Roche Diagnostics – Recall of CoaguChek® XS PT Test Strips

- On November 5, 2018, Roche announced a consumer-level recall of some lots of CoaguChek XS PT test strips because some patients have been experiencing inaccurately high International Normalized Ratio (INR) test results due to a re-calibration of the test strips due to a different international standard.

- The recall involved more than 1.1 million packages of CoaguChek XS PT test strips that were distributed nationwide from January 12, 2018 to October 29, 2018.

Product Description	Catalog Number	Lot #s
CoaguChek XS PT Test 2x24 Strips	04625315160	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
CoaguChek XS PT Test, 6 Strips	04625374160	
CoaguChek XS Tests USA	07797826160	

- CoaguChek XS PT test strips are used with CoaguChek XS plus, CoaguChek XS Pro, CoaguChek XS professional, CoaguChek XS PST, and CoaguChek Vantus meters to monitor INR levels for patients that require long-term warfarin therapy, have certain types of heart arrhythmias, a heart valve, or have some other condition that requires INR monitoring.

    — INR monitoring with a CoaguChek meter may be done in office by a healthcare provider or at home by the patient or caregiver.

- The FDA warns that the recalled test strips may provide results that are higher than the actual INR, resulting in the prescribing of an insufficient warfarin dose or an interruption of warfarin therapy, which may increase the risk for dangerous blood clots.

    — Approximately 90 medical device reports and two serious patient injuries involving strokes were reported to the FDA.

- Incorrect INR results are of particular concern for individuals at an increased risk of blood clots including those with mechanical heart valves, atrial fibrillation who are at a high risk of stroke, or

Continued . . .

those who had a recent blood clot. It is important to note that problems with the CoaguChek XS PT test strips are not likely to be evident to the patient.

- The FDA is warning patients and healthcare professionals that they should not rely on CoaguChek meters to monitor warfarin levels if they are using recalled test strips. Instead, they should have blood drawn from a vein and have their levels measured by a laboratory test or use an alternative meter device.

- Roche instructs healthcare providers and self-testing patients to stop use and discard any remaining supply of recalled CoaguChek XS PT Test strips.

- Roche will replace recalled CoaguChek XS PT test strip lots with new, unaffected test strips.

    — There are new batches of CoaguChek XS PT test strips available that have been calibrated to the previously used International Reference Preparation (IRP) rTF/09 standard to address the potential for inaccurately high INR test results.

- Patients who are using CoaguChek meters should contact their healthcare provider to get information about alternative test methods and to address questions regarding their individual testing schedule.

- Patients should also contact their patient self-testing service providers to find out when they will be getting their corrected test strips.

- Contact Roche Diagnostics Point of Care Technical Service at **1-800-428-4674** for more information about this recall.