Alere Scarborough
10 Southgate Road
Scarborough, ME 04074

June 2018

Dear Valued Customer:

We are writing to you with respect to the Alere™ Influenza A&B Test – catalog number 412-000 (Test Product). FDA's new requirements related to the reclassification of antigen-based rapid influenza detection test systems (RIDTs) took effect on January 12, 2018, at which time RIDTs were required to comply with new special controls (described in 21 CFR § 866.3328), including certain new minimum clinical performance criteria. Alere Scarborough, Inc. (Alere) has been communicating with FDA about the Test Product, and has continued to distribute the Test Product while evaluating the assay under the new minimum clinical performance criteria.

The clinical study conducted during the 2008-2009 respiratory season to support CLIA waiver for the Test Product included both prospectively collected nasal swab specimens and testing swab samples prepared with archived respiratory specimens. The performance assessment based on these data meets FDA's new minimum clinical performance criteria. However, FDA subsequently informed us that assessments of product performance relative to the new minimum clinical performance criteria should be conducted using only prospectively collected samples. We are conducting a clinical study using *only* prospectively collected samples but have agreed, in consultation with FDA, to suspend distribution of the Test Product in the United States until we complete the study.

Alere plans to cease, and to instruct its distributors to cease, distribution of the Test Product effective as of June 18, 2018, while we complete the clinical study described above. While Alere and its distributors will stop distributing the Test Product, Alere has confirmed with FDA that *healthcare providers can continue to use any Test Product that is currently in provider facilities.*

Alere has alternative influenza products to meet your facility's testing needs and has increased production to meet demand. The Alere™ i Influenza test is the first CLIA waived molecular rapid flu test, and we plan to launch the Alere™ Reader and BinaxNOW® Influenza A&B Card 2 this fall.

To learn more about the Alere™ i platform or forthcoming Alere™ Reader, contact your local Alere Representative. You can contact our customer service directly at (877) 441-7440 or clientservices@alere.com with any questions or to be put in touch with your representative. Your local distributor representative can also assist with your questions.

Sincerely,

Steve Henn
Vice President
Global Marketing Infectious Disease