



December 9, 2013

Pharmacy Announcement

Urgent Product Recall from Abbott Diabetes Care: FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips

Abbott Diabetes Care has announced a recall for certain lots of their FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips.

- For recipients using a new FreeStyle Lite, Freedom or InsuLinx meter – The meter and the test strips are not included in this recall; no further action is required.
- For recipients using an older meter (e.g., FreeStyle Flash or FreeStyle) – Please contact Abbott Customer Service at the number below; they will assist recipients in obtaining a free replacement meter or free replacement test strips.
- For recipients using an OmniPod Insulin Pump – New test strips will be provided by contacting Abbott Customer Service at the number below.

Please visit the Abbott Diabetes Care website at <https://www.abbottdiabetescare.com/press-room/2013/2013-g.html> or call **(888) 736-9869** for more information.

Please review the following three pages for additional details from Abbott Diabetes Care.

November 18, 2013

IMPORTANT: URGENT PRODUCT RECALL

FreeStyle® and FreeStyle Lite® Test Strips

Dear Valued Customer,

Recently, it has come to our attention that certain lots of FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips produce erroneously low blood glucose results when using FreeStyle® Blood Glucose Meters, FreeStyle Flash® Blood Glucose Meters and the FreeStyle® blood glucose meter built into the OmniPod® system. Erroneously low results that are not recognized may pose significant risks to your health.

If you do not use the meters in the photographs below, your blood glucose test results are not affected and you do not need to read any further.

FreeStyle Flash®
Blood Glucose Meter



FreeStyle®
Blood Glucose Meter



OmniPod®



The FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips lots listed below may give out of range control solution results and produce erroneously low blood glucose results when using the Blood Glucose Meters illustrated in the photographs above.

The affected FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips lots are found in the table below:

Lot Numbers						
1281732	1283345	1283603	1285007	1350414	1363015	1363109
1363321	1365056	1365920	1365921	1365934	1366006	1366111
1366337	1366347	1366515	1367917	1373262	1374907	

A test strip insert is included with every carton of test strips, and provides very important product information. **Please read your test strip insert carefully to ensure that you are using the correct Blood Glucose Meter for your test strip type.**

If you have affected product, we recommend you take the following steps:

1. Call Abbott Diabetes Care Customer Service immediately at 1-888-736-9869 for replacement of the affected test strips. When you call, Abbott will send you unaffected FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips at no charge.
2. While waiting for your replacement strips to arrive, either use an alternate method to measure your blood glucose (such as test strips from an unaffected lot number or a different blood glucose monitoring system). This issue only affects the lot numbers which are detailed in the table above when using FreeStyle® Blood Glucose Meters, FreeStyle Flash® Blood Glucose Meters.

If the only test strips available to you are from affected lots, do not stop testing your blood glucose. Control solution should be used to check the performance of your test strips and meter until you receive your replacement test strips. However, if any reading from a strip appears lower than you would expect or does not seem to match



the way you are feeling, you should contact your health care provider. Pay special attention to signs and symptoms of high blood sugar (hyperglycemia).

Symptoms of high blood sugar may include: Excessive thirst, excessive urination, blurred vision, weakness, nausea, vomiting, and abdominal pain. If you are experiencing any of these symptoms or are not feeling well, contact your health care professional immediately.

3. Please dispose of the test strips in accordance with your local and state disposal regulations.

If the lot number of the test strips you are using is NOT in the table on this letter, you may continue to test your blood glucose as directed by your health care provider with your FreeStyle® Blood Glucose Test Strips. There are no other Abbott Diabetes Care products impacted by this issue.

We recognize the importance of blood glucose testing and are committed to responding quickly to customers' requests for replacement test strips.

We want to assure you that our first priority is you, our customer. We sincerely regret any inconvenience this situation may cause. We thank you for your continued support of the FreeStyle Blood Glucose Monitoring System and Abbott Diabetes Care. If you have any further questions, please call Abbott Diabetes Care Customer Service at 1-888-736-9869.

Sincerely,

A handwritten signature in black ink that reads 'Kelly E. Duffy'.

Kelly E. Duffy
Division Vice President, Quality Assurance and Compliance
Abbott Diabetes Care

November 21, 2013

IMPORTANT: URGENT PRODUCT RECALL

FreeStyle® and FreeStyle Lite® Test Strips

Dear Valued Customer,

Please allow this communication to serve as an important notification regarding the recall of certain lots of FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips.

Abbott Diabetes Care (ADC) has initiated a voluntary product recall on 20 lots of FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips. The affected FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips may produce out of range control solution results and erroneously low blood glucose results when used with older technology blood glucose meters: FreeStyle® Blood Glucose Meters, FreeStyle Flash® Blood Glucose Meters, and the FreeStyle® blood glucose meter built into the OmniPod® system (please reference the meters shown in the attached Consumer Letter). When the affected test strips are used with newer FreeStyle brand meters such as FreeStyle Freedom®, FreeStyle Lite®, FreeStyle Freedom Lite® and FreeStyle® Insulinx®, clinically acceptable blood glucose results are produced. No other ADC products are affected by this issue.

Patients that have received the affected test strip lots are currently being notified of this issue in the form of a notification letter (which has been attached for your reference as noted above). Additionally, the notification letter has been posted to the Abbott Diabetes Care website, www.AbbottDiabetesCare.com.

If a customer has affected test strips and uses any of the older technology meters shown in the photos within the attached letter, we recommend that they call Abbott Diabetes Care Customer Service immediately at 1-888-736-9869 for a no-charge replacement of the affected test strips. Once they have called for their replacement, they can dispose of the test strips in accordance with local and state disposal regulations. Additional instructions for customers are provided in the notification letter.

Patients whose test strips are not from affected test strip lots can continue to use those strips.

We have contacted regulatory authorities and agencies regarding this issue and notified them Abbott is recalling the impacted lots. We are also notifying healthcare professionals, pharmacies, and distributors who have received the affected lots. Our first priority is always patient safety and this voluntary recall is an example of that commitment.

Should you have any questions, please contact your Account Manager.

Sincerely,



Kelly E. Duffy
Division Vice President, Quality Assurance and Compliance
Abbott Diabetes Care