HOLOGIC®

Rapid fFN® Control Kit

REF 01166

For *In Vitro* Diagnostic Use Only
Store at 2° to 8°C. Do not freeze.

Rx only

For Professional Use Only
The Hologic Rapid fFN Control Kit is for use with Rapid fFN for the TLi$_{IQ}$® 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 TLi$_{IQ}$ 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 TLi$_{IQ}$ 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

RapidfFN® for the TLi$_{IQ}$® System

Rapid fFN® Control Kit

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.

TECHNICAL SERVICE AND ORDERING INFORMATION

USA/CANADA ONLY

Tel: 1-800-442-9892

Fax: 1-508-263-2956

ALL OTHER COUNTRIES

Tel: +1-508-263-2900

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

Rapid fFN® Control Kit

Following is an explanation of the symbols that may appear on your product.

Symbol	Title	Description	Standard information
	Caution, consult instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.4
	Biological risks	Indicates that there are potential biological risks associated with the medical device.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.1
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.4
	*In vitro* diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.5.1
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.5
	Temperature limit	Indicates the upper and lower limit of temperature to which the medical device can be safely exposed.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.3.7
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.6
	Manufacturer	Indicates the medical device manufacturer, as defined in the EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1

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