Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

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PBM-2018-03 **MAY 18, 2018**

ITEM: **Accu-Chek Aviva Plus Health Network Strips Urgent Medical Device Correction**

SPECIFIC INCIDENT(S): Roche issued an Urgent Medical Device Correction recommending that patients discard select lots of Accu-Chek® Aviva Plus test strips due to a potential for error and seek replacement by contacting the manufacturer directly. The manufacturer has not issued a recall for these items.

GENERAL INFORMATION:

- Roche has identified four test strip lots that are out of specification. However, there is only 1 impacted lot number pertinent to VA that was awarded under solicitation. (The other lots affected were distributed in retail outlets.)
- Affected test strips show an increased potential for:
  - strip errors prior to applying a blood sample, or
  - strips not detected once inserted, or
  - an inaccurate result, which may not be detectable.
- The affected strips had cracked reagent, which may lead to the issues described above.
- Affected lot pertinent to VA is listed below:

Description	Lot #	Exp Date	NDC	UPC	Catalogue #
Accu-Chek Aviva Plus Health Network Strips	497296	04/30/2019	65702-0438-10	3-65702-438-10-1	06908349001

- To date, the manufacturer has not received any reports of adverse events related to this issue.
- This alert is an extension of the product sequestration actions in **Product Recall Office Log #13075** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of Accu-Chek Aviva Plus Health Network Strips by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm, or by mail).
- VA Pharmacy is working to identify Veterans who may have gotten the defective strips, and those patients will be contacted.

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, endocrinology**

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staff, and pharmacy staff, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.

- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 6/1/2018):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home use. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
  - If an affected lot(s) was dispensed to patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home use by letter.
      - Manufacturer's patient letter with instructions for product replacement directly from Roche can be found at: https://www.accu-chek.com/sites/g/files/iut341/f/UMDC-18-002.pdf
      - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%_20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template._doc .
      - This template can be altered according to site-specific needs and to accommodate the manufacturer's instructions on how patients can order replacement product directly from the manufacturer.
    - Provide patient(s) who have received the affected product with instruction on the following:
      - How to locate and check the product's lot number.
      - How to obtain new supply of product from the manufacturer.
      - Patients should not continue to use the affected product until they obtain replacement product.
      - When the correct product is received from the manufacturer, patients should begin using the new product.
  - Communicate to PBM/VAMedSAFE that letters have been sent to all impacted patients via the VHA Alerts and Recalls Website: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html.

SOURCE: Manufacturer

REFERENCE(S):

1. Roche Urgent Medical Device Correction [Data on file, Date 5/09/18]. Roche Urgent Medical Device Correction Notice 18-002, written communication, Roche Diabetes Care, Inc. May 07, 2018.
2. Roche Urgent Medical Device Correction [Data on file, Date 5/09/18]. Roche Urgent Medical Device Correction Letter regarding Federal Supply Schedule Contract – Notice of Urgent Medical Device Correction, written communication, Bradley T. Moore, President, Roche Diabetes Care, Inc. May 08, 2018.

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.