2. Rapid fFN Cassettes for the TLiIQ system, **Catalog No.: 01200**
   Stored at room temperature (15° to 30°C / 59° to 86°F).
   A. Rapid fFN Cassettes:
      1. 26 cassettes containing all necessary reagents (murine monoclonal anti-fFN antibody conjugated to blue microspheres, goat polyclonal anti-human fibronectin antibody, and goat polyclonal anti-mouse IgG antibody) dried onto nitrocellulose membranes.
      2. Each cassette contains a desiccant and is sealed in a foil pouch.
      3. Stability
         a. The shelf life of the Rapid fFN Cassette is 18 months from the date of manufacture.
         b. Unopened cassettes may be used until the expiration date printed on the foil pouch.
         c. The test device must remain in the sealed pouch until use.
         d. Once the foil pouch is opened, the Rapid fFN Cassette should be used immediately.
         e. The Rapid fFN Cassette should be stored at room temperature (15° to 30°C / 59° to 86°F).
   B. Directional insert
3. Rapid fFN Control Kit, **Catalog No.: 01166**. Store in refrigerator at 2° to 8°C.
   a. Contains: One Rapid fFN Positive Control: 2.5 mL (>0.050 µg/mL fFN)
      One Rapid fFN Negative Control: 2.5 mL (< 0.050 µg/mL fFN)
      Controls contain Human fetal fibronectin in a stable protein matrix with sodium azide as a preservative.
      Directional Insert
   b. Use at room temperature
   c. The shelf life of the Rapid fFN Calibration/Control Kit is one year from manufacture.
   d. Unopened Controls may be used until the expiration date printed on the bottle.
   e. **Once opened, they should be used within 6 months**. However, they should not be used if they are cloudy or discolored.
4. TLiIQ QCette, **Catalog No.: 01175**. Stored at room temperature (15° to 30°C / 59° to 86°F).
   Contains: One TLiIQ QCette
   Directional Insert
5. One 200 µL MLA pipettor with tips

Controls

See Attachment: *Fetal Fibronectin IQCP*

Frequency of Running Quality Control (QCette)

Daily quality control of the TLiIQ analyzer is run once every 24 hours or whenever there is uncertainty about the analyzer or whenever technical service requests that quality control of the TLiIQ analyzer be performed. The TLiIQ QCette is the control device for use in monitoring the performance of the TLiIQ analyzer every 24 hours.

The TLiIQ QCette® is a quality control device used to verify that the TLiIQ® Analyzer performs within specification. The QCette Setup software determines a value for the QCette. Daily quality control data collected from the QCette are automatically compared to this setup value to verify analyzer performance.

The TLiIQ QCette is a Rapid fFN Cassette replica containing a membrane with printed test and control lines, which is read by the TLiIQ analyzer. Three different levels of response are measured with this QC device:

1. 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.
2. 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.
3. Negative: The white space between the blue lines is measured and should always be in the negative range for QC to pass.

University of California, Davis Health System
Department of Pathology and Laboratory Medicine
Automated Chemistry/Urinalysis

Individualized Quality Control Plan (IQCP)- Fetal Fibronectin testing on cervicovaginal secretion specimens using the Hologic TLiQ analyzer

Effective Date: December 15, 2015

The Automated Chemistry/Urinalysis section procedure #3401, Fetal Fibronectin (fFN) – Cervicovaginal secretions, Solid-phase immunochromatographic assay by Hologic, Inc. has been updated and includes the following information.

1. Risk Assessment (RA)
    a. A Risk Assessment has been conducted, assessing multiple factors across the pre-analytic, analytic, and post-analytic phases of testing.
    b. The Risk Level for each Risk Factor has been deemed Acceptable.
2. Quality Control Plan
    a. The manufacturer's requirements for quality control and assurance are listed in the manufacturer's directional inserts as well as the Chemistry section policy #3401. These requirements have been in effect in our laboratory since the adoption of this test/method in 2007.
    b. These controls are adequate to ensure an Acceptable level of risk of harm to the patient in the event that they fail.
3. Quality Assessment
    a. The monitoring of the IQCP may include:
        i. QC review
        ii. Proficiency testing records (*e.g.,* scores, testing failures, trends)
        iii. Incident Reports and associated follow-up.
        iv. Personnel competency records
4. Authorization of the IQCP

    By conducting a Risk Assessment, the Clinical Laboratory has attempted to identify all relevant potential failures that could lead to errors in test results and has included an assessment of the pre-analytical, analytical, and post-analytical phases of testing. We have developed a IQCP based on the RA to ensure we will meet the quality goals within the organization. We have determined that the *Hologic TLiQ Rapid fFN* Quality Control requirements are acceptable for this test.

    The IQCP will be reviewed regularly to ensure that it remains effective to control for risks. It will also be reviewed, including but not limited to, when there is a significant change to the testing personnel, environment, specimens, reagents, and/or test system or when significant changes are noted from the review of QA documents.

I authorize use of this IQCP with the Hologic TLiQ rapid fFN test system.

Section Director, Automated Chemistry/Urinalysis:
Name _____
Signature _____ Date _____

Director, Department of Pathology and Lab Medicine:
Name _____
Signature _____ Date _____

University of California, Davis Health System
Department of Pathology and Laboratory Medicine
Automated Chemistry/Urinalysis

Individualized Quality Control Plan (IQCP) Risk Assessment (RA) - Fetal Fibronectin

	Phase of Testing Process	Risk Assessment Component	Risk Factor (possible source of error)	Can the risk be reduced? Y / N / N/A	How Mitigate Risk?	Est. Frequency of Occurrence	Est. Severity of Harm to Pt. False Neg.	Est. Severity of Harm to Pt. False Pos.	Risk Level
1	Preanalytic	Specimen	Incorrect collection technique may result in a non-representative sample and an inaccurate result.	Y	Detailed collection instructions for the medical professionals collecting the sample are provided in the Specimen Collection Kit directional insert. If identified, recollect specimen.	Remote[1]	Serious	Negligible	Acceptable
2	Preanalytic	Specimen	Sample transported and/or stored before testing outside of the recommended temperature range of 2-25oC or frozen leads to an inaccurate result	Y	Detailed transport and storage instructions are described in the Specimen Collection Kit directional insert. If identified, recollect specimen. Section policy and online test directory also reflect these conditions.	Remote[1,2]	Serious	Negligible	Acceptable
3	Preanalytic	Specimen	Incorrect patient tested or specimen mislabelled.	Y	Staff collecting specimen must follow UCDHS policy 2024 Specimen labeling for Laboratory Processing for proper specimen collection/identification.	Remote[1,2]	Serious	Negligible	Acceptable
4	Preanalytic	Specimen	Sample not allowed to come to room temperature; tested in a cold or partially frozen state. Sample not mixed before removing swab. Possible inaccurate results.	Y	The Rapid fFN Cassette Kit directional insert and Chemistry section policies specify that Specimen Transport Tubes must come to room temperature before testing and that samples be gently mixed. Testing staff required to read policy. Initial competency established.	Remote[1]	Serious	Negligible	Acceptable
5	Preanalytic	Specimen	The patient sample contains visible blood or another potential interfering substance, but is still tested.	Y	The Rapid fFN Cassete Kit directional insert and Chemistry section policy list sample components that may cause assay interference, including blood.	Remote[1]	Serious	Negligible	Acceptable

6	Preanalytic	Reagent	Cassettes damaged by exposure to extreme conditions (e.g. temperature) during shipment.	Y	The Rapid fFN Cassette Kit directional insert and section policy specifies that testing of liquid controls is required each time a new lot or new shipment of cassettes is received.	Remote[1,3-6]	Serious	Negligible	Acceptable
7	Preanalytic	Reagent	Cassettes stored unpouched	Y	The Rapid fFN Cassette Kit directional insert and section policy specifies that once the foil pouch is opened the cassette should be used immediately.	Remote[1,3-6]	Serious	Negligible	Acceptable
8	Preanalytic	Reagent	Cassette used past lot expiration date.	Y	Expiration date is printed on each cassette pouch. Cassettes have an 18 month shelf life.	Remote[1,3-6]	Serious	Negligible	Acceptable
9	Preanalytic	Reagent	Cassette storage - store at room temperature.	Y	Temperature of storage and testing rooms is monitored and recorded daily.	Remote[1,3-6]	Serious	Negligible	Acceptable
10	Preanalytic	Test System	Cassette lot number entered does not match the cassette lot currently calibrated on the test system.	Y	System recognizes that a different lot number has been entered and prompts the user to calibrate. The cassette lot number is printed on the end of each Rapid fFN Cassette pouch.	Remote[1,3-6]	Negligible	Negligible	Acceptable
11	Analytic	Test System	Incorrect volume of sample is dispensed, causing an "INVALID" result.	Y	The Rapid fFN Cassette Kit directional insert describes how internal controls monitor all components of the test system and are performed automatcally with every test. These internal controls check for a threshold level of signal at the control position, proper sample flow across the cassette, and absence of conjugate aggregation.	Remote[1,3-6]	Negligible	Negligible	Acceptable
12	Analytic	Environment	Loss of scan accuracy caused by a power interruption or power surge causes an invalid result.	Y	Per the System manual, the test system was designed in compliance with safety standards for electrical equipment for laboratory use.	Remote[1,3-6]	Negligible	Negligible	Acceptable

13	Analytic	Environment	Excessive ambient light or bumping of the cassette or analyzer during operation leads to an "INVALID" result.	Y	The User manual specifies that the analyzer is not to be placed in direct sunlight. The analyzer gives an error code for a high light level. The analyzer displays a statement that states not to remove cassette during operation. The analyzer is not in direct sunlight.	Remote[1,3-6]	Negligible	Negligible	Acceptable
14	Analytic	Environment	Room temperature: operate instrument at temperatures between 18 - 30oC	Y	Room temperature is monitored and recorded daily.	Remote[1,3-6]	Minor	Negligible	Acceptable
15	Analytic	Environment	Room humidity: operate instrument at humidity < 80%	Y	Humidity is monitored and recorded daily.	Remote[1,3-6]	Minor	Negligible	Acceptable
16	Analytic	Test System	Patient sample does not flow completely across the cassette due to sample quality (too viscous), which leads to an "INVALID" result.	Y	The Rapid fFN Cassette Kit directional insert describes how internal controls monitor all components of the test system and are performed automatcally with every test. These internal controls check for a threshold level of signal at the control position, proper sample flow across the cassette, and absence of conjugate aggregation. Mucoid samples noted by testing personnel and centrifuged before analysis.	Remote[1,3-6]	N/A	N/A	Acceptable
17	Analytic	Test System	QCette serial number is entered incorrectly.	Y	Per the System User Manual, the system recognizes a new Qcette serial number and requires a new setup before proceeding.	Remote[1,3-6]	Negligible	Negligible	Acceptable
18	Analytic	Test System	QCette result is "SYSTEM FAIL" or "INVALID", but operator proceeds with patient testing.	Y	The directional insert specifies that patient samples not be tested until an acceptable result is obtained from the Qcette. Invalid test upon repeat and troubleshooting resulted as INVALID.	Remote[1,3-6]	Serious	Negligible	Acceptable
19	Analytic	Test System	Control result(s) are unacceptable - "FAIL" result or "INVALID" result, but operator proceeds with patient testing.	Y	The Rapid fFN Control kit directional insert specifies that patient samples not be tested until acceptable results are obtained for the liquid controls.	Remote[1,3-6]	Serious	Negligible	Acceptable

20	Analytic	Test System	Expired liquid controls are used.	Y	The Rapid fFN Control kit directional insert describes the stability requirements for both unopened and opened controls. Space is provided on the control box for recording of the opened date.	Remote[1,3-6]	Serious	Negligible	Acceptable
21	Post-Analytic	Testing Personnel	Improperly trained personnel	Y	Train testing personnel on specimen requirements, and proper performance of test according to manufacturer instructions.	Remote[1,3-6]	Serious	Negligible	Acceptable
22	Post-Analytic	Testing Personnel	Incorrect result entered into LIS.	Y	Results are co-signed by a different CLS.	Remote[1,3-6]	Serious	Negligible	Acceptable

[1] fFN retrospective chart review conducted 11/2015. 200 patient charts reviewed, 40 ea. Per yrs. 2011 - 2015. One potential false negative test result identified. Estimated potential false negative result rate = 1/1.5 years.

[2] Patient specimen cancellation statistics by lab compiled 11/29/15. Period covered: 11/29/12 - 11/29/15. 412 patient specimens collected. 10 samples cancelled: 5 = MD request, 2 = quantity not sufficient for testing, 3 = broken/leaking sample.

[3] External quality control checks using liquid QC compiled and reviewed 11/29/15 covering 3/27/08 - 10/19/15. All results = PASS.

[4] Internal quality control checks compiled and reviewed 12/5/15. 528 patient specimens tested from 11/8/11 - 11/4/15. Result for Internal Controls for Analyzer = PASS, Cassette = PASS.

[5] External quality control checks using QCette compiled and reviewed 11/29/15 covering 8/28/12 - 10/24/15. All results = PASS.

[6] Testing section (Chemistry, 2P340) room temperature from 1/1/2012 - 12/5/2015 reviewed 12/5/15. All within 18 - 26^{o}C. Testing section (Chemistry, 2P340) Relative Humidity from 1/1/2012 - 12/5/2015 reviewed 12/5/15. All < 80%. Reagent storage room (HD, 2P612A) room temperature 1/1/2012 - 12/5/2015 reviewed 12/5/15. All within 18 - 26^{o}C.

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Individualized Quality Control Plan (IQCP) Quality Control Plan (QCP) - Fetal Fibronectin

Type of Quality Control	Frequency	Criteria for Acceptability (Range of Acceptable Values)
Temperature checks: Room 2P340, Rm. 2P612A, refrigerator.	Daily	Reagent storage requirement: 15 - 30°C. Acceptable range of room temperature 18 - 26°C.
Verify specimen collection tubes for acceptability upon receipt in the laboratory.	With each specimen	Refer to Fetal Fibronectin Chemistry policy 3401 for requirements.
Verify specimen collection time and time received by the laboratory.	With each specimen	Refer to Fetal Fibronectin Chemistry policy 3401 for requirements.
Internal quality control	Performed automatically with each test.	Result: "PASS"
External quality control (using QCette)	Performed daily.	Result: "SYSTEM PASS"
External quality control (using liquid controls)	Performed for each new shipment of fFN cassettes.	Result: "PASS"
Proficiency Testing (CAP survey)	Semi-annual	Result agreement with majority of peers.
Training	With each new testing personnel and when indicated.	Successful demonstration of test performance. Document training activities.
Competency Assessment	Six months and one year after initial training, annually thereafter.	All testing personnel must successfully meet all six CLIA elements for competency assessment.

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Individualized Quality Control Plan (IQCP) Quality Assessment - Fetal Fibronectin

QA Activity (to monitor)	Frequency
Supervisor reviews and signs Quality Control records.	Monthly
Review of environmental conditions: temperature, humidity.	Daily
Proficiency Testing records	Semi-annually
Hospital Incident Reports	Continuous

Risk Gradient Table*

Probability of Harm
Frequent = once/week
Probable = once/month
Occasional = once/year
Remote = once/few years
Improbable = once/lifetime
Severity of Harm
Negligible = inconvenient or temporary discomfort
Minor = temporary injury or impairment not requiring professional medical intervention
Serious = injury or impairment requiring professional medical intervention
Critical = permanent impairment or life-threatening injury
Catastrophic = patient death

Probability of Harm	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Probable	Acceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Occasional	Acceptable	Acceptable	Perform Risk-Benefit Analysis	Unacceptable	Unacceptable
Remote	Acceptable	Acceptable	Perform Risk-Benefit Analysis	Perform Risk-Benefit Analysis	Unacceptable
Improbable	Acceptable	Acceptable	Perform Risk-Benefit Analysis	Perform Risk-Benefit Analysis	Perform Risk-Benefit Analysis

*ISO 14971: Medical devices- Application of risk management to medical devices. www.iso.org

*Webinar: A Practical Approach to Developing an Individual Quality Control Plan (IQCP), Sharon Ehrmeyer, PhD,MT (ASCP), Slide 37 DCC# 031934 Rev.A. wwwabbottpointofcare.com/poc-work/knowledge-center/webinars.