URGENT NOTICE

TYPE: Class I Recall

Roche Warfarin Test Strips for INR Monitoring.

Drug Name: **CoaguChek XS PT Test Strips**

Audience: Patients and Healthcare Professionals

Date: **11/07/2018**

ISSUE

Roche Diagnostics, the manufacturer of CoaguChek meters and test strips, is recalling the CoaguChek XS PT Test Strips due to inaccurate INR test results, when compared to laboratory results. Roche re-calibrated the CoaguChek XS PT Test Strips in January 2018 to correspond to a newly released INR International Standard. Since this re-calibration, Roche Diagnostics has received reports of patients experiencing abnormally high or inaccurate INR test results when testing with the affected CoaguChek XS PT Test Strips listed below.

Use of affected products may increase the risk of serious adverse health consequences, including death.

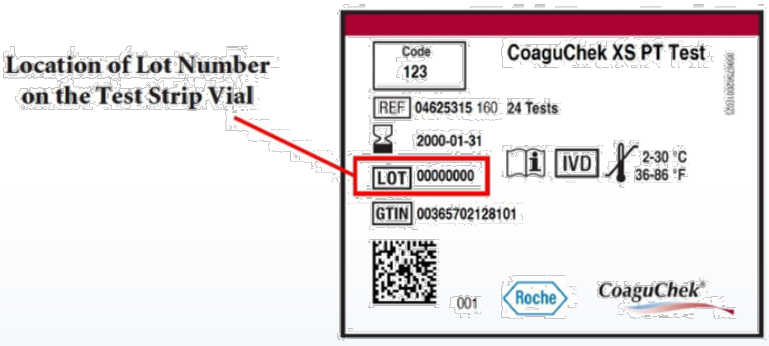
LOT NUMBERS:

28124111, 28124121, 28631911, 28631921, 28631924, 28632021, 28632213, 28632312, 28632412, 29415113, 29415123, 29494221, 29494312, 29494613, 29494711, 29778721, 29779012, 29779213, 29779214, 30497213, 30497311, 30497413, 30497423, 30497515, 31404314, 31404821, 32264116, 32264212, 32264316, 32264317, 32264411, 32264421, 33045913, 33046011, 33046113, 33046312, 33046314, 33046321, 33046322, 33449612, 33449712, 33449723, 33449817

Models: CoaguChek XS PT Test 2x24 Strips, CoaguChek XS PT Test 6 Strips, CoaguChek XS Test 24 Tests USA

Manufacturing and Distribution Dates: January 12, 2018 – October 29, 2018

The lot number is printed on the test strip label, which is applied to the test strip box and the test strip vial.



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WHO MAY BE AFFECTED

All patients who have been prescribed the blood thinner warfarin (also known by the brand names Coumadin and Jantoven) to prevent and treat blood clots.

Patients with the following conditions are at especially high risk for serious events associated with inaccurate INR measurements:

- Mechanical heart valve
- Atrial fibrillation and high-risk CHA2DS2-VASc scores
- Recent thromboembolic events

RECOMMENDATION

Patients and healthcare providers should switch to new batches of test strips that are calibrated to the previous international standard, which Roche Diagnostics will provide to customers within one month. Patients should also contact their patient self-testing service providers to find out when they will be receiving corrected test strips.

Patients who are using CoaguChek meters and CoaguChek XS PT Test Strips affected by the recall should contact their healthcare provider and patient self-testing service providers immediately to determine alternative test methods and address questions regarding their testing schedule.

Patients should consult with their healthcare provider before making any changes to their warfarin dose. Healthcare providers and patients with questions may contact Roche Diagnostics at 1-800-428-4674 to learn more details about the recall.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

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