RapidfFN™ for the TLiQ® System

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

CE

REF 71738-001

To be used by trained medical personnel only

Specimen Collection Kit

INTENDED USE

The Hologic Specimen Collection Kit 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. **Specimens should not be tested if the patient has had sexual intercourse within 24 hours prior to the sampling time because semen and/or sperm present in the sample may increase the possibility of a false positive result.**
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.
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.**

The Rapid fFN Cassette Kit, the TLiQ System, and the Specimen Collection Kit and their use are covered by one or more of the following patents granted or licensed to Hologic, Inc.: 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

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	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	2°C 25°C	Temperature limitation: 2°–25°C
IVD	*In vitro* diagnostic medical device	REF	Catalogue number
	Use by		Do not reuse
LOT	Batch code		Manufacturer
EC REP	Authorized Representative in the European Community		

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