**\*\*URGENT\*\***

***MEDICAL DEVICE CORRECTION***



1825 NW Vivion Road

## Riverside MO 64150

Dear Valued Customer: December 13, 2019

**URGENT: Accu-Chek Aviva Plus Test Strips**

***\*\*\*RETURN THIS LETTER, WHETHER OR NOT YOU HAVE ANY AFFECTED PRODUCT ON HAND\*\*\****

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description** | **NDC** | **LOT NUMBER** | **YES, I have**  **product to dispose of** | **NO, I do not have product to dispose of** |
| Accu-Chek Aviva Plus Test Strips 50ea | 65702040710 | 498315 |  |  |
| Accu-Chek Aviva Plus Health Network Strips | 65702043810 | 497864 | ***NOT STOCKED BY PBA HEALTH*** | |

Roche Diabetes Care has initiated an Urgent Medical Device Correction of the above lots of **Accu-Chek Aviva Plus Test Strips**. Roche received customer feedback where test strips from these lots could not be dosed as intended. The customer may experience this as blood application not detected, test strip defective, E-4 + Drop symbol flashing, M-54, and E-54 errors. The test strips consist of several material layers. During the manufacturing process, one of the layers was not assembled correctly, resulting in the inability to dose the test strips. Inability to dose test strips may result in a temporary inability to get a result that could lead to a delay in treatment and/or therapy decisions. To date, no adverse health events have been reported for this issue.

This notification is being made with the knowledge of the Food and Drug Administration and extends to the **Consumer Level.** Please examine your inventory and dispose of the lots referenced in this notice.

**PATIENT INSTRUCTIONS**

Please inform any patients who may have received the affected lots to visit <https://notices.accu-chek.com> to request replacement product at no charge for affected lots. Patients may call 1-800-358-4866 with questions.

If you purchased this product from the PBA Health Distribution Center, please fill in the quantity you have disposed of and sign below. The signed letter may be faxed to your PBA Health Customer Service Representative at

1-877-535-3803. For questions, please contact the Accu-Chek Customer Care line at 1-800-358-4866 Monday through Friday 8:00 am through 8:00 pm EST.

Pharmacy Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Account #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sincerely,

*The Recall team at PBA HEALTH*