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February 4, 2010

Urgent: Medical Device Correction
OneTouch® Ultra® Test Strips

Dear Valued Customer:

At LifeScan we hold our products to the highest standards of quality; constantly working to ensure they provide glucose results patients can rely on. For that reason, we're also committed to communicating with you when we learn of product that does not meet our expected standards.

We have recently determined that a single lot of OneTouch® Ultra® Test Strips contains vials of the wrong test strip. These incorrect test strips can be easily identified because they are dark blue and don't have a brand name printed on the strip (see picture). In addition, as a safety feature, these mislabeled test strips will not turn on a OneTouch® Ultra® Brand meter or provide a test result.

These mislabeled test strips are found only in 100-count packages (4 vials of 25 test strips each) of OneTouch Ultra Test Strips with Lot # **2964512**. This lot was shipped to two customers in September and October of 2009. Healthcare provider Kaiser Permanente received 1,812 packages from the affected lot, while distributor Cardinal Health received the balance of 7,812 packages.



Correct Incorrect

We estimate that up to 900 vials of mislabeled test strips are among the approximately 38,000 vials of OneTouch Ultra Test Strips in the affected lot. In addition, the mislabeled test strips can only be identified by opening the carton and inspecting the strips in each vial.

Due to the low incidence of mislabeled test strips and the inability to identify them without opening each carton, we request that you **do not return** any OneTouch Ultra Test Strips from the affected lot unless further notified by LifeScan to do so.

No Action On Your Part Is Needed - LifeScan Is Notifying Patients and Pharmacies Directly

While it is important that you are aware of this issue, we believe patients are in the best position to identify the small number mislabeled test strips through their normal receipt and inspection of the product before use. That's why we are conducting a broad-based notification program to directly alert patients, healthcare professionals and pharmacists of this issue. As part of this program, we will be sending an alert to all retail pharmacies in the U.S. asking them to post the enclosed Consumer Notice in a prominent location in their pharmacy. As a result of this communication, no additional notifications on your part are required. The U.S. Food & Drug Administration is aware of this issue and the steps we are taking to address it.

We apologize for any inconvenience this may cause. For more general information please visit www.OneTouchProductID.com. If you have specific questions about this issue or LifeScan's notification program please contact your LifeScan Account Manager. Thank you for your continued support of LifeScan.

Sincerely,

LifeScan Customer Service

Enclosure