



Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: December 27, 2010
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Abbott Diabetes Care Recall

SUGGESTED

ACTION: Unclassified Recall; 359 lots (approximately 359 million strips) of Precision Xtra®, Precision Xceed Pro®, MediSense® Optium™, Optium™, OptiumEZ and ReliOn® Ultima Blood Glucose Test Strips. The affected test strips may give falsely low blood glucose results; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the products being recalled may be distributed in the State of Indiana. The recalled products were sold nationwide. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Abbott Diabetes Care Announces Recall of Certain Lots of Precision Xtra®, Precision Xceed Pro®, MediSense® Optium™, Optium™, OptiumEZ and ReliOn® Ultima Blood Glucose Test Strips in the United States and Puerto Rico

*No other Abbott Diabetes Care products are affected
More information is available at: www.precisionoptiuminfo.com*

Contact:
Abbott Diabetes Care Customer Service
(800) 448-5234 (English)
(800) 709-7010 (Español)

Media Contact:

Scott Davies
(847) 938-8898
Greg Miley
(510) 502-7076

FOR IMMEDIATE RELEASE – ALAMEDA, Calif. December 22, 2010 — Abbott Diabetes Care today announced that it has initiated a recall of 359 lots (approximately 359 million strips) of Precision Xtra®, Precision Xceed Pro®, MediSense® Optium™, Optium™, OptiumEZ and ReliOn® Ultima Blood Glucose Test Strips in the United States and Puerto Rico.

The test strips are used with Abbott's Precision Xtra, Precision Xceed Pro, MediSense Optium, Optium and OptiumEZ blood glucose monitoring systems. ReliOn Ultima test strips are used with the ReliOn Ultima blood glucose monitoring system. The blood glucose monitors are not being recalled and customers can continue to use the blood glucose monitors.

The affected test strips may give falsely low blood glucose results, which can lead users to try to raise their blood glucose when it is unnecessary and to fail to treat elevated blood glucose due to a falsely low reading. The problem appears to be related to longer than expected blood fill times. This may be dependent on the age of the strips and if the strips have been stored in (or exposed to) higher temperatures (above 72°F and not to exceed 86°F) for an extended period of time.

Customers who have test strips from these affected lots should discontinue use of the product. Abbott Diabetes Care will replace affected test strips at no charge. Abbott Diabetes Care initiated this recall following a routine internal quality review that indicated certain lots of Precision Xtra, Precision Xceed Pro, MediSense Optium, Optium, OptiumEZ and ReliOn Ultima blood glucose test strips may experience longer than normal blood fill times which may cause falsely low blood glucose readings.

Customers are advised to contact their health care provider to determine testing options if they do not have any unaffected test strips to use.

However, if consumers must use affected test strips while in the process of obtaining new strips, they should:

1. Check the amount of time it takes for their blood glucose meter to start the “countdown” after they first apply blood to the test strip. They should start timing immediately after blood first makes contact with the test strip. If the meter takes longer than five seconds to start the countdown, that test strip is affected and the result should not be used. Users should check the time for each test strip they use because all of the strips in a package may not be affected to the same degree. If any reading appears lower than they would expect or does not seem to correlate with the way they are feeling, the user should contact their health care provider immediately.

2. If they do not immediately have access to unaffected strips and are unable to test their blood sugar, users need to be aware of symptoms of high blood sugar (hyperglycemia) and low blood sugar (hypoglycemia).

- Symptoms of high blood sugar include excessive thirst, excessive urination, blurred vision, weakness, nausea, vomiting, and abdominal pain. If a user is experiencing any of these symptoms or is not feeling well, they should contact their health care professional immediately.
- Symptoms of low blood sugar may include trembling, excessive sweating, weakness, hunger, confusion, and headache. Some individuals may have no symptoms at all before they develop unconsciousness or seizures. It is important to treat low blood sugars promptly to avoid loss of consciousness or a seizure. If a user is unable to obtain unaffected strips, they should contact their health care provider for advice on how to treat these symptoms before they occur.

The recommendation is that hospitals and user facilities stop using the recalled test strips and follow the steps below:

1. Use test strips from unaffected lots.

2. If the health care facility does not have any test strips from unaffected lots but has an alternative point-of-care blood glucose testing system, begin using the alternative system until new, unaffected test strips can be obtained.

3. If the health care facility does not have any test strips from unaffected lots or immediate access to an alternative point-of-care blood glucose testing system, health care providers should take the following steps:

- Verify any critical glucose test results (e.g., test results that may be used to adjust insulin therapy in vulnerable patient populations) generated on the Precision Xceed Pro Blood Glucose Monitoring System using a central laboratory blood glucose method. Clinical judgment should be applied when deciding whether to act on results prior to verification.
- Verify any Precision Xceed Pro Blood Glucose Monitoring System results that do not match a patient's symptoms, or seem unexpected for the patient's clinical status, using a central laboratory blood glucose method.
- Monitor the amount of time it takes for the Precision Xceed Blood Glucose Meter to start the "countdown" after blood is first applied to the test strip. If the amount of time exceeds five seconds, discard that test strip immediately to prevent the risk of receiving a falsely low blood glucose result (if this occurs, health care providers should note the lot number of that test strip, discard all the test strips from that lot, and notify Abbott Diabetes Care immediately).

Customers can check if they have test strips from the affected lots by visiting www.precisionoptiuminfo.com and looking up their product lot number.

Precision Xtra, Precision Xceed Pro, MediSense Optium, Optium, OptiumEZ and ReliOn Ultima customers can also get information by calling Abbott Diabetes Care customer service at 1-800-448-5234 (English) and 1-800-709-7010 (Español).

The website and customer service phone numbers listed above will also provide customers with information about returning affected test strips.

Unaffected Precision Xtra, Precision Xceed Pro, MediSense Optium, Optium, OptiumEZ and ReliOn Ultima Blood Glucose Test Strip lots may be used by customers to test their blood glucose as directed by their health care providers.

Abbott Diabetes Care has reported this situation to the U.S. Food and Drug Administration and is working to make the necessary corrective actions to prevent this situation from recurring.

OptiumEZ Blood Glucose Test Strips
45358, 45369, 45377, 45504, 45677, 45678, 45681, 45789, 45841, 45848, 45849, 45999, 46000, 46008, 46061, 46067, 46102, 46104, 46117, 46159, 46179, 46201, 46202, 46211, 46230, 46247, 46311, 46312, 46341, 46368, 46369, 46371, 46395, 46399, 46401, 46436
ReliOn Ultima Blood Glucose Test Strips
45358, 45369, 45377, 45379, 45466, 45504, 45511, 45608, 45613, 45641, 45642, 45644, 45672, 45674, 45675, 45676, 45677, 45721, 45734, 45736, 45739, 45742, 45743, 45789, 45790, 45800, 45801, 45840, 45841, 45849, 45850, 46008, 46009, 46061, 46067, 46069, 46072, 46103, 46105, 46148, 46201, 46202, 46214, 46215, 46232, 46313, 46332, 46336, 46338, 46341, 46368
MediSense Optium Blood Glucose Test Strips
45001A159, 45001A195, 45001A228, 45001A233, 45001A236, 45001A243, 45001A247, 45001A249, 45001A250, 45001A255, 45001A279, 45001A285, 45001A295, 45001A298, 45001A306, 45001A317, 45001A318, 45001A327, 45001A346, 45001A398, 45001A449, 45001A469, 45001A578, 45001A693, 45001A697, 45001A747, 45001A790, 45001A795, 45001A839, 45001A917
Optium Blood Glucose Test Strips
45001A484, 45001A486, 45001A512, 45001A514, 45001A517, 45001A519, 45001A527, 45001A541, 45001A544, 45001A552, 45001A558, 45001A564, 45001A572, 45001A598, 45001A665, 45001A677, 45001A709, 45001A713, 45001A732, 45001A771, 45001A819, 45001A852 45455, 45516, 45708, 45709, 45737, 45738, 45777, 45778, 45783
Precision Xceed Pro Blood Glucose Test Strips
44535H, 44545H, 44565H, 445A5H, 44645H, 44665H, 446E5H, 44725H, 44755H, 44925H, 44945H, 44945H, 44975H, 44995H, 449A5H, 44A15H, 44A35H, 44A75H, 44A85H, 44C65H, 44C75H, 44CE5H, 44CH5H, 44CP5H, 44CR5H, 45025H, 45035H, 450A5H, 450C5H
Precision Point of Care Blood Glucose Test Strips
45515, 45517, 45701, 45791, 45963, 45964, 46367
Precision Xtra Blood Glucose Test Strips
45001A330, 45001A467, 45001A481, 45001A482, 45001A483, 45001A487, 45001A488, 45001A496, 45001A497, 45001A499, 45001A500, 45001A503, 45001A505, 45001A506, 45001A510, 45001A511, 45001A513, 45001A519, 45001A520, 45001A521, 45001A530, 45001A532, 45001A534, 45001A536, 45001A537, 45001A545, 45001A556, 45001A565, 45001A566, 45001A568, 45001A573, 45001A577, 45001A584, 45001A594, 45001A595, 45001A597, 45001A605, 45001A607, 45001A608, 45001A609, 45001A613, 45001A614, 45001A626, 45001A634, 45001A637, 45001A641, 45001A644, 45001A645, 45001A656, 45001A660, 45001A664, 45001A669, 45001A670, 45001A671, 45001A677, 45001A678, 45001A682, 45001A685, 45001A694, 45001A700, 45001A705, 45001A706, 45001A707, 45001A709, 45001A712, 45001A730, 45001A732, 45001A739, 45001A742, 45001A744,

45001A751, 45001A753, 45001A757, 45001A762, 45001A777, 45001A778, 45001A786, 45001A788, 45001A790, 45001A798, 45001A806, 45001A814, 45001A815, 45001A816, 45001A820, 45001A840, 45001A842, 45001A847, 45001A852, 45001A856, 45001A860, 45001A861, 45001A872, 45001A876, 45001A882, 45001A910, 45001A912, 45001A914, 45001A918, 45001A920, 45001A921, 45001A940, 45001A947, 45001A948, 45001A949, 45001A971, 45001A976, 45001A979, 45001A982, 45001A983, 45001C008, 45001C011, 45001C012 45384, 45388, 45396, 45407, 45418, 45455, 45456, 45463, 45464, 45512, 45514, 45516, 45521, 45611, 45612, 45614, 45619, 45627, 45632, 45639, 45645, 45646, 45653, 45670, 45679, 45680, 45682, 45707, 45708, 45724, 45729, 45731, 45732, 45733, 45735, 45737, 45738, 45755, 45777, 45782, 45783, 45784

Precision Xtra Blood Glucose & Ketone Monitoring System

01P107D, 01P128D, 01P139D, 02P140D, 01P153D, 02P201D, 02P223D, 02P229D, 03P107D, 03P155D, 03P158D, 03P194D, 03P209D, 03P222D, 03P223D, 03P242D, 04P154D, 04P194D, 04P201D, 04P315D, 05P106D, 05P107D, 05P127D, 05P130D, 05P138D, 05P139D, 05P140D, 05P152D, 05P201D, 06P180D, 06P322D, 07P141D, 08P106D, 08P138D, 08P279D, 09P106D, 09P140D

Precision G3b Smartblue Blood Glucose Test Strips

45001A710

MediSense Optium Blood Glucose Electrodes

45001A133, 45001A137, 45001A226, 45001A252, 45001A257, 45001A277, 45001A285, 45001A817, 45001A835, 45001A921, 45001C001