

February 4, 2010

Urgent: Medical Device Correction
OneTouch® Ultra® Test Strips

Dear Pharmacist:

At LifeScan we hold our products to the highest standards of quality; constantly working to ensure they provide glucose results you 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 up to 900 packages of OneTouch® Ultra® Test Strips contain 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 test strips will not turn on a OneTouch® Ultra Brand Meter or provide a test result.



Correct Incorrect

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**.

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.

Please Help Us Reach Patients With This Important Information

While it is important that distributors and pharmacists 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 request your assistance by posting the enclosed patient notification in your pharmacy and referring any patients with questions directly to LifeScan for assistance.

We take this issue very seriously and are conducting a broad-based notification program to alert patients, healthcare professionals, pharmacists and distributors. 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 information please visit www.OneTouchProductID.com. If you still have any questions, please call our Customer Service line at **877 564-5348**. Thank you for your continued support of LifeScan.

Sincerely,

LifeScan Customer Service

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