

RAPID fFN (FETAL FIBRONECTIN) FOR THE HOLOGIC TLiQ QUALITY CONTROL

Policy Quality control for Fetal Fibronectin is done using one Positive Control and one Negative Control each day of patient testing; each time a new lot or a new shipment of Rapid fFN cassette is received, or whenever there is uncertainty about Rapid fFN cassettes. Run the *TLiQC*ette before running any patient sample.

Workplace Safety All laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, and the safety of others and adhering to all departmental and medical center safety policies and procedures.

- For standard precautions and safety practices in the laboratory; see LGM 8000, specifically, but not limited to, equipment safety, proper body mechanics, sharps exposure and proper use of personal protective equipment (PPE).
 - For Universal Body Substance precautions, see LGM 8005, specifically, but not limited to, exposure to body fluids.
 - For proper handwashing, see LGM 8010, specifically, not limited to, proper handwashing.
 - For proper infection control, see LGM 8004, specifically, but not limited to, proper use of gloves.
 - For proper handling of regular and infectious waste, see LGM 8006, specifically, but not limited to, proper disposal of regular and biohazardous waste.
 - For proper cleaning of work area, see LGM 8007 – Cleaning Work Areas.
 - For proper handling of chemicals and reagents, see the Chemical Hygiene Plan.
 - For proper storage and disposal of chemical hazardous waste, see LGM 8012.
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RAPID *f*FN (FETAL FIBRONECTIN) FOR THE HOLOGIC *TLi*Q QUALITY CONTROL

Reagents And Materials

Rapid *f*FN Control kit contains:
One Rapid *f*FN positive control
One Rapid *f*FN negative control
One directional insert
Liquid negative and positive controls

*TLi*Q QCette stored at room temperature
One *TLi*Q QCette
One directional insert

200 µl pipette
Pipet tips
Printer

Procedure

Analyzer quality control procedure

Step	Action
1.	From the main menu, press 3 to select Daily QC
2.	Enter User ID and press enter
3.	Enter the QCette SN (serial number located on green QCette), and press enter. If QCette SN is already present, press enter to confirm
4.	Remove the QCette (gree) from the black case and insert the QCette and press enter. The analyzer will perform daily qc for 3-4 minutes, when complete, the result will be displayed on the analyzer screen and the printed label as SYSTEM PASS. Repeat a FAIL or INVALID result
5.	Place the label in laboratory Fibronectin log
6.	Press ESC to return to the main menu

RAPID *f*FN (FETAL FIBRONECTIN) FOR THE HOLOGIC *TLiQ* QUALITY CONTROL

Procedure

Running positive and negative control using Internal Incubation mode

Step	Action
1.	Note: The liquid positive and negative controls are to be processed each time a new shipment or lot number of <i>f</i> FN cassettes are to be used for testing purposes Remove the <i>f</i> FN negative control and positive control vials from the control kit box. When first opened, write the date opened, your initials, and date of expiration (12 weeks from the date first used or the expiration date on outside of the control kit, or whichever comes first)
2.	Shake control vials for a few seconds
3.	Place in plastic biohazard bag and seal to prevent compromising controls
4.	Allow control vials to come to room temperature before testing
5.	After controls have to room temperature go to main menu
6.	Press ↑ or ↓ key to the third screen
7.	Select or press 8 Liquid Controls
8.	Enter user ID (your 3 initials) and press enter
9.	Enter the last two numbers of the Hologic cassette lot number, and press enter
10.	Select or press 1 Negative control
11.	Enter the negative control lot number and press enter
12.	The analyzer will then prompt you to insert the cassette and press enter
13.	Remove the cassette from the foil pouch and insert the cassette and press enter
14.	The instrument will display while beeping “Add sample and immediately press enter”

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Procedure

Running positive and negative control using Internal Incubation mode

Step	Action		
15.	Add 200 microliter of prepared negative control sample into sample well and press enter. The analyzer will automatically start a 20 minute timer which will allow the immunoassay reaction to take place. After the 20 minute internal incubation the analyzer will analyze the Rapid <i>f</i> FN cassette for 3.5 minutes		
16.	Set a timer for 25 minutes so as to know the negative control is finished and when to perform the positive control. Walk away, results will be displayed and printed in 24 minutes. The result for the <i>f</i> FN negative control will be displayed on the analyzer display screen as PASS or FAIL. The analyzer will automatically print the result		
17.	Place the negative control sticker on the daily <i>f</i> FN log sheet <div style="text-align: center;">Expected Results</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">Negative Control Result: Pass</td> <td style="width: 50%; border: none;">Positive Control Result: Pass</td> </tr> </table>	Negative Control Result: Pass	Positive Control Result: Pass
Negative Control Result: Pass	Positive Control Result: Pass		
18.	Press EXC to return to the main menu		
19.	Repeat steps 3 through 17 for the positive control		
20.	Place you positive and control printout/tapes on the sheet provided		

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Controlled Documents The controlled documents are as follows:

Document No.	Name of Documents
LCM 268	Rapid fFN for the Hologic Sample Processing
LCM 425	Rapid fFN for the Hologic Maintenance
LCM 426	Rapid fFN for the Hologic Calibration
LGM 8000	Safety Practices
LGM 8004	Infection Control
LGM 8005	Universal Body Substance Precautions
LGM 8006	Handling of Regular and Infectious Waste
LGM 8007	Cleaning Work Areas
LGM 8010	Handwashing Policy
LGM 8012	Storage and disposal of Chemical Hazardous Waste

Non Controlled Documents The Non Controlled Documents are as follows

Document No.	Name of Documents
	User Manual
