sensitivity: 98.1% (95%CI:*93.2%-99.8%)
Relative Specificity: 98.7% (95%CI:*95.3%-99.8%)
Overall Accuracy: 98.4% (95%CI:*96.0%-99.6%) *Confidence Intervals

Precision

Intra-Assay

Within-run precisions has been determined by using 10 replicates tests for each of three lots using three fFN antigen levels at 0 ng/mL, 25 ng/mL, 50 ng/mL. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by using the same fFN antigen levels at 0 ng/mL, 25 ng/mL and 50 ng/mL of fFN in 10 independent assays. Three different lots of the fFN Rapid Test Device (vaginal secretion) have been tested using these specimens. The specimens were correctly identified >99% of the time.

【REFERENCES】

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2. Matsuura H, Takio K, Titani K, Greene T, et al. The oncofetal structure of human fibronectin defined by monoclonal antibody FDC-6. Unique structural requirement for the antigen specificity provided by a glycosylhexapeptide. J Biol Chem 1988;263:3314–22
3. Lockwood CJ, Senyei AE, Dische MR, Casal DC, et al. Fetal fibronectin in cervical and vaginal secretions as a predictor of preterm delivery. New Engl J Med 1991;325:669–74.
4. Morrison JC, Allbert JR, McLaughlin BN, Whitworth NS, et al. Oncofetal fibronectin in patients with false labor as a predictor of preterm delivery. Am J Obstet Gynecol 1993;168:538–42.
5. Bartnicki J, Casal DC, Kreaden US, Saling E, Vetter K. Fetal fibronectin in vaginal specimens predicts preterm delivery and very low birth weight infants. Am J Obstet Gynecol 1996;174:971–4.
6. Lockwood CJ, Wein R, Lapinski R, Casal D, et al. The presence of cervical and vaginal fetal fibronectin predicts preterm delivery in an inner-city obstetric population. Am J Obstet Gynecol 1993;169:798–804.
7. Morrison JC, Naef RW, Botti JJ, Katz M, et al. Prediction of spontaneous preterm birth by fetal fibronectin and uterine activity. Obstet Gynecol 1996;87:649–55.

Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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Number:
Effective date: