HOLOGIC®

Rapid fFN® for the TLiQ® System Specimen Collection Kit

REF 71738-001

For *In Vitro* Diagnostic Use Only
Store at 2° to 25°C.

Rx only

To be used by trained medical personnel only

INTENDED USE

The Hologic Specimen Collection Kit test contains specimen collection devices consisting of a sterile polyester tipped swab and a specimen transport tube containing 1 mL extraction buffer. This specimen collection device is intended for collection of cervicovaginal specimens for Hologic's in vitro diagnostic test, Rapid fFN® (fetal fibronectin) for the TLiQ® System. Specimens should be obtained only during a speculum examination.

PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only.
2. Do not use kit if swab package integrity is compromised or if specimen transport tubes have leaked.
3. The extraction buffer is an aqueous solution containing protease inhibitors and protein preservatives including aprotinin, bovine serum albumin, and sodium azide. Sodium azide may react with plumbing to form potentially explosive metal azides. Avoid contact with skin, eyes, and clothing. In case of contact with any of these reagents, wash area thoroughly with water. If disposing of this reagent, always flush the drain with large volumes of water to prevent azide build-up.
4. Specimens of human origin should be considered potentially infectious. Use appropriate precautions in the collection, handling, storage, and disposal of the specimen and the used kit contents. Discard used materials in a proper biohazard container.
5. **Specimens for fetal fibronectin testing should be collected prior to collection of culture specimens.** Collection of vaginal specimens for microbiologic culture frequently requires aggressive collection techniques that may abrade the cervical or vaginal mucosa and may potentially interfere with sample preparation.
6. **Specimens should be obtained prior to digital cervical examination or vaginal probe ultrasound examination as manipulation of the cervix may cause the release of fetal fibronectin.**
7. **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.**
8. **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 Fetal Fibronectin tests.
9. **Fetal Fibronectin tests are not intended for use in women with moderate or gross vaginal bleeding.** The presence of vaginal bleeding may contribute to difficulty in interpreting the fetal fibronectin test result. Testing a bloody sample may lead to false positive results. However, if the test is negative, it should be considered a valid result. If upon visual examination you are concerned about the presence of moderate or gross vaginal blood, we recommend collecting a sample following cessation of active vaginal bleeding.
10. Rupture of membranes should be ruled out prior to specimen collection since fetal fibronectin is found in both amniotic fluid and the fetal membranes.
11. Specimens for fetal fibronectin testing should not be obtained from patients with suspected or known placental abruption or placenta previa.
12. Fetal Fibronectin tests are not intended for use in patients with cancers of the reproductive tract.
13. Assay interference from the following components has not been ruled out: douches, white blood cells, red blood cells, bacteria, and bilirubin.
14. The presence of infections has not been ruled out as a confounding factor to risk of preterm delivery.

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15. Information is insufficient regarding the association of fetal fibronectin expression to delivery in asymptomatic women with HIV/AIDS.
16. Do not use the Specimen Collection Devices past the expiration date.
17. Use only one Specimen Collection Device per patient sample.
18. Care must be taken not to break the swab during specimen collection.
19. Specimens not tested within eight hours of collection must be stored refrigerated at 2° to 8°C and assayed within three days of collection, or frozen and assayed within three months.

INSTRUCTIONS FOR USE

This Specimen Collection Kit is the only acceptable specimen collection system that can be used to collect specimens for the Hologic Rapid fFN test.

1. During a speculum examination, prior to any examination or manipulation of the cervix or the vaginal tract, lightly rotate the sterile swab across the posterior fornix of the vagina for approximately 10 seconds to absorb cervicovaginal secretions. Subsequent attempts to saturate the swab may invalidate the test.
2. Remove swab and immerse tip in buffer. Break the shaft (at the score) even with the top of the tube.
3. Align the shaft with the hole inside the tube cap and push down tightly over the shaft, sealing the tube. **Warning:** The shaft must be aligned to avoid leakage.
4. Write the patient's name and other identifying information required on the specimen transport tube label.
5. Send the tube to the laboratory for testing. Transport specimens at 2° to 25°C, or frozen.
6. **Specimens not tested within eight (8) hours of collection must be stored refrigerated at 2° to 8°C and assayed within three (3) days of collection, or frozen and assayed within three (3) months to avoid degradation of the analyte. Do not expose to temperatures above 25°C.**

This product may be covered by one or more U.S. patents identified at http://hologic.com/patentinformation

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

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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
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.3
	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
	Do not re-use	Indicates a medical device that is intented for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.2
	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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