Generic Name:
Test strips
Trade Name:
CoaguChek XS PT Test Strips
Company:
Roche Diagnostics, Terrific Care/Medex Supply
Notes:

FDA is warning that CoaguChek XS PT Test Strips used with CoaguChek test meter devices to monitor warfarin levels may provide results that are higher than the actual INR and should not be relied upon to adjust the drug dosage. As a result of incorrect INR results, some patients may be prescribed an insufficient warfarin dose or be instructed to interrupt warfarin use. This may increase the risk for dangerous blood clots.

FDA classified this action as a Class I recall, the most serious type of recall, which means use of these devices may cause serious injuries or death.

This recall is related to the November 2018 Roche Diagnostics recall, which is still in effect and involved more than 1.1 million packages that were distributed nationwide from January 12, 2018, to October 29, 2018.

The test strips were manufactured by Roche but distributed by Terrific Care/Medex Supply. They include catalog numbers that were not in the previous Roche recall because the strips were not labeled or authorized for sale in the United States and were only distributed by Roche outside the country. Terrific Care/Medex Supply purchased the Roche test strips from an unknown source and imported and sold them in the United States.

Incorrect INR results are of particular concern for individuals at an increased risk of blood clots, including those with mechanical heart valves, those with atrial fibrillation who are at high risk of stroke, or 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 test strips are used with the CoaguChek XS plus, CoaguChek XS Pro, CoaguChek XS professional, CoaguChek XS PST, and CoaguChek Vantus test meter devices.

Patients and health care providers who are using CoaguChek meters should immediately stop using test strips purchased from Terrific Care/Medex Supply and use an alternative test method.

All health care providers, patients, and caregivers are strongly encouraged to voluntarily report INR test meter problems directly to FDA through MedWatch. Problems should be reported whenever one suspects that there may be an issue with an INR test meter such as a malfunction or incorrect result, or that the meter caused or contributed to a serious injury or death.

FDA said it will provide updates related to this recall when they are available.

Medication Monitor Categories:
Alerts and Recalls