Rapid ƒFN Assay FETAL FIBRONECTIN

Policy and Principle

Detection of ƒFN in cervicovaginal secretions is associated with preterm delivery in symptomatic and asymptomatic pregnant women. This test is used as an aid in assessing the risk of a preterm delivery.

Materials and Reagents

- TIi_{IQ} Analyzer, Printer & User's Manual
- Rapid ƒFN System. Store at room temp at **15 - 30°C**.
- Cassettes (18 months shelf life from date of manufacture and are good until expiration date printed on foil pouch). Once the foil pouch is opened, the cassette must be used immediately.
- Directional Insert
- Rapid ƒFN Control Kit. Store refrigerated at **2 - 8°C**. Shelf life is one year from date of manufacturer and may be used until expiration date printed on the bottle.
- Positive Control: (0.090 to 0.100 μg/ml ƒFN)
- Negative Control: (<0.020 μg/ml ƒFN)
- TIi_{IQ} QCette: Store at room temp at **15 - 30°C.**

Specimen Collection

Step	Action
Collection	The physician or designee will collect the specimen per protocol.
Storage	Specimens that are not tested within 8 hours of collection must be stored refrigerated at 2°C to 8°C and **assayed within 72 hours of collection.**
Transport	Transport at room temperature. **Specimens left at 2°C to 8°C (refrigerated) are stable for 72 hrs.** Do not expose to heat!
Unacceptable Specimens	The following are unacceptable: Specimens Collected: • In or by any sample device other than the Adeza Collection Kit. • With insufficient volume • Received unlabeled • Received 72 hours after collection

Safety

All specimens, reagents and controls should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing scheduled maintenance. Refer to: Policy and Procedures Safety Manual Infection Control and Procedures 11-085-01.

Precautions

- Test results may not be interpreted visually and must be based on the use of the analyzer.
- **Do not use anything glass,** as ƒFN binds to glass. Polypropylene or polyethylene tubes and pipettes are acceptable.
- **Do not** mix materials from different kit lots.
- **Do not** use reagents that are cloudy or discolored
- **Do not** use external incubation mode at Irvine Medical Center

Quality Control

External QC – Liquid Controls must be run:

- Each time a new shipment or new lot of Rapid ƒFN cassettes is received
- At least once each day patient specimens are assayed.

Daily Analyzer QC:

- Daily running of the Qcette is the quality control method for analyzer performance.

Step	Action
1	Select Option 3 (DAILY QC) from the Main Menu of the analyzer. Enter the User ID and press ENTER.
2	Enter the QCette Serial Number and press ENTER.
3	Insert the QCette and press ENTER.
4	When analysis is complete (approx. 3 min.), the result will be displayed on the analyzer screen and the printed label as SYSTEM PASS. **A FAIL or INVALID result should be repeated**.

Setting Calibration for a Rapid ƒFN Cassette Lot

THIS IS DONE WITH EACH NEW LOT NUMBER AND/OR SHIPMENT OF CASSETTES.

Step	Action
1	Select Option 2 (SET CALIBRATION) from the Main Menu of the analyzer.
2	Enter the User ID and press ENTER.
3	Enter the Cassette Lot number. All letters and numbers must be entered. Enter the number that corresponds to the correct letter and use the up and down arrows to scroll to the correct letter. Press ENTER when completed.
4	Enter the Calibration Code (always 2 letters and 2 numbers) provided on each box of cassettes. The calibration code consists of two letters followed by two numbers. If the code is not entered correctly or does not match the cassette lot number that has been entered, the analyzer will request that the code be re-entered. This calibration code will be used for all cassettes of that lot number
5	When calibration is complete, the result will be displayed on the analyzer screen and the printed label as SYSTEM CALIBRATED. Press ESC to return to the Main Menu.

Control and Sample Preparation

INTERNAL INCUBATION MODE: in this mode pressing ENTER will prompt you to add the sample within the 2-minute allotted time or the analyzer will automatically invalidate the run.

For **external** incubation mode see Page 4 of the procedure.

If	Then
Controls	**Once opened, controls must be used within 6 months**. 1. Allow to reach room temp before testing (20min) 2. Invert to mix before testing
Specimen Preparation	1. Allow all Specimen Transport tubes to come to room temperature before testing (20 min.). 2. Gently mix the Specimen Transport Tube prior to removing the Dacron swab. 3. Open the Tube cap and swab assembly. The shaft should be seated in the cap. 4. Express as much liquid as possible from the swab by rolling the tip against the inside of the tube. Swab is stored in the refrigerator for 72 hours

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Incubation Mode

This setting allows you to use the analyzer to time the incubation and start the analysis **(INTERNAL MODE)** or manually time the incubation and start the analysis **(EXTERNAL MODE).** To change from one mode to the other:

Step	Action
1	From the second screen on the MAIN MENU, select **6-CHANGE SET UP.**
2	Select **3-INCUBATION MODE** (flashing number with mode is what the instrument is currently in).
3	Select the mode you choose to be in, Press ENTER
4	Press ESC twice to go back to MAIN MENU.

Performing the Quality Controls

INTERNAL INCUBATION MODE

If	Then
Negative Control	From the main menu: 1. Select LIQUID CONTROLS. 2. Enter User ID, then press **ENTER**. 3. Enter Cassette Lot #, press **ENTER**. 4. Select **1-Negative Control.** 5. Enter the Control Lot Number, press **ENTER**. 6. Remove one ƒFN Cassette from the foil pouch. 7. Insert the Cassette and press Enter. The instrument will display “ADD SAMPLE and IMMEDIATELY PRESS ENTER”.

Performing the Quality Controls, continued

If	Then
Negative Control	From the main menu: 1. Select LIQUID CONTROLS. 2. Enter User ID, then press ENTER. 3. Enter Cassette Lot #, press ENTER. 4. Select **1 Negative Control**. 5. Enter the Control Lot Number, press ENTER. 6. Remove one ƒFN Cassette from the foil pouch. 7. Insert the Cassette and press Enter. The instrument will display "ADD SAMPLE and IMMEDIATELY PRESS ENTER". 8. Add 200 µL (using add 200 µL MLA pipettor with tip) to the sample application well and press **ENTER**. 9. The FN analyzer will count down for 20 minutes and analyze the ƒFN Cassette 10. The result for the Negative Control will be displayed as **Pass or Fail** and automatically print. 11. Press **ESC** to return to the MAIN MENU.
Positive Control	Repeat the above steps except **SELECT POSITIVE** Control when it prompts you in the Main Menu. If both Controls indicate **Pass**, then proceed to Patient Specimen. If not, repeat test.

EXTERNAL INCUBATION MODE

See protocol on page 3 for selecting external incubation mode. In this mode, you are responsible for timing the incubation and starting the analysis. **The positive and negative controls samples must be added to their respective cassettes,** 2-5 minutes apart.

Incubation Phase:

Step	Action
1	See page 'SAMPLE PREPARATION' for Controls on page 2.
2	Remove one Rapid ƒFN Cassette from the foil pouch for each of the controls.
3	Using 200 µL MLA pipettor with tip, add 200 µL of positive and negative control solutions to sample well on respective cassettes 2-5 minutes apart. Set timer for 20-minute room temperature incubation.

Reading Phase: Controls

Step	Action
1	A few minutes prior to the completion of the initial 20-minute incubation phase, select Run Controls from the Main Menu and enter the necessary information until the analyzer prompts for cassette insertion. At the end of the 20-minute incubation phase, insert the cassette into the analyzer and press **ENTER**.
2	Do this for each control level.
3	The result for the Negative and Positive Control will be displayed as Pass or Fail and automatically print.
4	Press **ESC** to return to the main menu.

Performing Patient Samples

INTERNAL INCUBATION MODE

Step	Action
1.	Prepare the patient specimen according to instructions on page 4.
2.	Select Test Patient from Main Menu and enter necessary information until the Tli analyzer prompts for cassette insertion.
3.	Follow steps **#6 to #9** under "running the controls".
	The result for the sample will be displayed on the display screen as **POSITIVE** or **NEGATIVE**. If an **invalid result** is obtained, see page 7: Invalid results.

Aborting a RUN

You may be requested to cancel a test during the incubation phase of testing. To do this, Press **ESC**. A test warning screen will appear, prompting you to choose **ENTER OR ESC**. **ENTER** will continue the test and **ESC** will end the test.

Reporting Results

Interpretation of results:

If	Then
The data record reports the patient sample as positive and the specimen is **NOT bloody.**	Report as **Positive** in computer and manual log.
The data record reports the patient sample as positive and the specimen is **BLOODY.**	Convert result section to [**FREETEXT**] and put "See Comment" then click the comment section. Under [**RESULT COMMENT**] report as "Bloody specimen received, **may be false positive** result." in CERNER and manual log.
The data record reports the patient sample as negative.	Report as **Negative** in computer and manual log.
The data record reports the patient sample as **INVALID**	Retest
Specimen is received >72 hours from collection time	Convert result section to [FREETEXT] and put "See Comment" then click the comment section. Under [RESULT COMMENT] report as "Specimen is >72 hrs. Test not performed." in CERNER.

Results are manually entered in Cerner under the Accession Result Entry (ARE) mode. For detailed instructions of entering results, please refer to Laboratory Informatics – Cerner Genlab Policies & Procedures Manual, "*Resulting in Cerner GenLab: Manual Entry*" LIS.SCPMG.041 document.

Error Message

If you get an error message:

1. Turn off the Analyzer, wait 10 seconds, turn the Analyzer back on and allow the instrument to go through the diagnostics test. When the main menu is displayed, retest sample.
2. If the problem persists, call Adeza Technical Support at 1-877-945-0208.

Invalid Results

Retest with 200 μL of additional patient sample using a new cassette. If invalid result occurs again inspect the cassette and:

If	Then
You see a clean white membrane (no blue lines)	Sample was not added or sample was too thick to flow
You see a heavy dark blue line and the Control line has a very faint or no blue color	Sample probably contains amniotic fluid, which contains high levels of *f*FN. This is a contraindication to the test.
The membrane is discolored from a bloody *f*FN sample	The membrane becomes so discolored as to not allow a large enough difference from the background to the Control line.

Maintenance

As needed:

1. Clean Tli system
2. Add paper to printer. See section 7 pages 1-4 of Tli system users manual.

Limitations

1. The Rapid *f*FN result should **not** be interpreted as absolute evidence for the presence or absence of a process that will result in delivery in less than or equal to 7 or 14 days from specimen collection in symptomatic women or delivery in less than or equal to 34 weeks, 6 days in asymptomatic women evaluated between 22 weeks, 0 days and 30 weeks, 6 days of gestation. A positive Rapid *f*FN result may be observed for patients who have experienced cervical disruption caused by, but not limited to, events such as sexual intercourse, digital cervical examination, or vaginal probe ultrasound.

2. Test results **may not** be interpreted visually and must be based on the use of the TLi system.

3. The safety and effectiveness of using a cutoff other than that provided by the *f*FN Positive Reference Calibrator has not been established.

4. Assay interference from the following components has not been ruled out: douches, white blood cells, red blood cells bacteria, and bilirubin.

5. Patients with suspected or known placental abruption, placenta previa, or moderate or gross vaginal bleeding should not be tested for *f*FN.

Reference

2004 Azeda Biomedical Corporation.
Rapid *f*FN Cassette Package Insert, 2/1999
Tli Qcette Package Insert 5/2001
Technical Bulletin #46

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Implemented
Major	Page 2 Liquid controls: added controls must be run every 30 days	Diana Davodi 1/28/11			
Major	Updated format and procedure, added the safety and revised result reporting section to reflect the changes for new LIS, Cerner.	Julius Salomon 04/30/14			
Major	Updated Liquid Control section to reflect external QC to be run on day of use.	Julius Salomon 1/08/16			
Minor	Updated format and revised index number.	Julius Salomon, 7/1/17			