Adventist HealthCare

TRAINING UPDATE

Lab Location:	SGMC & WOMC	**Date Distributed:**	3/8/24
Department:	Chemistry, Core Lab	**Due Date:**	4/8/24
		Implementation:	**Immediately**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
AHC.C41 Fetal Fibronectin
Description of change(s):
Added the requirement to file the patient results (FFP worksheet) with the QC. (Do not file in the Iron Mountain boxes)

Document your compliance with this training update by taking the quiz in the MTS system.

AHC.C41 Fetal Fibronectin

Copy of version 6.0 (approved and current)

Last Approval or Periodic Review Completed	3/7/2024
Next Periodic Review Needed On or Before	3/7/2026
Effective Date	3/7/2024

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Printed By Demetra Collier (110199)

Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	3/7/2024	6.0	 Nicolas Cacciabeve	
Approval	Core lab approvals	3/7/2024	6.0	 Robert SanLuis	
Periodic review	Lab Service director	10/23/2023	5.0	 Robert SanLuis	
Approval	Lab Director	11/15/2021	5.0	Nicolas Cacciabeve	
Approval	Core lab approvals	11/10/2021	5.0	 Robert SanLuis	
Approval	QA approval	11/10/2021	5.0	Leslie Barrett (104977)	
Periodic review	Lab Service director	10/22/2021	4.0	 Robert SanLuis	
Periodic review	QA review	10/19/2021	4.0	Leslie Barrett	
Periodic review	Lab Service director	10/22/2019	4.0	 Robert SanLuis	
Periodic review	QA review	10/22/2019	4.0	Leslie Barrett	
Approval Captured outside MediaLab	Lab Director	12/14/2017	4.0	Nicolas Cacciabeve	Recorded on 12/13/2018 by Leslie Barrett (104977) when document added to MediaLab
Periodic review Captured outside MediaLab	Designated Reviewer	12/14/2017	4.0	Nicolas Cacciabeve	Recorded on 12/13/2018 by Leslie Barrett (104977) when document added to MediaLab

Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.

Prior History

Updated prefix 11/22/21

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
6.0	Approved and Current	Major revision	3/5/2024	3/7/2024	Indefinite
5.0	Retired	Major revision	11/10/2021	11/22/2021	3/7/2024
4.0	Retired	First version in Document Control	12/13/2018	12/22/2017	11/22/2021

Linked Documents

- AG.F155 Fetal Fibronectin QCette Log
- AG.F156 Fetal Fibronectin Adeza Tli Analyzer Maintenance Log

Technical SOP

Title	**Fetal Fibronectin**	
Prepared by	Ashkan Chini	Date: 3/8/2011
Owner	Robert SanLuis	Date: 8/31/2015

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Fetal Fibronectin	Hologic TLi_{IQ} System	FFIBR

Synonyms/Abbreviations
Rapid fFN, fFN

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The Rapid fFN Cassette is a lateral flow, solid-phase immuno-chromatographic assay. The cervicovaginal specimen is extracted into a buffer and dispensed into the sample well of the cassette. The sample flows across a nitrocellulose membrane via capillary action through a reaction zone containing murine monoclonal anti-fetal fibronection antibody conjugated to blue microspheres. The conjugate is mobilized by the flow of the sample. The sample then flows through a zone containing polyclonal anti-mouse IgG antibody which captures unbound conjugate, resulting in a control line. After 20 minutes incubation, the intensities of the test line and control line are interpreted with the TLi_{IQ} analyzer.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	None
Special Collection Procedures	**Collection from Symptomatic Women**: The specimen should be obtained from the posterior fornix of the vagina during a sterile speculum examination. The polyester tipped applicator provided in the Specimen Collection Kit should be inserted into the vagina and lightly rotated across the posterior fornix for approximately 10 seconds to absorb the cervicovaginal secretions. **Collection from Asymptomatic Women:** The specimen can be obtained from either the posterior fornix of the vagina or the ectocervical region of the external cervical os during a sterile speculum examination. The polyester tipped applicator provided in the Specimen Collection Kit should be inserted into the vagina and lightly rotated across the posterior fornix or around the ectocervical region of the external cervical os for approximately 10 seconds to absorb the cervicovaginal secretions.

Component	Special Notations
Specimen Collection and/or Timing	Once the specimen is obtained, carefully remove the applicator from the vagina or cervical os and immerse the polyester tip in the tube of buffer provided with the Specimen Collection Kit. Break the shaft (at the score) even with the top of the tube. Align the shaft with the hole inside the tube cap and push down tightly over the shaft, sealing the tube.
Other	• Specimens should be obtained prior to digital examination or manipulation of the cervix. • Specimens should not be collected less than 24 hours after intercourse. However, even when a patient reports having had intercourse in the previous 24 hours, a negative fetal fibronectin test result is valid. • Patients with suspected or known placental abruption, placenta previa, or moderate or gross vaginal bleeding should not be tested for fFN.

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Vaginal swab N/A	
Collection Container	Hologic, Inc Specimen Collection Kit	
Volume - Optimum **- Minimum**	N/A N/A	
Transport Container and Temperature	Same as collection container, preferred temperature 2-8°C, but 2-25°C is acceptable	
Stability & Storage Requirements	Room Temperature:	Within 8 hours
	Refrigerated (2-8°C):	3 days
	Frozen (- 20°C or colder):	3 months
Timing Considerations	Reject and request recollection for • Specimens received > 3 days after the sampling date refrigerated (2-8°C) • Specimens received > 3 months after sampling date frozen (-20°C or colder) • Specimens received at temperatures >25°C	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for “test not performed” message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.	

Criteria	
Compromising Physical Characteristics	Excessively mucoid specimens that are difficult to pipette properly are unacceptable. Reject the specimen and notify a caregiver.
Other Considerations	N/A

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Rapid fFN for the TLi_{IQ} System – **Rapid fFN Cassettes**: 26 cassettes containing all necessary reagents dried onto membranes. Each cassette contains a desiccant and is sealed in a foil pouch.	Hologic, Inc, ref # 01200

Note: Do not mix materials from different kit lots.

4.2 Reagent Preparation and Storage

Reagent	Rapid fFN Cassette
Container	N/A
Storage	Room temperature (15-30°C)
Stability	• Stable until expiration date stamped on the foil pouch (shelf life is 18 months from the date of manufacture) • Once the foil pouch is opened, cassette should be used immediately
Preparation	None required. Handle cassettes with care: Do not touch, scratch, or compress membrane materials in the Rapid fFN Cassette.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

None

5.2 Calibrator Preparation and Storage

N/A

5.3 Calibration Procedure

Calibration is set every time a new lot of cassettes is placed into use.
See section 8.2 for the procedure.

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Rapid fFN Control Kit (positive & negative)	Hologic, Inc. ref #. 01166
TLi_{IQ} QCette™	Hologic, Inc. ref # 01175

6.2 Control Preparation and Storage

Control	Rapid fFN Control Kit (positive & negative)
Preparation	Allow the Rapid fFN Positive and Negative Controls to come to room temperature before testing. Invert to mix before testing.
Storage	2-8°C
Stability	• **Unopened**: may be used until expiration date printed on bottle • **Opened**: must be used within 6 months • Should not be used if cloudy or discolored

Control	TLi_{IQ} QCette™
Preparation	None
Storage/Stability	Room temperature (15-30°C)

6.3 Frequency

- The Rapid fFN Control Kit (Positive and Negative) is run with each new kit lot number or shipment or every 30 days, whichever is more frequent.
- Internal controls are part of the TLi_{IQ} System and are performed automatically with every test. These internal controls check for (1) a threshold level of signal at the procedural control position, (2) proper sample flow across the Rapid fFN Cassette, (3) absence of conjugate aggregation (Cassette: Pass/Fail), and (4) proper function of analyzer hardware (Analyzer: Pass/Fail).
- The TLi_{IQ} QCette is run once every 24 hours of patient testing.
- The TLi_{IQ} QCette Setup must be performed PRIOR to running the QCette as a daily quality control device. Setup is performed once for the QCette received with the TLi_{IQ} System. (See the TLi_{IQ} QCette directional insert for details).

6.4 Tolerance Limits and Criteria for Acceptable QC

1. The TLi_{IQ} QCette™ is a quality control device used to verify that the TLi_{IQ}™ Analyzer performs within specification. The TLi_{IQ} QCette is a Rapid fFN Cassette replica containing a membrane with printed test and control lines, which is read by the TLi_{IQ} analyzer. Three different levels of response are measured with this QC device:
   a. High Level: The blue line at the procedural control position, which is in the high positive range, must be above a minimum threshold value for QC to pass.
   b. Low Level: The blue printed line at the test line position is in the cutoff range. This line is measured and compared with a value established during instrument setup and must be within 5% of that value for QC to pass.
   c. Negative: The white space between the blue lines is measured and should always be in the negative range for QC to pass.
   d. The result should be **SYSTEM PASS.** A **FAIL** or **INVALID** result must be repeated.

2. The Rapid fFN Control Kit contains two liquid controls: one Rapid fFN Positive Control and one Rapid fFN Negative Control for use in monitoring the performance of the Rapid fFN Cassette. The control results should be PASS. A FAIL or INVALID result must be repeated. To ensure accurate and reliable test results, performance testing should be done only with the controls from the Rapid fFN Control Kit.

3. Internal controls are part of the TLi_{IQ} System and are performed automatically with every test. These internal controls check for
   a. a threshold level of signal at the procedural control position,
   b. proper sample flow across the Rapid fFN Cassette,
   c. absence of conjugate aggregation (Cassette: Pass/Fail),
   d. proper function of analyzer hardware (Analyzer: Pass/Fail)

4. If the controls do not perform as expected, repeat the test. Do not report patient results until acceptable QC results are obtained. If any control fails upon repeat testing, notify the supervisor.

6.5 Documentation

- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials. Performance of the new lot must be equivalent to the previous lot.

- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

TLi_{IQ} Analyzer and printer, operate at room temperature (18-30°C)

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- 200 µL micropipettor

7.3 Supplies

200 µL disposable plastic tips

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Maintenance
1.	Clean surface of meter.
2.	Check printer paper.
3.	Clean Cassette Insertion Site using 10% bleach or 75% Isopropyl alcohol.
4.	Document on Fetal Fibronectin Adeza Tli Analyzer Maintenance Log.

8.2	Instrument Set-up Protocol for Performing Daily Analyzer Quality Control
1.	Select Option 3 (DAILY QC) from the Main Menu of the analyzer.
2.	Enter the User ID and press ENTER.
3.	Enter the QCette Serial Number and press ENTER.
4.	Insert the QCette and press ENTER.
5.	When analysis is complete, the result will be displayed on the analyzer screen and the printed label as SYSTEM PASS. A FAIL or INVALID result must be repeated.
6.	Place the QCette printout on the FFN QCette log.

8.3	Instrument Set-up Protocol for Setting Calibration for a Rapid fFN Cassette Lot
1.	Select Option 2 (SET CALIBRATION) from the Main Menu of the analyzer.

8.3	Instrument Set-up Protocol for Setting Calibration for a Rapid fFN Cassette Lot
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 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.

8.4	Specimen / Reagent Preparation
1.	Allow all Specimen Transport Tubes to come to room temperature before testing.
2.	Gently mix the Specimen Transport Tube prior to removing the Dacron swab.
3.	Open the Specimen Transport Tube cap and swab assembly. The swab shaft should be seated in the cap. Express as much liquid as possible from the swab by rolling the tip against the inside of the tube. When handling a mucoid specimen attempt to remove as much mucous as you can at this point when you remove the swab. Dispose of the used swab in a manner consistent with handling of biohazardous materials. DO NOT CENTRIFUGE THE SPECIMEN PRIOR TO TESTNG.
4.	Mix the tube prior to pipetting the sample. Note: if the specimen is mucoid attempt to pipette around the mucous. The pipette must move in a smooth manner. If the specimen is too mucoid to pipette reject the specimen for testing.

8.5	Test Run
	Note: The TLi_{IQ} analyzer has two incubation modes for testing samples INTERNAL and EXTERNAL. The incubation mode refers to the timing of the incubation process and the initiation of the cassette analysis. In the internal mode, the analyzer times the incubation and starts the analysis. In the external mode, the user will be responsible for timing the incubation and for starting the analysis.
A.	**Internal Incubation Mode:** Turn on the TLi_{IQ} analyzer and the attached printer. Select option 6 from the Main Menu for CHANGE SETUP by pressing the down arrow once and then entering the number 6.
1.	Select option 3 from the Setup Menu for INCUBATION MODE. Then select option 1 for INTERNAL. Press ESC to return to Main Menu.
2.	Select the appropriate option (Test Patient or Liquid Controls) from the Main Menu of the TLi_{IQ} analyzer.
3.	Enter User ID and press ENTER (or bypass by pressing ENTER).

8.5	Test Run
4.	Enter the cassette lot number (printed on the foil pouch and the box containing the pouched cassettes). The first three characters of the lot number will be displayed because the calibration has been set for a specific cassette lot number. Enter the remaining numbers of the lot number and press ENTER.
5.	Enter control lot numbers in the same manner.
6.	Remove one Rapid fFN Cassette from the foil pouch being careful not to touch the sample well or the reaction area. When prompted, insert the cassette into the analyzer. Push it in until it clicks, and press ENTER.
7.	Invert patient sample (or liquid control) to mix before testing. Using a calibrated pipette, add 200 µL of patient sample (or liquid control) to sample well and **immediately** press ENTER.
8.	The analyzer times the 20 minute incubation of the cassette and starts the analysis. When the analysis is complete, the result will be displayed on the analyzer screen and the printed label. Press ESC to return to the Main Menu. Print the LIS worksheet WUR3 for WAH or SIM1 for SGAH and attach the patient result label to it **and file in the QC binder.**
9.	Remove the cassette from the analyzer.
10.	A FAIL or INVALID control result must be repeated before any further patient testing can be done.
B.	**External Incubation Mode**
1.	Turn on the TLi_{IQ} analyzer and the attached printer. Select option 6 from the Main Menu for CHANGE SETUP by pressing the down arrow once and then entering the number 6.
2.	Select option 3 from the Setup Menu for INCUBATION MODE. Then select option 2 for EXTERNAL. Press ESC to return to Main Menu.
3.	Select the appropriate option (Test Patient or Liquid Controls) from the Main Menu of the TLiIQ analyzer.
4.	Enter User ID and press ENTER (or bypass by pressing ENTER).
5.	Enter the cassette lot number (printed on the foil pouch and the box containing the pouched cassettes). The first three characters of the lot number will be displayed because the calibration has been set for a specific cassette lot number. Enter the remaining numbers of the lot number and press ENTER.
6.	Enter control lot numbers in the same manner.
7.	Remove the desired number of Rapid fFN Cassettes from the foil pouches being careful not to touch the sample well or the reaction area. Label each cassette appropriately
8.	Using a calibrated pipette, add 200 µL of sample #1 to the sample well on the appropriately labeled cassette, and set a timer for 20 minutes.
9.	If additional cassettes are run, wait at least five minutes before adding sample to the next cassette.
10.	When sample #1 cassette has completed the 20-minute incubation period, insert the cassette into the analyzer. Push it in until it clicks, and **immediately** press ENTER.

8.5	Test Run
11.	When the analysis is complete, the result will be displayed on the analyzer screen and the printed label. Press ESC to return to the Main Menu. Print the LIS worksheet WUR3 for WAH or SIM1 for SGAH and attach the patient result label to it.
12.	Remove the cassette from the analyzer.
13.	A FAIL or INVALID control result must be repeated before any further patient testing can be done.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

Rapid fFN is a qualitative test.

- The result is positive if the value derived from the patient sample is greater than or equal to the reference calibration value specified by the calibration code.
- The result is negative if the value derived from the patient sample is less than the reference calibration value specified by the calibration code.
- The result is invalid if the test does not meet internal quality controls.

If a bloody specimen is received, note the appearance and attach the LIS comment code **FFBS** ("Bloody specimen received, interpret Positive results with caution. Bloody specimens can cause false positive or invalid result.")

10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions, such as an unusually high percentage of abnormal results.

10.6 Repeat Criteria and Resulting

If the assay does not meet internal acceptance criteria for a valid test, retest with 200 µL of additional sample, if available, on a new Rapid fFN Cassette. If the problem is not corrected, contact Hologic, Inc for technical assistance.

10.7 Resulting

Use function **MEM** to enter results.

Enter Shift (1, 2, or 3)
Worksheet: Use WUR3 for WOMC or SIM1 for SGMC
Test: <Enter>
Enter "A" (Accept)
Enter Accession number
Press <Enter> until Result screen displayed

Enter Results as listed below:

IF the result is …	THEN report with LIS code
Positive	POS
Negative	NEG

11. EXPECTED VALUES

11.1 Reference Ranges

Negative

11.2 Critical Values

None established

11.3 Standard Required Messages

The following comment is automatically added to the report by the LIS:

Elevated levels of fetal fibronectin (greater than or equal to 0.050 µg/ml) in:
Symptomatic Women between 24 weeks 0 days and 34 weeks 6 days gestation indicate increased risk of delivery in less than or equal to 7 or 14 days from sample collection.
Asymptomatic Women between 22 weeks 0 days and 30 weeks 6 days indicate increased risk of delivery in less than or equal to 34 weeks 6 days of gestation.

The fetal fibronectin test should not be used in symptomatic women with:
advanced cervical dilation (greater than or equal to 3 cm)
rupture of amniotic membranes
cervical cerclage
moderate or gross vaginal bleeding

The fetal fibronectin test should not be used in asymptomatic women with:
multiple gestations
cervical cerclage
placenta previa (partial or complete)
within 24 hours of sexual intercourse

Specimens should be obtained prior to manipulation of the cervix which can cause false positive results

12. CLINICAL SIGNIFICANCE

1. The Rapid fFN test is to be used as an aid in assessing the risk of preterm delivery is less than or equal to 7 or 14 days from the time of cervicovaginal sample collection in pregnant women with signs and symptoms of early preterm labor, intact amniotic membranes and minimal cervical dilatation (< 3 cm), sampled between 24 weeks, 0 days and 34 weeks, 6 days gestation.
2. The Rapid fFN test is further indicated for use in conjunction with other clinical information as an aid in assessing the risk of preterm delivery in less than or equal to 34 weeks, 6 days when a cervicovaginal sample is obtained during a routine prenatal visit between 22 weeks, 0 days and 30 weeks, 6 days of gestation in women with a singleton pregnancy.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

Modification of the assay protocol described herein may yield erroneous results.

14.3 Interfering Substances

- Assay interference from the following components has not been ruled out: douches, white blood cells, red blood cells, bacteria and bilirubin.
- The presence of infections has not been ruled out as a confounding factor to risk of preterm delivery.
- Assay interference from semen has not been ruled out. Specimens should not be collected less than 24 hours after intercourse. However, even when a patient reports having had intercourse in the previous 24 hours, a negative fetal fibronectin test result is valid.

- Manipulation of the cervix may lead to false positive results. Specimens should be obtained prior to digital examination or manipulation of the cervix.
- Care must be taken not to contaminate the swab or cervicovaginal secretions with lubricants, soaps, disinfectants, or creams (e.g., K-Y Jelly lubricant, Betadine disinfectant, Monistat cream, hexachlorophene). These substances may interfere with absorption of the specimen by the swab or with the antibody-antigen reaction of the Rapid fFN test.
- Patients with suspected or known placental abruption, placenta previa, or moderate or gross vaginal bleeding should not be tested for fFN.

14.4 Clinical Sensitivity/Specificity/Predictive Values

The Rapid fFN 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 fFN 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. The Rapid fFN result should always be used in conjunction with information available from the clinical evaluation of the patient and other diagnostic procedures such as cervical examination, cervical microbiological culture, assessment of uterine activity, and evaluation of other risk factors.

14.5 Precautions and Warnings

- **Do not use glass tubes or glass pipettes, as fetal fibronectin binds to glass. Tubes and pipettes of polypropylene or polyethylene are acceptable.**
- Test results may not be interpreted visually and must be based on the use of the TLi_{IQ} analyzer.
- **Do not mix materials from different kit lots.**
- Avoid cross-contamination of reagents. When using a micropipettor, change tips between each control and patient sample. Recap controls tightly with the correct color-coded caps.
- Labels (e.g., bar code labels) can be placed on the thumb grip area of the cassette. Do not place labels on an area of the cassette that will be inserted into the TLI_{IQ} analyzer.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

Laboratory Quality Control Program
Fetal Fibronectin QCette Log (AG.F155)
Fetal Fibronectin Adeza Tli Analyzer Maintenance Log (AG.F156)
Current package insert Rapid fFN Cassette Kit

17. REFERENCES

1. Fetal Fibronectin Enzyme Immunoassay and Rapid fFN for the TLi System, Hologic, Inc., MAN-01669-001 Rev. 002; 2009
2. Rapid fFN Specimen collection Kit, Hologic, Inc., REF 71738-001, MAN-01484-4201 Rev. 001
3. Rapid fFN Cassette Kit, Hologic Inc, REF 01200, Man-01489-4201 Rev 001
4. Customer Technical Bulletin, Hologic, Inc. April 1, 2008. A Summary of the Quality Control Recommendations for the TLiq System

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP C034.003		
000	8/22/2011		Update owner	L Barrett	C Reidenauer
000	8/22/2011		Changed all references to Adeza Biomedical to Hologic, Inc.	C Reidenauer	C Reidenauer
000	8/22/2011	2	Update analytical principle	L Barrett	C Reidenauer
000	8/22/2011	3.1	Changed Dacron swab to polyester tipped applicator	C Reidenauer	C Reidenauer
000	8/22/2011	3.2	Update timing consideration for specimens rec'd after 3 days and add > 3 months frozen Add handling of mucoid specimens	C Reidenauer	C Reidenauer
000	8/22/2011	4.1	Removed use of specimen filters and specimen storage tubes	C Reidenauer	C Reidenauer
000	8/22/2011	5.3	Added calibration frequency	C Reidenauer	C Reidenauer
000	8/22/2011	6.3	Removed word simulator, replaced with QCette. Changed QC frequency from daily to daily with patient testing.	C Reidenauer	C Reidenauer
000	8/22/2011	8.4	Removed instructions for specimen filter and transport tube. Added instructions for handling mucoid specimens. Added specific note not to centrifuge samples.	C Reidenauer	C Reidenauer
000	8/22/2011	15	Update to approved format	L Barrett	C Reidenauer
001	2/15/2012	8.1	Add maintenance steps, renumber	L Barrett	C Reidenauer
001	2/15/2012	10.1	Revise result comment	L Barrett	C Reidenauer
001	2/15/2012	19	Add QCette and Maintenance logs	L Barrett	C Reidenauer
002	8/31/2015		Update owner	L Barrett	R SanLuis
002	8/31/2015	6.3	Change external QC frequency	L Barrett	R SanLuis
002	8/31/2015	8.5	Add attaching result to LIS worksheet	L Barrett	R SanLuis
002	8/31/2015	10.6	Add detail for LIS reporting	L Barrett	R SanLuis
002	8/31/2015	16	Move forms from section 19	L Barrett	R SanLuis

Version	Date	Section	Reason	Reviser	Approval
002	8/31/2015	Footer	Version # leading zeros dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis
3	12/5/17	Header	Add WAH	L Barrett	R SanLuis
3	12/5/17	4, 6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
3	12/5/17	10.5	Review data moved from section 6	L Barrett	R SanLuis
3	12/5/17	11.3	Move report comment from 10.1	L Barrett	R SanLuis
3	12/5/17	15	Update to new standard wording	L Barrett	R SanLuis
4	11/10/21	Header	Changed WAH to WOMC	L Barrett	R SanLuis
4	11/10/21	Footer	Updated prefix to AHC	L Barrett	R SanLuis
5	3/5/24	8.5	Step 8 Specified storage of the worksheet	C Bowman	R SanLuis

19. ADDENDA

None