TP-00454
11/05/18

URGENT MEDICAL DEVICE RECALL AMENDMENT

Healthcare Professionals and Clinics Furnishing PT/INR Test Strips to Patients for Home Testing Use

CoaguChek® XS PT Test Strips for Professional and 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 September 17, 2018.

Introduction

Roche Diagnostics will be proactively replacing all affected CoaguChek XS PT Test Strips (refer to the table below).

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 below.

Product	Catalog Number	Affected Lot Number Range
CoaguChek XS PT Test 2x24 Strips	04625315160	27216700 through 33449899
CoaguChek XS PT Test, 6 Strips	04625374160	
CoaguChek XS Test 24 Tests USA	07797826160	

CAUTION

Stop using and discard your remaining supply of affected CoaguChek XS PT Test Strips listed above. Please advise your self-testing patients to do the same.

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☑ CoaguChek XS Plus
☑ CoaguChek XS Pro
☑ CoaguChek XS Professional
☑ CoaguChek Vantus
☑ CoaguChek XS PST

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New Unaffected Lots of CoaguChek® XS PT Test Strips Available

New CoaguChek XS PT test strips are now available that do not require testing with another method. Refer to the table below for new unaffected lots of CoaguChek XS PT Test Strips.

Product	Catalog Number	Unaffected Strips Lot Numbers
CoaguChek XS PT Test 2x24 Strips	04625315160	33449900 and higher
CoaguChek XS PT Test, 6 Strips	04625374160	
CoaguChek XS Test 24 Test USA	07797826160	

Test strips starting with the above lot number have been calibrated to the previously used International Reference Preparation (IRP) rTF/09 standard to address the potential for inaccurately high INR test results. These lots and subsequent CoaguChek XS PT Test Strip lots shipped by Roche Diagnostics are unaffected by the prior Urgent Medical Device Corrections (UMDCs) related to this issue.

Replacement Product

Roche Diagnostics will replace affected CoaguChek XS PT Test strip lots that are in your inventory with new, unaffected test strips. Please do not return product to distributor for replacement.

To request replacement of affected lots of CoaguChek XS PT Test strips, complete whichever of the following two forms is included with this communication:

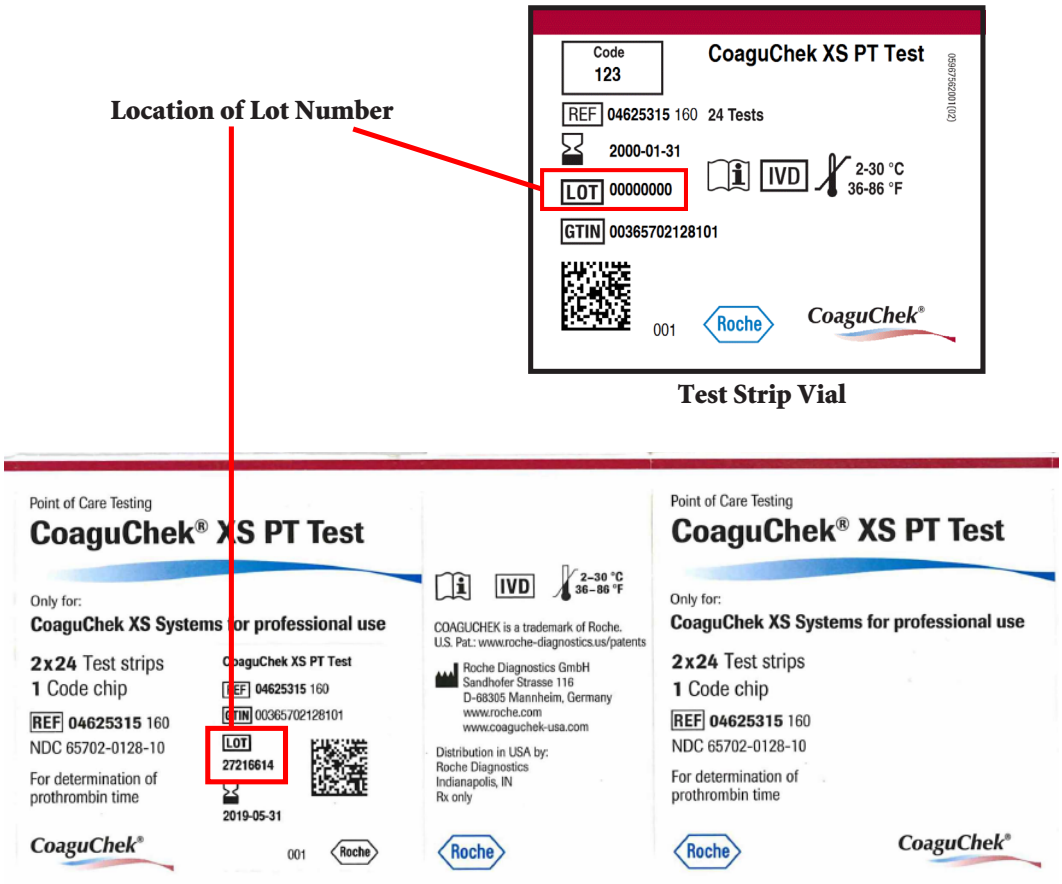
- TP-00460, Fax form for Healthcare Professionals and Clinics Furnishing PT/INR Test Strips to Patients for Home Testing Use, **OR**
- TP-00480, Product Replacement Form

By signing one of these forms, you will confirm the count of affected product in your inventory for which you are requesting replacement, and agree that affected product will be discarded and not sold or distributed to customers or other third parties. Fax your completed, signed form to 1-888-627-2279 or email it to roche3866@stericycle.com.

For clinics that furnish CoaguChek test strips to their patients for home testing use, please include on fax form TP-00460 the number of affected CoaguChek XS PT Test, 6 strips (catalog number 04625374160) that you need to replace your patients' supply.

How to Identify the Lot Number

Refer to the pictures below for an example of the location of the lot number on the test strip box and test strip vial.



Test Strip Vial

Test Strip Box

Enclosures

- TP-00453, Urgent Medical Device Recall Amendment for CoaguChek Patients (enclosed only for HCPs who receive test strips directly from Roche)
- TP-00460, Fax form for Healthcare Professionals and Clinics Furnishing PT/INR Test Strips to Patients for Home Testing Use, **OR**
- TP-00480 Product Replacement Form

Actions Required

- Stop using and discard your remaining supply of affected strips (lot numbers 27216700 through 33449899) per your local regulations. Please advise your patient self-testers to do the same.
- For replacement of **affected** test strips currently in your inventory, complete fax form TP-00460 **OR** Product Replacement Form TP-00480 (depending on which of the two forms was enclosed with this communication). For clinics that furnish CoaguChek test strips to their patients for home testing use, include the number of **affected** CoaguChek XS PT Test, 6 strips (catalog number 04625374160) that you need to replace your patients' supply on fax form TP-00460. **If you did not receive any fax form, please disregard this action**.
- When using CoaguChek XS PT Test Strips lot number 33449900 and higher, confirmation lab tests will no longer be required.
- If you furnish CoaguChek XS PT Test Strips directly to your patients for their self-testing use, distribute a copy of the enclosed Urgent Medical Device Recall Amendment for CoaguChek Patients, TP-00453 to your self-testing patients with their new test strip shipment. You can also find a copy of TP-00453 on coaguchek-usa.com.
- If you do not furnish CoaguChek XS PT Test Strips directly to your patients for their self-testing use, you may distribute a copy of the enclosed Urgent Medical Device Recall Amendment for CoaguChek Patients, TP-00453 to your self-testing patients at your discretion. You can also find a copy of TP-00453 on coaguchek-usa.com.
- Provide copies of this Urgent Medical Device Recall Amendment (TP-00454) and if enclosed Urgent Medical Device Recall Amendment for CoaguChek Patients (TP-00453) to other clinicians who may need to be aware of this information and the availability of new, unaffected test strips. You can also find a copy of TP-00453 on coaguchek-usa.com.
- If your facility has distributed the affected product to another site, please ensure this Urgent Medical Device Recall Amendment (TP-00454) is provided to that site.
- Complete all sections of the enclosed fax form (TP-00460) even if you are not requesting replacement product and fax it to 1-888-627-2279 or email it to roche3866@stericycle.com. **If you did not receive TP-00460 with this communication, disregard this action**.

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.