



**URGENT MEDICAL DEVICE RECALL
AMENDMENT**

CoaguChek® Patients

**CoaguChek XS PT Test Strips for Patient Self-Testing Use
- Stop Using Affected Test Strips
- Unaffected Test Strips Now Available**

This notification supplements previous Urgent Medical Device Correction (UMDC) communications issued by Roche Diagnostics on September 12, 2018 and October 17, 2018.

Introduction

Roche Diagnostics will be proactively replacing all CoaguChek XS PT Test Strips. You will receive replacement test strips from your self-testing service provider.

The affected CoaguChek XS PT Test Strips are used with the CoaguChek XS PST and CoaguChek Vantus patient self-testing point-of-care meters.

Issue

Roche Diagnostics recently calibrated the CoaguChek XS PT Test Strips to the most recent International Normalized Ratio (INR) Standard. Since calibrating to this new standard, Roche Diagnostics has been informed of patients experiencing inaccurately high INR test results when testing with the affected lots of CoaguChek XS PT Test Strips listed in the table on the next page.

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**Roche Diagnostics
Corporation**

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<input checked="" type="checkbox"/> CoaguChek XS PST
<input checked="" type="checkbox"/> CoaguChek Vantus

Issue, continued

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



CAUTION

Stop using and discard any affected CoaguChek® XS PT Test Strips listed above.



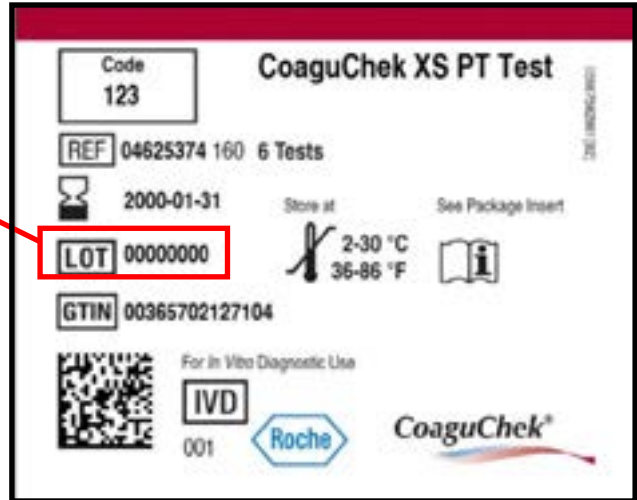
NOTE

If you have any questions regarding your testing, please contact your healthcare provider.

How to Identify the Lot Number

As a reminder, the lot number is printed on the test strip vial label. See the picture below for an example of the location of the lot number on the test strip vial.

Location of Lot Number on the Test Strip Vial



New Unaffected CoaguChek® XS PT Test Strips Available

New, unaffected CoaguChek XS PT test strips are now available and are included in this shipment. Test strips starting with the lot number below do not require testing with another method. Report your INR test results as you normally would and follow the directions given by your healthcare provider.

Product	Catalog Number	Lot Numbers of New Unaffected Strips
CoaguChek XS PT Test, 6 Strips	04625374160	33449900 and higher

Actions Required

- Stop using and discard any CoaguChek XS PT Test Strips listed on page two (2) of this communication.
- Start using the new CoaguChek XS PT Test Strips (lot number 33449900 and higher) included in this shipment. Report your INR test result as you normally would and follow the directions given by your healthcare provider.
- If you have any questions regarding your testing, please contact your healthcare provider.

Questions

Please contact Roche Diagnostics Point-of-Care Technical Service, 24 hours a day, seven days a week at 1-800-428-4674 if you have questions about the information contained in this document.

This action is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Adverse reactions or quality problems experienced with the use of this product may be reported to Roche Diagnostics Point-of-Care Technical Service at 1-800-428-4674 and the FDA's MedWatch Adverse Events Reporting Program either online, by regular mail, or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

COAGUCHEK is a trademark of Roche.