

Alere Home Monitoring

November 6, 2018

Dear Alere Home Monitoring Customer,

Roche Diagnostics, the manufacturer of the CoaguChek® INR monitor and test strips, has issued an Urgent Medical Device Recall (UMDR) indicating they will be replacing all CoaguChek XS PT Test Strips in the chart below. Further, they advise patients to STOP USING and DISCARD any CoaguChek XS PT test strips from affected lots.

Product	Catalog Number	Affected Lot Numbers	Expiration Date
CoaguChek® XS PT Test, 6 Strips	04625374160	28124121	06/30/2019
		28631921	06/30/2019
		28631924	06/30/2019
		28632021	06/30/2019
		29415123	07/31/2019
		29494221	07/31/2019
		29778721	09/30/2019
		30497423	10/31/2019
		31404821	10/31/2019
		32264421	12/31/2019
		33046321	01/31/2020
		33046322	01/31/2020
		33449723	01/31/2020

In response, Alere Home Monitoring will be proactively shipping a vial of 6 replacement strips to all patients beginning Monday, November 5th.

While you wait for your replacement strips:

- **Contact your physician for a testing plan until you receive the new strips**
- **Stop using test strips if they are from the affected lots**

If you have already received your shipment of replacement strips, please contact your physician to confirm your testing plan.

Roche Diagnostics has communicated that the new replacement test strips are not impacted by the Urgent Medical Device Recall (UMDR) and can be used without the need for confirmatory measurements with a laboratory method. Please continue to follow your physician's advice regarding your testing schedule.

Your experience is very important to us and we want to let you know that if you have any questions or concerns, please feel free to contact our Customer Service team at 1-866-918-8768. Thank you for choosing Alere Home Monitoring as your INR monitoring partner. We appreciate the opportunity to serve you.

Warm regards,
Alere Home Monitoring