

# Expanded recall of warfarin level monitoring test strips

February 5 2019

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(HealthDay)—Certain lots of Roche Diagnostics test strips should not be

used with CoaguChek test meter devices to check levels of the blood thinner warfarin because patients may get inaccurate results and be at risk for serious injury or death, the U.S. Food and Drug Administration says in an updated recall notice.

Last November, Roche recalled more than 1.1 million packages of CoaguChek XS PT Test Strips that were distributed across the United States from Jan. 12, 2018, to Oct. 29, 2018. Last month, medical product distributor Terrific Care/Medex Supply LLC issued a voluntary recall of certain Roche Diagnostics test strip lots used with CoaguChek, the FDA said.

The CoaguChek XS PT Test Strips announced in the latest recall were made by Roche but distributed by Terrific Care/Medex Supply, and they were not included in the recent Roche recall because these strips were not labeled or authorized for sale in the United States. They were only distributed by Roche Diagnostics outside the country. Terrific Care/Medex Supply bought the Roche test strips from an unknown source and imported and sold them in the United States, the FDA said.

"Monitoring [warfarin](#) dosing is a critical part of using the drug properly to prevent and treat blood clots. Using faulty strips can lead to errors in medication dosage that could cause serious harm or death in some patients," FDA Commissioner Scott Gottlieb, M.D., said in an agency news release. "That's why it's so concerning that this distributor continued to sell these test strips in the United States even though domestic sales had been stopped due to safety concerns. To reduce risks to patients, we're warning [health care providers](#) and the public about the dangers associated with this product."

**More information:** [More Information](#)

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