INTENDED USE
The Rapid fFN Control Kit, consisting of the Rapid fFN Positive and Negative Controls, is intended to be used to monitor the performance of the Rapid fFN Cassettes with the TLiIQ Analyzer.

PRECAUTIONS AND WARNINGS
1. For in vitro diagnostic use only.
2. The Rapid fFN Control Kit is for use only with the Rapid fFN Cassette and the TLiIQ Analyzer.
3. Source material used to prepare the controls is of human origin. The donors were tested and found to be negative for HIV 1, HIV 2, and HCV antibody and hepatitis B surface antigen (HBsAg) using established methods. No known test method can offer total assurance that HIV, hepatitis C virus, hepatitis B virus or other infectious agents are absent. Handle these reagents and all patient specimens as if potentially infectious.
4. Carefully follow the instructions and procedures described in this insert.
5. Do not use glass tubes or glass pipettes, as fetal fibronectin binds to glass. Tubes and pipettes of polypropylene or polyethylene are acceptable.
6. Reagents in this kit contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. Thus, when disposing of the reagents, always flush the drain with large volumes of water to prevent azide build up.
7. Do not use controls beyond the expiration date printed on the bottle.
8. Do not use controls if they are cloudy or discolored, or if the bottles have leaked.
9. Avoid cross-contamination of reagents. Use a new pipette for each control or patient sample. Recap reagents tightly with the correct color-coded caps.

STORAGE
Store the Rapid fFN Control Kit at 2° to 8°C.

STABILITY
The shelf life of the Rapid fFN Control Kit is one year from the date of manufacture. Unopened controls may be used until the expiration date printed on the bottle. Once opened, they should be used within 6 months.

MATERIALS PROVIDED
1. Rapid fFN Positive Control: One bottle containing 2.5 mL human fetal fibronectin (>0.050 µg/mL) in a stable protein matrix with sodium azide as a preservative. Store at 2° to 8°C. Use at room temperature.
2. Rapid fFN Negative Control: One bottle containing 2.5 mL human fetal fibronectin (<0.050 µg/mL) in a stable protein matrix with sodium azide as a preservative. Store at 2° to 8°C. Use at room temperature.
3. Directional Insert

PROCEDURE
Transfer 200 µL of the Rapid fFN Positive Control into the sample application well of the Rapid fFN Cassette and run the liquid control as if testing patient sample, as directed in the Rapid fFN Cassette Kit directional insert. Repeat with the Negative Control. The recommended frequency of use is one Positive Control and one Negative Control each time a new lot or a new shipment of Rapid fFN cassettes is received, or whenever there is uncertainty about Rapid fFN cassettes. Deviation from the recommended frequency of quality control testing must be validated by the laboratory.

EXPECTED RESULTS
Acceptable results for the Rapid fFN Positive and Negative Controls will be displayed on the TLiIQ Analyzer as PASS. Unacceptable results will be displayed as FAIL or INVALID. Retest failed and invalid controls. Do not test patient samples until acceptable results are obtained with controls. If the problem continues, please call Holicoeg for technical assistance. The Rapid fFN Cassette Kit, the TLiIQ Analyzer, and the Specimen Collection Kit and their use are covered by U.S. patent numbers: 4,894,326; 4,919,889; 5,056,859; 5,243,059; 5,281,522; 6,267,722; 6,894,952; 6,867,051; 6,936,476; and one or more corresponding foreign patents.

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