TP-00438
10/08/18

URGENT MEDICAL DEVICE CORRECTION

CoaguChek® Patients

Update: CoaguChek XS PT Test for Patient Self-Testing Use
– Important Information About Your Test Strips
– Additional Affected Test Strip Lots

Issue

You are receiving this document because records indicate that you were shipped CoaguChek XS PT test strips on or after January 1, 2018 for home testing use. This document provides important information regarding your INR test results. **Please read this entire document.**

Although you may have received a prior communication regarding this issue, this update lists additional affected CoaguChek XS PT test strip lot numbers that were not previously available for shipment.

Roche Diagnostics, the manufacturer of CoaguChek meters and test strips, recently calibrated the CoaguChek test strips to provide INR test results that correspond to the latest industry standards. Since this calibration, Roche Diagnostics has been informed of patients experiencing abnormally high INR test results when testing with the affected CoaguChek test strips listed in the table on page two of this document.

As a result of an internal investigation, Roche Diagnostics recommends you follow the additional instructions outlined on the following pages of this communication until new batches of test strips are available.

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over...

☑ CoaguChek XS PST
☑ CoaguChek Vantus

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USA
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Issue, continued

The additional instructions outlined in this communication apply to the test strip lot numbers listed below:

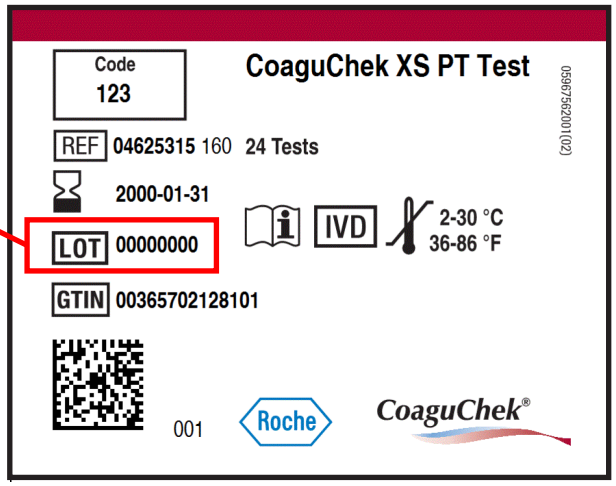
Product	Catalog Number	Affected Lot Numbers (only valid up to 4.5 INR)	Expiration Date
CoaguChek® XS PT Test, 6 Tests	04625374160	28124121	06/30/2019
		28631921	06/30/2019
		28631924	06/30/2019
		28632021	06/30/2019
		29415123	07/30/2019
		29494221	10/31/2019
		29778721	09/30/2019
		30497423	10/31/2019
		31404821	10/31/2019
		32264421*	12/31/2019
		33046321*	01/31/2020
		33046322*	01/31/2020
		33449723*	01/31/2020

* Indicates a new affected lot number.

How to Identify an Affected Lot

The lot number is printed on the test strip vial label. See the picture below for an example of the location of the lot number on the test strip vial.

Location of Lot Number on the Test Strip Vial



What Does This Mean to Me as a CoaguChek® Patient?

If you are currently testing with CoaguChek XS PT test strips from the lot numbers listed on the previous page, we recommend the following:

- Always follow your healthcare professional's instructions.
- Your CoaguChek meter and the CoaguChek XS PT test strips from the lots listed on the previous page are approved for continued use; however, you should do the following:
  - Any INR test result received above an INR of 4.5 on a CoaguChek meter should be confirmed with another testing method. Immediately contact your physician to request instructions for obtaining a confirmatory test.
  - Work with your physician to determine if any changes are necessary to your testing until your results return to within your therapeutic range.
- Continue to report the CoaguChek INR test results as you normally would (e.g., report results to your IDTF service provider).

Future Test Strip Lot Numbers

In the near future, Roche Diagnostics will have new batches of test strips available that have been re-calibrated to address the potential for abnormally high INR test results caused by this calibration issue. These re-calibrated test strips will work in the CoaguChek meter that you already have. For test strip lot number 33449900 and higher, report the INR test result as you normally would and follow the directions given by your healthcare provider.

Actions Required

- Follow the instructions outlined in the *What Does This Mean to Me as a CoaguChek Patient* section of this communication.
- If you receive test results you feel are not accurate with a CoaguChek product, please report this to Roche Diagnostics Point-of-Care Technical Service at 1-800-428-4674.
- Keep this document for future reference.

Questions

Please contact Roche Diagnostics Point-of-Care Technical Service, 24 hours a day, seven days a week at 1-800-428-4674 if you have questions about the information contained in this document.

This action is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Events Reporting Program: Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or call FDA 1-800-FDA-1088.