



URGENT MEDICAL DEVICE CORRECTION

06-266
10/19/06

Attention: Health Care Professional

CoaguChek® PT Test Strips – Potential for Erroneous Test Results Due to Insufficient Thromboplastin in the Test Strip

Issue

Roche Diagnostics has confirmed the potential for random falsely high INR test results with the test strips listed below. To date, the company has confirmed one incident and its internal investigation suggests that a small percentage of strips may be affected.

Affected Product	Catalog No.	Lot No.
CoaguChek PT Test Strips	3116247	All lot numbers
CoaguChek PST Test Strips	3116239	All lot numbers

Clinical Significance

If one of the test strips is affected by this problem, it can result in either a “Test Error” message displayed on the meter or a positive bias of the patient’s test result without a “Test Error” message being displayed. If the test results are biased, the amount of the bias cannot be predicted although it will always be a positive bias.

Because of our concerns that the patient self-testers may not be able to conduct and interpret duplicate test results, we are instructing them to discontinue use of, and discard, the test strips. We recommend that you follow-up with your patients to ensure that they have done this. Please instruct patients to keep their meter for future use.

You may continue to use the CoaguChek PT test strips within your facility; however, to reduce the risk of inaccurate results, you must perform duplicate tests on each patient as described in “Duplicate Testing” section below.

Please consult with the physician or pathologist at your facility to determine specific clinical implications for your patients.

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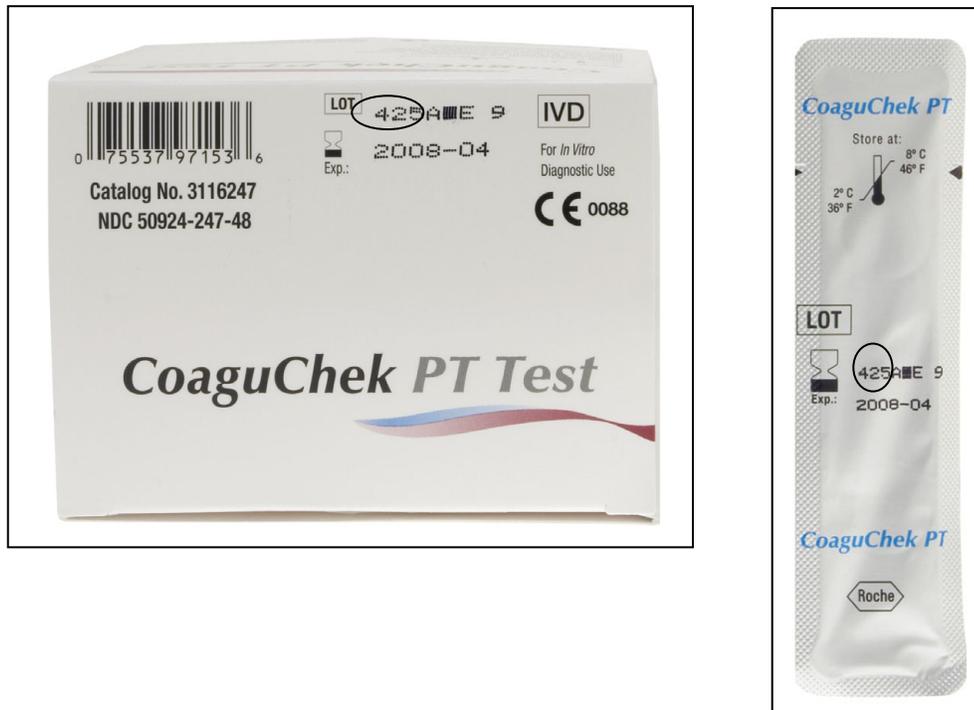
Root Cause

A falsely high INR test result can occur due to insufficient active ingredient (thromboplastin) in the test strip. Our investigation has revealed a root cause of this issue and we are working to correct the situation. While in most cases, strips with this reduced amount of thromboplastin give “test error” messages, in some cases erroneous test results can occur.

Duplicate Testing

You may continue to use the CoaguChek PT test strips within your facility; however, to reduce the risk of inaccurate results, follow the information provided below until further notice.

- You must perform INR testing for each patient in duplicate using CoaguChek PT test strips from two different lot numbers (see enclosure for “Tips For Duplicate Testing”).



The lot number is the first three numbers following the word “LOT,” as circled in the pictures above.

- If you do not have different lot numbers, please contact your medical supply distributor for additional lots. Be sure to provide your current lot number when requesting additional lots.
- A patient’s duplicate test results should be within 0.4 INR for values less than or equal to 2.0 and within 30% for INR values greater than 2.0. All patient test results should be based on a single lot of test strips; the second lot is for confirmation purposes.
- If test results are not within these limits, do not initiate patient treatment until you confirm the test result with an alternate method. Prior to any additional testing, contact Roche Diagnostics Point of Care Technical Service at 1-800-820-0995 for further instructions and to report this discrepancy.
- Do not distribute any CoaguChek PT Test Strips to your patients for self-testing.
- Instruct your patients performing self-testing to immediately discontinue use of and discard these test strips.
- Make sure that all locations and testing personnel are aware of this situation.
- File this urgent medical device correction for future reference.

Note: Always follow package insert instructions to avoid erroneous test results or test errors from other causes.

Questions

If you have questions regarding the information contained in this Urgent Medical Device Correction, please contact Roche Diagnostics Point of Care Technical Service at 1-800-820-0995.

This correction is being conducted in cooperation with the Food and Drug Administration (FDA).

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail to [MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

CoaguChek is a trademark of Roche.