


## Rapid Fetal Fibronectin (fFN) Cassette Validation

**Purpose** This procedure describes how to validate fFN cassettes before use.

**Policy** Calibration and quality control will be performed on each new lot, every 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
TliQ Analyzer & Printer	-----	-----
Heat block or water bath	37° C	----- 
Pipette – 200 µl	-----	-----
Rapid fFN Positive Control	2-8° C	6 months from open date, or exp. date on kit – whichever is first
Rapid fFN Negative Control	2-8° C	6 months from open date, or exp. date on kit – whichever is first

**Procedure A** Follow the steps below to prepare control material for use.

Step	Action						
1.	Retrieve liquid Controls from the Urinalysis Refrigerator ❖ fFN Positive Control ❖ fFN Negative Control						
2.	Check liquid controls <table border="1" data-bbox="581 1528 1404 1690"> <thead> <tr> <th>If</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Cloudy or discolored</td> <td>Discard and select a new control</td> </tr> <tr> <td>Not cloudy or discolored</td> <td>Proceed to Step 3</td> </tr> </tbody> </table>	If	Then	Cloudy or discolored	Discard and select a new control	Not cloudy or discolored	Proceed to Step 3
If	Then						
Cloudy or discolored	Discard and select a new control						
Not cloudy or discolored	Proceed to Step 3						
3.	Remove controls from the refrigerator and allow them to equilibrate to room temperature for 5-10 minutes.						

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**Procedure B** Follow the steps below to enter Lot Number and Calibration Code into the Tli<sub>i</sub>Q analyzer.

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  <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;">                     Note: Instrument should immediately autoprint label from printer.                 </div>						
8.	Remove label from printer.						
	<table border="1" style="width: 100%;"> <thead> <tr> <th>If</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Label Present</td> <td>Go to step 9</td> </tr> <tr> <td>Label not present</td> <td>Turn on Printer and Press the &lt; ENTER &gt; key</td> </tr> </tbody> </table>	If	Then	Label Present	Go to step 9	Label not present	Turn on Printer and Press the < ENTER > key
If	Then						
Label Present	Go to step 9						
Label not present	Turn on Printer and Press the < ENTER > key						
9.	Verify label reads “SYSTEM CALIBRATED”						
	<table border="1" style="width: 100%;"> <thead> <tr> <th>If</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Yes</td> <td>Go to step 10</td> </tr> <tr> <td>No</td> <td> <ul style="list-style-type: none"> <li>Go back to step 1 and repeat procedure.</li> <li>If second time call customer support.</li> </ul> </td> </tr> </tbody> </table>	If	Then	Yes	Go to step 10	No	<ul style="list-style-type: none"> <li>Go back to step 1 and repeat procedure.</li> <li>If second time call customer support.</li> </ul>
If	Then						
Yes	Go to step 10						
No	<ul style="list-style-type: none"> <li>Go back to step 1 and repeat procedure.</li> <li>If second time call customer support.</li> </ul>						
10.	Adhere label to “fFN Calibration and Quality Control” worksheet under appropriate heading and initial with tech code.						

**Procedure C** Follow the steps below to Run Liquid Controls.

Step	Action
1.	Press <ESC> key to exit to the main menu.
2.	Press < > key twice till come to option 8 “Liquid Controls”

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3.	Press number < <b>8</b> > key						
4.	Enter SQ Tech Code using numbers on key pad						
5.	Press the < <b>ENTER</b> > key						
6.	Enter cassette lot number from label on side of box using letters and numbers key pad.						
7.	Press the < <b>ENTER</b> > key						
8.	Press the number < <b>2</b> > 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 < <b>ENTER</b> > key						
11.	Select an unopened cassette from box and remove from pouch.						
12.	Insert cassette into the Tli <sub>i</sub> Q instrument insertion site.						
13.	Press the < <b>ENTER</b> > key						
14.	Open the prepared positive control bottle.						
15.	Use MLA Pipette to transfer 200 µl of the control into sample well of the inserted cassette.						
16.	<p><b>Immediately</b> Press the &lt; <b>ENTER</b> &gt; key</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;">                     Note: Instrument should immediately display “Testing in process, Do Not Remove Cassette”.                 </div>						
17.	<p>Wait 25 minutes</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;">                     Note: When testing is completed the system will autoprint a label.                 </div>						
18.	Remove label from printer.						
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; padding: 5px;"><b>If</b></th> <th style="text-align: left; padding: 5px;"><b>Then</b></th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">Label Present</td> <td style="padding: 5px;">Go to step 19</td> </tr> <tr> <td style="padding: 5px;">Label not present</td> <td style="padding: 5px;">Turn on Printer and Press the &lt; <b>ENTER</b> &gt; key</td> </tr> </tbody> </table>	<b>If</b>	<b>Then</b>	Label Present	Go to step 19	Label not present	Turn on Printer and Press the < <b>ENTER</b> > key
<b>If</b>	<b>Then</b>						
Label Present	Go to step 19						
Label not present	Turn on Printer and Press the < <b>ENTER</b> > key						
19.	Perform Procedure D steps 1 and 2.						
20.	Repeat steps 1 to 7						
21.	Press the number < <b>1</b> > key to enter into the negative control						
22.	Repeat steps 9 to 13						
23.	Open the prepared negative control bottle.						
24.	Repeat steps 15 to 18.						

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**Procedure D** Follow the steps below to Confirm successful QC.

Step	Action						
1.	Confirm successful QC <table border="1" data-bbox="581 422 1401 842"> <thead> <tr> <th data-bbox="581 422 992 453">If</th> <th data-bbox="992 422 1401 453">Then</th> </tr> </thead> <tbody> <tr> <td data-bbox="581 453 992 569">Successful – Printout will display “PASS”</td> <td data-bbox="992 453 1401 569">Go to step 2</td> </tr> <tr> <td data-bbox="581 569 992 842">Not successful – Printout will display “FAIL”</td> <td data-bbox="992 569 1401 842"> <ul style="list-style-type: none"> <li>• Perform trouble shooting as described in User manual on page 7-5.</li> <li>• Go to Procedure C step 1</li> <li>• Notify Supervisor</li> <li>• Document corrective action on fFN worksheet</li> </ul> </td> </tr> </tbody> </table>	If	Then	Successful – Printout will display “PASS”	Go to step 2	Not successful – Printout will display “FAIL”	<ul style="list-style-type: none"> <li>• Perform trouble shooting as described in User manual on page 7-5.</li> <li>• Go to Procedure C step 1</li> <li>• Notify Supervisor</li> <li>• Document corrective action on fFN worksheet</li> </ul>
If	Then						
Successful – Printout will display “PASS”	Go to step 2						
Not successful – Printout will display “FAIL”	<ul style="list-style-type: none"> <li>• Perform trouble shooting as described in User manual on page 7-5.</li> <li>• Go to Procedure C step 1</li> <li>• Notify Supervisor</li> <li>• Document corrective action on fFN worksheet</li> </ul>						
2.	Adhere label to “fFN Calibration and Quality Control” worksheet under appropriate heading and initial with tech code.						
3.	Indicate “Ready For Use” on each box of cartridges of the same lot number received in the same shipment.						

**Reference:** Adeza® Biomedical Corporation – Tli<sub>i</sub>Q System User’s Manual – 2001 version 01188:01  
 Adeza® Biomedical Corporation – fFN® Rapid Control Kit package inserts – April 2001.