HOLOGIC®

Rapid fFN® Test Specimen Collection Kit

REF PRD-01020

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

For near patient testing. To be used by trained medical personnel only.
The Hologic Rapid fFN Specimen Collection Kit is for use with the Rapid fFN® Tests (PeriLynx™ System, Rapid fFN® 10Q System).

INTENDED USE

The Rapid fFN® Test 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 the Rapid fFN Tests (PeriLynx™ System, Rapid fFN® 10Q 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. Rupture of membranes should be ruled out prior to specimen collection since fetal fibronectin is found in both amniotic fluid and the fetal membranes.
8. The presence of infections has not been ruled out as a confounding factor to risk of preterm delivery.
9. Information is insufficient regarding the association of fetal fibronectin expression to delivery in asymptomatic women with HIV/AIDS.
10. Do not use the specimen collection devices past the expiration date.
11. Use only one specimen collection device per patient sample. Each collection device is a single-use device. Do not reuse.
12. Care must be taken not to break the swab during specimen collection.

STORAGE AND STABILITY

Specimens not tested within eight (8) hours of collection must be stored refrigerated at 2° to 8°C and assayed within two (2) 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.

INSTRUCTIONS FOR USE

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

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 the Hologic Perinatal Swab (sterile, polyester-tipped swab) and immerse tip in buffer. Break the shaft (at the score) even with the top of the tube.

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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 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 two (2) 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.**

LIMITATIONS

1. A fetal fibronectin sample can be collected in patients who report having had sexual intercourse in the prior 24 hours, but healthcare providers should be aware of the following information relevant to these patients:

   A sample contaminated with semen may lead to a falsely elevated fFN result. However, healthcare providers can be assured that interference from semen will not cause a falsely lowered fFN result. For example, a result of less than 10 ng/mL can be relied on to be a valid result of less than 10 ng/mL, even if the patient has had sexual intercourse in the prior 24 hours.

   The above example is also applicable to higher management thresholds used by some facilities.
2. **Care must be taken not to contaminate the swab or cervicovaginal secretions with lubricants, soaps, disinfectants, or creams (e.g., K-Y® Jelly lubricant, vaginal progesterone, 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.
3. **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. 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.
4. Specimens for fetal fibronectin testing should not be obtained from patients with suspected or known placental abruption or placenta previa.
5. Fetal fibronectin tests are not intended for use in patients with cancers of the reproductive tract.
6. Assay interference from the following components has not been ruled out: douches, white blood cells, red blood cells, bacteria, and bilirubin.

TECHNICAL SUPPORT AND ORDERING INFORMATION

For country-specific Technical Support and Customer Service email addresses and telephone numbers, visit www.hologic.com/support.

In case of serious incident, please notify the Manufacturer and Competent Authority in your region.

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Do not reuse	Use by	Consult instructions for use
REF Catalogue number	Manufacturer	Do not use if package is damaged. Do not use if the product sterile barrier system or its packaging is compromised.
IVD *In Vitro* diagnostic medical device	LOT Batch code	EC REP Authorized Representative in the European community
2°C 25°C Temperature limitation: 2°–25°C	Open here	
For near-patient testing.		

REVISION HISTORY

Part Number	Date	Description
AW-26017-001 Rev. 001	05-2022	• Created Rapid fFN Test Specimen Collection Kit Instructions for Use AW-26017-001 Rev.001 based on AW-22728-001 Rev.002 for regulatory compliance with IVDR. • Updated specimen storage instructions • Updated contact information including: EC Rep authority, Australian sponsor details, and technical support information.

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