Date: 05 January 2018

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URGENT: MEDICAL DEVICE RECALL NOTIFICATION
Fetal Hemoglobin Monoclonal Antibody (HBF-1)

Product Name	UDI	Catalog Number	Lot Number	Expiration Date
Fetal Hemoglobin Monoclonal Antibody (HBF-1), FITC	(01)10190302005579(17)190131 (10)1848553A(240)MHFH01	MHFH01	1848553A	1/31/2019

Dear Valued Customer,

This letter is to advise you that Life Technologies Corporation, a part of Thermo Fisher Scientific, is voluntarily recalling Fetal Hemoglobin Monoclonal Antibody (HBF-1). The Life Technologies' Fetal Hemoglobin (HbF) monoclonal antibody is conjugated with either fluorescein isothiocyanate (FITC), R-phycoerythrin (R-PE) or R-PE conjugated to the indodicarbocyanine dye, Cy5 (TRI-COLOR, TC). These reagents are intended for the identification, and subsequent enumeration of fetal red blood cells.

Thermo Fisher Scientific has become aware of a performance issue where specific lots of the Fetal Hemoglobin Monoclonal antibody may have difficulty detecting fetal cells. Since Feb 2017, we have received four (4) customer complaints pertaining to poor antibody detection whereby customers reported little to no antibody staining for the following product lot numbers: 1817629A, 1730479B, 1730479C and 1848553A. No adverse events have been associated with any of these complaints. Thirteen (13) additional product lots were identified as being affected and are also included in this recall. No customer complaints have been received for these thirteen additional lots.

The device may be used to aid a clinician in identifying fetal-maternal hemorrhaging. The issue pertains to staining, which would be identified through the use of required controls before any patient results are reported. Thus, the risk associated with this problem is a potential delay in testing while an alternative test is identified. This device is one of several testing options (using differing techniques) available for this purpose.

All QC testing data for the affected lots passed specifications. A historical review of manufacturing documentation revealed that the affected lots were formulated near the lower acceptable concentration range, which may have led to the poorer than expected staining.

How to recognize that the device may fail:

In the complaints received, customers identified a reduction in the intensity of staining, unequal staining, and in some instances, may have observed a reduction or shift in the positive population peak for fetal hemoglobin. Using controls, as required in the product labeling, the product deficiency is easily

identifiable before diagnostic samples are analyzed. If the positive controls do not perform as expected, discard the test results, repeat the test, and notify us immediately.

Please examine your inventory immediately to determine if you have any of the above referenced material on hand. If so, discontinue use immediately and discard per your internal procedures. Notify all affected users in your facility to do the same. If you have shipped this lot outside of your facility, you must notify those customers or facilities of this recall. Please inform us by replying the email to Techsupport.sg@lifetech.com if you require no charge replacement or credit for this product.

We appreciate your assistance and apologize for any inconvenience.

Sincerely,

Leon Lambry
Senior Manager QA/QC
Life Sciences Solutions
Thermo Fisher Scientific