

To be used by trained medical personnel only

The Hologic Rapid fFN™ Control Kit is for use with Rapid fFN™ for the TLiQ® System.

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 TLiQ® 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 TLiQ 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.

Note: For your convenience, space is provided on the Rapid fFN Cassette Kit box for control testing documentation.

EXPECTED RESULTS

Acceptable results for the Rapid fFN Positive and Negative Controls will be displayed on the TLiQ 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 Hologic for technical assistance.

The Rapid fFN Cassette Kit, the TLiQ Analyzer, and the Specimen Collection Kit and their use are covered by one or more of the following patents granted or licensed to Hologic Corporation: U.S. patent numbers 4,894,326; 4,919,889; 5,096,830; 5,243,029; 5,281,522; 6,267,722; 6,394,952; 6,867,051; 6,936,476; and one or more corresponding foreign patents.

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TECHNICAL SERVICE AND ORDERING INFORMATION

USA/CANADA ONLY

Tel: 1-888-PRETERM
(1-888-773-8376)
Fax: 1-508-263-2956

ALL OTHER COUNTRIES

Tel: +1-508-263-2900

For additional contact information, go to www.ffntest.com



Caution, consult accompanying documents



Temperature limitation: 2°-8°C



In vitro diagnostic medical device



Catalogue number



Use by



Do not reuse



Batch code



Manufacturer



Authorized Representative in the European Community