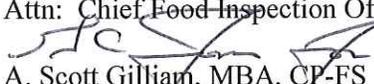




Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 29, 2013
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: 
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Nova Diabetes Care Recall [Drug]

SUGGESTED ACTION: Unclassified Recall; 21 lots of the Nova Max Glucose Test Strips distributed both in the USA and outside the continental USA. The company has recently determined that some of the blood glucose test strips contained within the indicated Nova Max Glucose Test Strip lots and Nova Max Plus glucose meter kits may report a false, abnormally high blood glucose result; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. Upon identifying the issue, Nova Diabetes Care promptly notified all registered users, health care professionals, pharmacies, and distributors where the Nova Max Glucose Test Strip and Nova Max Plus glucose meter kit are recommended or sold. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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.

Voluntary Recall of Specified Lots of Nova Max® Glucose Test Strips

Contact

Consumer:
1-800-681-7390



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

Media:

Paul MacDonald

781-647-3700

pmacdonald@novabio.com

FOR IMMEDIATE RELEASE - July 26, 2013 - Nova Diabetes Care today announced it is initiating a voluntary recall of 21 lots of the Nova Max Glucose Test Strips distributed both in the USA and outside the continental USA. Nova Max® Plus™ glucose meter kits that include test strips from the recalled lots are also included in this voluntary recall.

The company has recently determined that some of the blood glucose test strips contained within the indicated Nova Max Glucose Test Strip lots and Nova Max Plus glucose meter kits may report a false, abnormally high blood glucose result. **Those who use, recommend clinically, or sell Nova Max Glucose Test Strips for blood glucose testing should immediately discontinue using or distributing glucose test strips from the recalled lots (see attached list).**

A false abnormally high blood glucose result could, under certain conditions, result in an insulin dosing error that could lead to a serious health risk requiring immediate medical attention.

Customers can check to confirm if they have blood glucose test strips from the affected lots on the **attached list**, by visiting www.novacares.com/news/nova-max-recall.php¹ or by contacting Nova Diabetes Care customer service at 1-800-681-7390.

No other product or lot number from Nova Diabetes Care is impacted by this recall. Customers can contact Nova Diabetes Care customer service at 1-800-681-7390 to replace their affected test strip lot or meter kit at no charge.

Customers may continue to test blood glucose using any other Nova Max Glucose Test Strip lot not indicated as part of this recall while waiting for their replacement to arrive.

In the event that a customer must use affected test strips from the indicated lots above while waiting for replacement product to arrive, Nova Diabetes Care recommends customers take the following precautions:

1. As stated in the Blood Glucose Monitor Owners Guide and Nova Max Glucose Test Strip Product Insert, customers should perform a quality control solution test to confirm that the vial of Nova Max Glucose Test Strips is working correctly. Customers should not use a test strip vial if control solution results are not within the expected range.
2. Customers should verify all elevated blood glucose test results that are not consistent with their diabetes history by repeating the test using a new blood glucose test strip from a different vial (if available) or the same vial (if a new vial is unavailable).
3. Customers should contact their health care provider immediately if their reported blood glucose result(s) are not consistent with their diabetes history, how they feel, or if they think their results are not accurate (higher than expected).

4. Customers should never ignore symptoms or make significant changes to their diabetes management program without speaking to their health care professional.

People with Diabetes should be aware of symptoms of high blood sugar (hyperglycemia) and low blood sugar (hypoglycemia). Customers should contact their healthcare professional for advice on how to treat the symptoms noted below.

- Symptoms of high blood sugar include excessive thirst, excessive urination, blurred vision, weakness, nausea, vomiting, and abdominal pain.
- Symptoms of low blood sugar include trembling, excessive sweating, weakness, hunger, confusion, and headache. Some individuals may experience no symptoms before experiencing unconsciousness or seizures. It is important to treat low blood sugars promptly to avoid loss of consciousness or seizure.

Upon identifying the issue, Nova Diabetes Care promptly notified all registered users, health care professionals, pharmacies, and distributors where the Nova Max Glucose Test Strip and Nova Max Plus glucose meter kit are recommended or sold.

Nova Diabetes Care has reported this situation to the U.S. Food and Drug Administration and has taken the necessary corrective actions to prevent this situation from recurring.

Nova Diabetes Care remains committed to providing patients and health care professionals with the highest quality products and services. We apologize for any inconvenience this issue may cause. Thank you for your continued support of Nova Diabetes Care products.

For more information, visit www.novacares.com/news/nova-max-recall.php² or contact Nova Diabetes Care customer service at 1-800-681-7390.

Nova Max Test Strip Recalled Lots

Test Strip Lot Number
1020211346
1020411347
1020611348
1020811350
1020211355
1020212032
1020512087
1020212100
1020212101
1020212153
1020712206
1020212207
1020412255
1020212291
1020912292

1020412341
1020213043
1020213074
1020213109

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