Chuangxingwell

CE

Fetal Fibronectin (fFN) Rapid Test Kit
Package Insert

For in-vitro diagnostic use only.

IVD

INTENDED USE

Rapid immunochromatographic test for the qualitative detection of foetal fibronectin (fFN) in human vaginal swab as an aid in diagnosis of preterm delivery in pregnant women.

PRINCIPLE

The test is performed by applying the extracted vaginal sample to the sample well of the cassette and observing the formation of colored lines.

fFN is detected by utilizing a combination of colored anti-fFN conjugated colloidal gold particles and anti-fFN antibodies. The sample migrates by capillary effect along the membrane. fFN reacts with the colored anti-fFN conjugated colloidal gold particles and is captured by anti-fFN antibodies with the formation of a colored line in the Test (T) region. The presence of this colored line indicates a positive result, while its absence indicates a negative result.

As a procedure control a colored line has to appear in the Control (C) region confirming that sufficient sample has been absorbed.

COMPOSITION

Individually packed test cassette, desiccant, sterile collection swab Sample dilution tube with extraction buffer

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- For external use only. Do not swallow.
- Samples are potentially infectious and therefore have to be treated cautiously.
- Avoid cross-contamination of samples by using a new sample collection container for each sample obtained.
- Use gloves when performing the test.
- The test is designed for single use only. Discard after use according to the local regulations or laboratory rules for disposal of potentially infectious waste.
- Do not use test kit beyond expiry date.
- Do not use test kit in case that the pouch is punctured or not sealed correctly.
- Humidity and temperature affect the results.
- Keep out of the reach of children.

STORAGE AND STABILITY

When stored in the sealed pouch at 2-30℃ and protected from direct sunlight, moisture and heat the test kit is stable until the indicated expiry date. Shelf life is 24 months.

Do not open pouch until ready to perform the assay. It must be used within an hour if opened.

DO NOT FREEZE.

Care should be taken to protect components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SAMPLE COLLECTION AND PREPARATION

Collect the sample by immersing the sterile swab provided in the kit for 15 seconds in the posterior fornix of the vagina or in the cervix, in case no vaginal fluid is visible.

Open the sample dillution tube with the extraction buffer and keep it in a vertical position. Introduce the swab into the sample dillution tube and firmly swirl the swab for 10 seconds in order to extract the sample from the swab into the extraction buffer. Discard the swab and fit the cap of the extraction tube.

Samples must be used immediately after extraction and no more than 4 hours after collection and extraction.

Do no leave sample at room temperature for prolonged periods of time.

Sample may be stored at 2-8°C for up to 3 days or kept below -20°C for longer storage period.

Bring sample to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

PROCEDURE

Test cassette, buffer and sample must be at room temperature (15-30°C) prior to testing.

1. Remove test cassette from the foil pouch and place it on a flat and clean surface.
   For best results, the assay should be performed immediately.
2. Add **2 drops of sample** (appr. 80 µL) to the sample well (S) of the cassette.
3. Wait for the colored lines to appear and read the test result after **10 minutes**.
   IMPORTANT: **Do not read the result after 20 minutes.**

INTERPRETATION OF RESULTS

Positive (+)

Two colored lines appear on the membrane. One line appears in the Control (C) and another line in the Test (T) region.

Note: Color intensity of the line appearing in the Test (T) region may vary depending on the fFN concentration in the sample. Therefore, any shade of color in the Test (T) region is to be considered as a positive result.

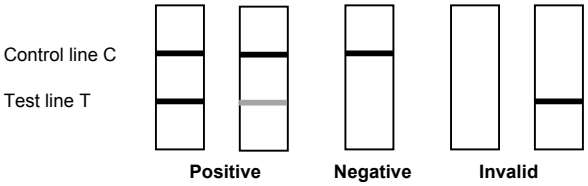
Negative (-)

Only one colored line appears in the Control (C) region. No colored line appears in the Test (T) region.

Invalid

If a color line is visible only in the Test (T) region or no color line is visible at all the test is invalid and needs to be repeated with a new test cassette.

Note: Insufficient sample volume, incorrect procedure or expired test are most common reasons of invalid results.



QUALITY CONTROL

Although the test itself includes an internal procedural control, use of external controls is highly recommended as part of Good Laboratory Practice to confirm and verify the test procedure and proper performance of the test. Controls are to be tested following the same procedure as applied for patient samples. Positive and negative controls shall give the expected results.

LIMITATIONS OF PROCEDURE

This test is for professional in vitro diagnostic use and is to be used for qualitative detection of fFN in women vaginal samples only. No quantitative result or rate of increase in fFN concentration can be determined with this test.

This test will only detect the presence of fFN in the vaginal secretion samples of women between week 24 and 34 of gestation and is not to be used as the sole criterion for diagnosis of preterm delivery in pregnant women.

High titer of Rheumatoid Factor or heterophile antibodies may affect the results of the test.

Excessive blood on the swab cause false positive results. As for all diagnostic tests, results must be interpreted by a physician only after all clinical and laboratory findings have been evaluated.

PERFORMANCE

Sensitivity and specificity:

Fetal Fibronectin (fFN) Rapid Test Kit has been tested versus a commercial fFN test. Sensitivity, specificity and correlation among the two methods has been found to be as following:

		fFN Rapid Test Kit		Total
		+	-	
Commercial Rapid Test fFN	+	101	2	103
	-	2	148	150
		103	150	253

Test sensitivity: 98.1 % (93.2 % - 99.8 %)*
Test specificity: 98.7 % (95.3 % - 99.8 %)*
Overall Agreement: 98.4% (96.0 % - 99.6%)*

*95 % Confidence Interval

Precision:

Intra-assay:

Negative, low positive and high positive samples have been tested in 10 replicates each. Results have been detected correctly for >99% of the samples.

Inter-assay:

Negative, low positive and high positive samples have been tested in 10 replicates each with Fetal Fibronectin (fFN) Rapid Test Kit from 3 different lots. Results have been detected correctly for >99% of the samples.

BIBLIOGRAPHY

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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

EXPLANATION OF SYMBOLS

	Caution	IVD	In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
LOT	Batch Code		Do Not Use if Package is Damaged
REF	Catalogue Number		Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
EC REP	Authorized representative in the European Community		

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
Add.: Building 1-2B-402, Liando U Valley, Gangyuan Sixth Road, Jinan Zhangjin Comprehensive Bonded Zone, Gaoxin District, Jinan city, Shandong Province, China
Tel: +86-0531-88894020
Email: s@1stiot.com

EC REP

Riomavix S.L.
Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain
E-mail: leis@riomavix.com
Tel.: +34 658 396 230
(SRN: ES-AR-000001202)