Roche Diagnostics Recalls CoaguChek® XS PT Test Strips Due t… Inaccurate INR Test Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Product

- Name and Version: CoaguChek XS PT Test Strips
- 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
- Devices Recalled in the U.S.: More than 1.1 million packages

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

Device Use

CoaguChek XS PT Test Strips are used with Roche INR Test Meters to monitor patient response to warfarin, a blood thinner prescribed to prevent and treat blood clots. The test strip is inserted into the test meter, and then a medical pricking needle (a lancet) is used to obtain blood which is applied to the test strip. The meter reads the test strip, measures how long it takes the blood to clot, and provides the result based on a standardized calculation in the form of the International Normalized Ratio, or INR. The INR is used by patients and physicians to determine if warfarin dosing is appropriate.

Reason for Recall

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 in the table below.

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

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 CHA_2DS_2-VASc scores
- Recent thromboembolic events

What to Do

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

Contact Information

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