

December 18, 2009

Important – Product Recall/Correction

Rapid fFN™ for the TLiQ® System associated products:
Specimen Collection Kit [00797 (8-pack), 71738-001 (25-pack)]
Rapid fFN™ Cassette Kit (01200/01200Q)
Rapid fFN™ Control Kit (01166)
TLiQ® QCette® (01175)

Dear Laboratory Director/Recipient of the Fetal Fibronectin Test,

Hologic, Inc. is conducting a voluntary recall to correct labeling associated with the Rapid fFN for the TLiQ System, also known as the fetal fibronectin test. This correction involves the removal of instances of “Full Term” from the product labeling and packaging. Our records indicate that you have ordered Rapid fFN Cassettes in the past 18 months and/or the Specimen Collection Kit (SCK) used with the fetal fibronectin test within the past 3 years. Note that these products may list Adeza or Cytac as the manufacturer.

This product recall is not related to the quality of the product, but rather to the product name. To date there have been no illnesses or injuries reported to Hologic associated with use of the “Full Term” name. A Health Hazard Evaluation conducted by both a Maternal-Fetal Medicine (MFM) physician and the Hologic Medical Director concluded that the name “Full Term” confers a low composite risk and therefore does not pose a health risk to patients.

This correction is being conducted because the Food and Drug Administration (FDA) has determined that the trade name “Full Term” reflects a change in the current intended use of assessing the risk of preterm delivery. FDA believes that the “Full Term” name implies that the test could be used to assess whether a patient’s pregnancy is full term (37 weeks) or to predict imminent delivery in women who are at full term gestation. As a consequence, use of the “Full Term” name constitutes “misbranding”, as defined by the FDA, and requires correction.

You may continue to use the fetal fibronectin products in your possession once you have followed the re-labeling instructions below. Products ordered after the date of this letter will already be over-labeled and require no further action on your part.

Once all products have been over-labeled and marketing materials destroyed, please fax or email the enclosed Customer Recall Response Form noting the lot number and count of products that were over-labeled. It is important that Hologic is able to demonstrate to FDA that our customers were notified and complied with this over-labeling request as soon as possible.

We appreciate the effort associated with this notification and have set up a Hotline to assist your needs (800-442-9892, Option 7# or 508-263-8510). Copies of the enclosed materials are also available at www.ffntest.com (listed under healthcare professionals, product support).

HOLOGIC™

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We apologize for the inconvenience caused by this recall/correction and appreciate your efforts to ensure successful implementation of this correction.

Sincerely,

Catherine A. Williams
Director, Regulatory Affairs

Enclosures:

Instructions for Correction and Over-Labeling

Rapid fFN Cassettes, Rapid fFN Control Kit, TL_iQ QCette, Specimen Collection Kits,
Marketing Materials

Additional Instructions for Re-Labeling (with pictures)

Customer Recall Response Form (Cassette)

Order Form for Additional Labels

Directional Inserts (1 each): Specimen Collection Kit, Health Care Providers Brochure,

Rapid fFN Cassette, Rapid fFN Control, TL_iQ QCette

Additional copies are available at www.ffntest.com (listed under healthcare professionals, product support)

Labels (30 sets of 10 small and 5 sets of 5 large) sufficient to over-label:

5 Rapid fFN Cassette Boxes and cassette pouches

5 Specimen Collection Kit Boxes and individual kits

Instructions for Correction and Over-Labeling Rapid fFN Cassette Kits, Rapid fFN Control Kit, TLI_{IQ} QCette, Specimen Collection Kits, Marketing Materials

Rapid fFN Cassette Kits, Rapid fFN Control Kit, TLI_{IQ} QCette

Step #1: Replace the Directional Inserts

Replace the directional inserts (DI) for the Rapid fFN Cassette Kit, Rapid fFN Control Kit and TLI_{IQ} QCette, with those provided in this package.

- Rapid fFN Control Kit and TLI_{IQ} QCette require no further correction.

Note: These replacement DIs contain the product name, Rapid fFN for the TLI_{IQ} System, in the left-hand corner where the “Full Term” branding was previously located. The only changes made to the DIs were those related to the name “Full Term”.

Step #2: Over-Label Rapid fFN Cassette Box

- Place one (1) small label over the “Full Term” logo on the front of the box.

Step #3: Over-Label Individual Cassette Pouches

- Place a label over each occurrence of the “Full Term” logo on the 26 individual pouches.

Specimen Collection Kit Boxes and Individual Kits

Step #1: Replace the Directional Inserts

Replace the directional inserts (DI) for the Specimen Collection Kit and Health Care Providers’ Brochure with those provided in this package.

Note: These replacement DIs contain the product name, Rapid fFN for the TLI_{IQ} System, in the left-hand corner where the “Full Term” branding was previously located. The only changes made to the DIs were those related to the name “Full Term”.

Step #2: Over-Label Specimen Collection Kit Box(es)*

For the 25-pack Specimen Collection Kit Box (71738-001):

- Place five (5) of the large labels over the similar text on the box (one on the top and four on the sides).
- Place five (5) of the smaller labels over the “Full Term” logo on the box (one on the top and four on the sides).

For the 8-pack Specimen Collection Kit (00797)

- Place one (1) small label over the “Full Term” logo on the front of the box.

Step #3: Over-Label Individual Specimen Collection Kits (25-pack only)

- Being careful not to break the swab, place a label over each occurrence of the “Full Term” logo on the 25 individual cellophane wrapped collection kits within the box.

Note: If the individual specimen collection kits are dispersed throughout the medical facility, please notify others, as appropriate, to locate the kits and over-label the “Full Term” logo.

Marketing and Educational Materials

Permanently destroy all marketing and educational materials with the “Full Term” brand name.

Let us know how we can help!

We appreciate the effort associated with this notification and have set up a Hotline to assist your needs (800-442-9892, Option 7#).

- Provide additional labels
- Replace marketing and educational materials
- Provide assistance by phone or through your local sales representative

Please do not hesitate to call us. Thank you.

*If you do not store the individual kits in the 25-pack box, you may discard it rather than over-label.