TP-00374
09/12/18

URGENT MEDICAL DEVICE CORRECTION

Healthcare Professionals

CoaguChek® XS PT Test for Professional and Patient Self-Testing Use — Alternate Testing Recommended for INR Values Above 4.5

Issue

The issue described in this Urgent Medical Device Correction (UMDC) applies to CoaguChek XS PT test strips that are used with all CoaguChek professional and patient self-testing instruments. Roche Diagnostics, the manufacturer of CoaguChek meters and test strips, has calibrated CoaguChek XS PT test strips to the latest World Health Organization International Reference Preparation (rTF/16). The previous International Reference Preparation (IRP) was rTF/09.

Since this calibration, Roche Diagnostics has been informed by some customers of abnormally high INR test results with the test strip lots listed in the table below.

In the near future, Roche Diagnostics will be providing new batches of test strips that have been re-calibrated to the previously used IRP rTF/09. This is being done to return CoaguChek systems to the performance expected by our customers. This communication provides additional instructions to follow until new test strips are available from Roche Diagnostics:

> Any INR test result received above an INR of 4.5 on a CoaguChek meter needs to be confirmed with another testing method (e.g., lab test). We recommend increasing the frequency of monitoring for these patients until their results fall below 4.5 INR.

The following test strip lot numbers are impacted:

Product	Catalog Numbers	Affected Lot Number Range (only valid up to 4.5 INR)
CoaguChek XS PT Test 2X24 Strips	04625315160	27216700 through 33449899
CoaguChek XS PT Test 6 Strips	04625374160	
CoaguChek XS Test 24 Tests USA	07797826160	

The lot number is printed on the test strip label, which is applied to the test strip box and the test strip vial at manufacturing. See the pictures on the following page for an example of the location of the lot number on the test strip box and test strip vial.

over...

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

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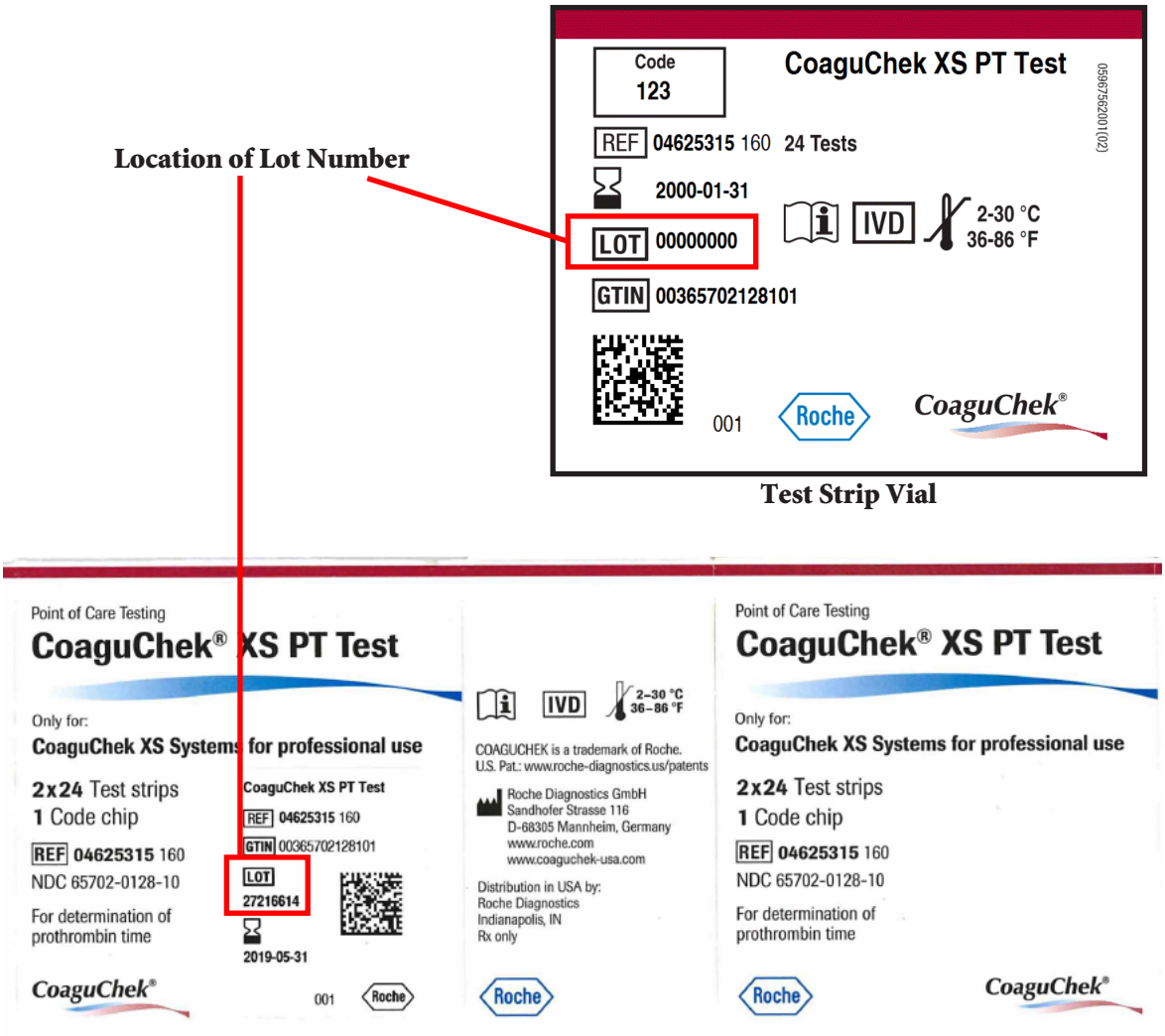
Issue, continued



Test Strip Vial

Test Strip Box

Clinical Significance

Patients under VKA (Warfarin) therapy who receive inaccurate INR test results above their therapeutic range may be at risk for inappropriate therapeutic measures such as withholding of VKA or unnecessary administration of vitamin K.

Patients with inaccurately high INR results might be monitored less frequently because the expected time to return to therapeutic range might be overestimated. Medical guidelines recommend increased frequency of testing of patients with INRs above the therapeutic range until the INR returns to therapeutic range.

As indicated in the CoaguChek XS PT Test method sheet, differences in reagents, instruments, and pre-analytical variables can affect prothrombin time results. These factors should be considered when comparing different prothrombin time test methods. Experience comparing results obtained using the CoaguChek XS System to those obtained using common clinical laboratory reagents shows that the CoaguChek XS System correlates well with the following clinical laboratory reagent: Dade Innovin. Other clinical laboratory reagents may not consistently correlate with the CoaguChek XS System.

A medical risk cannot entirely be excluded.

Actions for CoaguChek® Test Strip Affected Lots

In order to mitigate risk to patients, we ask you to take the following actions related to affected lots:

1. Health Care Professionals using one of the affected lots in their physician's office or hospital coagulation clinic:
   - Values ≤4.5 INR: Values are valid and can be used without lab comparison.
   - Values >4.5 INR: Until new test strips are available from Roche Diagnostics, for patients measuring a value above 4.5 INR with a CoaguChek meter, a comparable measurement with a laboratory method or with unaffected CoaguChek test strips is necessary. We recommend increasing the frequency of monitoring for these patients until their results fall below 4.5 INR.

2. Be advised that patients performing self-testing with affected CoaguChek test strips are being instructed as follows via UMDC TP-00373:
   - Values >4.5 INR: Until new test strips are available from Roche Diagnostics, for patients measuring a value above 4.5 INR with a CoaguChek meter, a comparable measurement with a laboratory method is necessary.
   - Patients should work with their prescribing physician to determine if any changes are necessary to their testing until their results return to within their therapeutic range.
   - Patients should continue to report the CoaguChek INR test results as they normally would (e.g., report results to their IDTF service provider).

Service providers (e.g., IDTFs) which furnish CoaguChek test strips to patients for home testing use are being notified of this situation and have been advised to notify their patients. We have enclosed a copy of the CoaguChek Patient UMDC (TP-00373) which you may distribute to your self-testing patients at your discretion. This document is also available on the www.coaguchek-usa.com website.

Future Test Strip Lot Numbers

In the near future, Roche Diagnostics will be providing new batches of test strips that have been re-calibrated to the previously used IRP rTF/09. This is being done to return CoaguChek systems to the performance expected by our customers. For test strip lot number 33449900 and higher, confirmation lab tests will no longer be required for INR results >4.5 as described in this UMDC.

Once these lots are available, Roche Diagnostics will mail an additional communication to inform our customers and distributors.

Enclosures

- CoaguChek Patients UMDC, TP-00373
- Faxback form, TP-00379

Actions Required

- For the affected lots listed in this UMDC, for patients measuring a value above 4.5 INR with a CoaguChek® meter, a comparable measurement with a laboratory method or with unaffected CoaguChek test strips is necessary. We recommend increasing the frequency of monitoring for these patients until their results fall below 4.5 INR.
- For test strip lot number 33449900 and higher, confirmation lab tests will no longer be required for INR results >4.5 as described in this UMDC.
- We have enclosed a copy of the CoaguChek Patients UMDC (TP-00373), which you may distribute to your self-testing patients at your discretion.
- Provide copies of this UMDC and the enclosed CoaguChek Patients UMDC (TP-00373) to other clinicians who may need to be aware of this issue.
- If your facility has distributed the affected product to another site, please ensure this UMDC is provided to that site.
- Complete all sections of the enclosed faxback form and fax it to 1-888-714-5070 or email it to Roche3364@stericycle.com.
- The information in this UMDC supersedes Analyzer Bulletin TP-00300 (dated 07/06/18); please discard Analyzer Bulletin TP-00300.
- File this UMDC and the enclosed CoaguChek Patients UMDC for future reference.

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 UMDC.

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

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Events Reporting Program: Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or call FDA 1-800-FDA-1088.