Sutter Health
Sutter Roseville Medical Center

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Owner:	*Matthew Sawyer: Spvr, Laboratory*
Policy Area:	*Lab - Chemistry*
References:	
Applicability:	*Sutter Roseville Medical Center*

Performing Rapid Fetal Fibronectin (fFN) Cassette Validation, Daily Quality Control and Patient Testing

PURPOSE

This Procedure describes how to perform cassette validation, daily quality control and patient testing on the TLI_{IQ} analyzer using the Qcette® as well as performing patient testing.

PRINCIPLE

The Rapid fFN Assay is a qualitative test for the detection of fFN. Detection of fFN in cervicovaginal secretions is associated with preterm delivery in symptomatic pregnant women between 24 weeks and 34 weeks, 6 days gestation and in asymptomatic pregnant women 22 weeks to 30 weeks, 6 days gestation.

POLICY

Validation and quality control will be performed on each new lot, new shipment and monthly for each in-use lot of Rapid fFN cassettes.

EQUIPMENT AND MATERIALS

Material/Equipment	Storage Requirements	Stability
Rapid fFN cassettes	15 - 30 C	Expiration date on package
TLI_{IQ} Analyzer & Printer	—	-----
Pipette – 200 uL	—	-----
Rapid fFN Positive Control	2 - 8 C	6 months from open date, or exp. date on kit – whichever comes first
Rapid fFN Negative Control	2 - 8 C	6 months from open date, or exp. date on kit – whichever comes first
Specimen Storage Tubes	15 - 30 C	-----
TLI_{IQ} Qcette®	15 - 30 C	Indefinite if protected from light and moisture

SPECIMEN

Acceptable Specimens	Unacceptable Specimens	Transport/Storage
Collected only in an ADEZA specimen transport tube	Bloody - any evidence of blood Specimens exposed to heat Specimens in contact with glass QNS <200uL	Transport at room temp. (15 - 30 C) Store 8 hours at room temp. (15 - 30 C) Store up to 72 hours refrigerated (2 - 8 C)

PROCEDURE

Cassette Validation

Preparing control material for use.

Step	Action
1.	Retrieve liquid Controls from the Urinalysis Refrigerator and allow them to equilibrate to room temperature for 5-10 minutes.

	• fFN Positive Control • fFN Negative Control	
2.	Check liquid controls	
	If	**Then**
	Cloudy or discolored	Discard and select a new control
	Not cloudy or discolored	Proceed with QC testing.

Entering Lot Number and Calibration Code into the TLI_{IQ} analyzer.

NOTE: Only 1 lot can be used at a time.

Step	Action	
1.	Press the **<ESC>** key to exit to the main menu.	
2.	Press the number < **2** > key.	
3.	Enter SQ Tech Code using numbers on key pad.	
4.	Press the < **ENTER** > key.	
5.	Enter cassette lot number from label on side of box using letters and numbers key pad.	
6.	Press the < **ENTER** > key.	
7.	Enter the 2 letter and 2 number calibration code from label on side of box using letters and numbers on the key pad.	
8.	Press the < **ENTER** > key. Note: Instrument should immediately auto-print label from printer.	
9.	Remove label from printer.	
	If	**Then**
	Label Present	Go to step 10
	Label Not Present	Turn on Printer and Press the < **ENTER** > key
10.	Verify label reads "**SYSTEM CALIBRATED**"	
	If	**Then**
	Yes	Go to step 11.
	No	• Go back to step 1 and repeat procedure. • If "NO" a second time, then call customer support.
11.	Adhere label to "fFN Calibration and Quality Control" worksheet under appropriate heading.	

Running Liquid Controls.

Step	Action
1.	Press **<ESC>** key to exit to the main menu.
2.	Press < down arrow> twice until you get to option 8 "Liquid Controls."
3.	Press number < **8** > key.
4.	Enter SQ Tech Code using numbers on key pad.
5.	Press the < **ENTER** > key.
6.	Enter cassette lot number from label on side of box using letters and numbers key pad.
7.	Press the < **ENTER** > key.
8.	Press the number < **2** > key to enter into the positive control.
9.	Enter Control lot number from label on bottle using letters and numbers key pad.
10.	Press the < **ENTER** > key.
11.	Select an unopened cassette from box and remove from pouch.
12.	Insert cassette into the TLI_{IQ} instrument insertion site.
13.	Press the < **ENTER** > key.

14.	Open the prepared positive control bottle.	
15.	Use MLA Pipette to transfer 200 uL of the control into sample well of the inserted cassette.	
16.	**Immediately** Press the < ENTER > key.	
	Note: Instrument should immediately display "Testing in process, Do Not Remove Cassette."	
17.	Wait 25 minutes.	
	Note: When testing is completed the system will autoprint a label.	
18.	Remove label from printer.	
	If	**Then**
	Label Present	Go to step 19
	Label not present	Turn on Printer and Press the < **ENTER** > key
19.	Confirm successful QC.	
	If	**Then**
	Successful – Printout will display "PASS"	Go to step 20
	Not successful – Printout will display "FAIL"	• Repeat by starting at DAILY QUALITY CONYROL Step1. • Perform troubleshooting as described in the user manual on page 7-4. • Document corrective action on fFN worksheet. • Notify Supervisor.
20.	Adhere label to "fFN Calibration and Quality Control" worksheet under appropriate heading.	
21.	Indicate "Ready For Use" on each box of cartridges of the same lot number received in the same shipment.	
22.	Repeat steps 1 to 7.	
23.	Press the number < **1** > key to enter into the negative control.	
24.	Repeat steps 9 to 13.	
25.	Open the prepared negative control bottle.	
26.	Repeat steps 15 to 20.	

Daily Quality Control

Step	Action	
1.	Press number <3> on the keypad while in the main menu.	
2.	Enter SQ Tech Code using numbers on the key pad.	
3.	Press the <ENTER> key.	
4.	Enter Qcette Serial Number using letters and numbers on the keypad.	
5.	Press the <ENTER> key.	
6.	Remove Qcette from storage box.	
7.	Insert Qcette into the TLI_{IQ} instrument insertion site until it beeps.	
8.	Press the <ENTER> key.	
9.	Wait 5 minutes.	
10.	Remove Qcette and return to storage box.	
11.	Close box lid tightly.	
12.	Remove label from printer.	
13.	Confirm Successful QC.	
	If	**Then**
	Successful - Printout will display "PASS"	Go to step 14
	Not Successful - Printout will display "FAIL"	• Repeat by starting at Step 1. • Perform troubleshooting as described in user manual on page 7-4. • Document corrective action on fFN worksheet.

		• Notify Supervisor.
14.	Adhere label to TLI_{IQ} Patient results worksheet under appropriate heading.	

PATIENT TESTING

Step	Action
1.	Specimen must be at room temperature prior to testing.
2.	Gently mix the specimen transport tube prior to removing the swab.
3.	Open the specimen transport tube cap. **NOTE:** The swab shaft should remain seated in the cap.
4.	Express as much liquid as possible from the swab into the specimen transport tube. Then discard the swab.
5.	If specimen is cloudy or mucoid, centrifuge @2500 rpm for 5 minutes at room temperature.
6.	Press the number <1> key while in the main menu.
7.	Enter SQ tech code using numbers on keypad.
8.	Press the <ENTER> key.
9.	Enter the cassette lot number from the label on the side if the box using letters and numbers on the keypad.
10.	Press the <ENTER> key.
11.	Enter patient accession number.
12.	Press the <ENTER> key.
13.	Select an unopened cassette from the box and remove from the pouch.
14.	Insert cassette into the TLI_{IQ} instrument insertion site.
15.	Press the <ENTER> key.
16.	Use a MLA pipette to transfer 200uL of specimen into the sample well of the inserted cassette.
17.	**Immediately** press the <ENTER> key. Note: Instrument should immediately display "Testing in process, Do Not Remove Cassette."
18.	Retrieve the TLI_{IQ} Qcette - Patient Results Worksheet. • Adhere the Sunquest barcode patient label into the name box. • Write date/time specimen was received. • Note specimen condition and/or any phone information in the comments box.
19.	Wait 20 minutes.
20.	Remove label with results from the printer.
21.	Adhere label to the TLI_{IQ} Qcette - Patient Results Worksheet.

INTERPRETATION AND REPORTING

Step	Action	
1.	Verify results are valid.	
	If	**Then**
	Patient report label has valid result	Go to step 2
	Patient report label does not have a valid result	• Repeat by starting at PATIENT TESTING Step 1. • Perform troubleshooting as described in user manual on page 7-6. • Document corrective action on fFN worksheet. • After 2nd failure result is invalid, go to step 2. • Notify Supervisor, save all invalid cassettes and label in zip lock bag.
2.	Enter results into the LIS using the function MEM. • Enter RVFFN for worksheet. • Enter FFN for test code. • Enter accession number.	
	If	**Then**

	Result is positive	Enter POS
	Result is negative	Enter NEG
	Result is Invalid	Enter INVAL and notify RN for need to recollect.
3.	File TLI_{IQ} Qcette - Patient Results worksheet in the fFN result folder in the chemistry file cabinet.	

REFERENCE

Adeza® Biomedical Corporation – TIi_{Q} System User's Manual – 2001 version 01188:01

Adeza® Biomedical Corporation – fFN ® Rapid Control Kit package inserts – April 2001.

All revision dates: 3/16/2020

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Director	Lindsey Westerbeck: Dir, Lab	3/16/2020
Laboratory Director	Lindsey Westerbeck: Dir, Lab	2/10/2020