URGENT PRODUCT RECALL: UPDATE

03-194
09/30/03

Diagnostics

CoaguChek™ PT Test Strips – Potential for Erroneous Patient Results Due to Packaging Issue with Test Strips

Issue

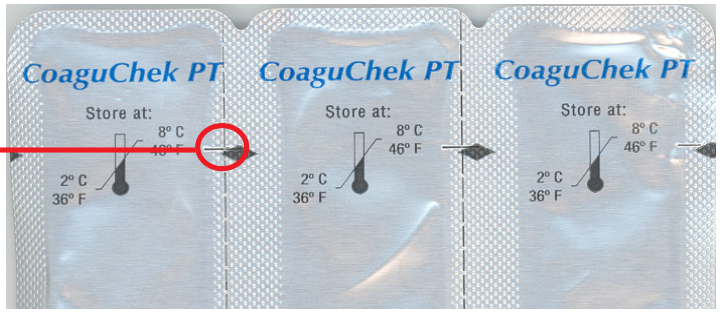
Roche Diagnostics recently notified you of the potential for erroneous patient results or "Test Error" readings with CoaguChek PT test strips, catalog number 3116247, lot numbers 591 and 619. Upon investigation of this issue, it was determined that the CoaguChek PT test strip foil pouches were misaligned during manufacturing, causing the "easy-open" notch (located on the side of the pouch) to be moved so that it cuts into the sealed portion of the foil pouch. This misalignment can allow moisture and air to enter the pouch, potentially leading to problems with the test strips.

Warning

Roche Diagnostics has now determined that all lot numbers of catalog numbers 3116247 (professional use) and 3116239 (patient self testers) with a lot number prior to 669 may be affected by this issue. You may continue to use the CoaguChek PT test strips; however, to ensure accurate CoaguChek PT test strip results, please follow the information provided below for all lots prior to lot number 669:

- ***You must inspect each test strip foil pouch before use to make sure the pouch is sealed properly, regardless of the lot number.***
- ***If a foil pouch appears to be bad, do not use any of the strips from that box and open a new box for use.***
- ***Even when you visually inspect each pouch you may not be able to determine if the pouches are affected; therefore, you must run each patient sample twice using two different CoaguChek PT test strips as noted below.***
  - ***A patient's duplicate test results should be within ± 1.0 INR of each other for values less than 4.5 INR.***
  - ***For results that are less than 4.5 INR, but greater than ± 1.0 INR between each other, or greater than 4.5 INR, consult with the physician or pathologist at your facility to determine specific clinical implications for your patients.***
- ***If at any time you obtain suspicious results, retest the patient sample with a strip from another box or consult with the physician or pathologist at your facility.***

This is an example of an affected pouch. Please note the ***incorrect*** *placement of the "easy open" notch. The printed diamond should not be used as an indicator of the defect.*



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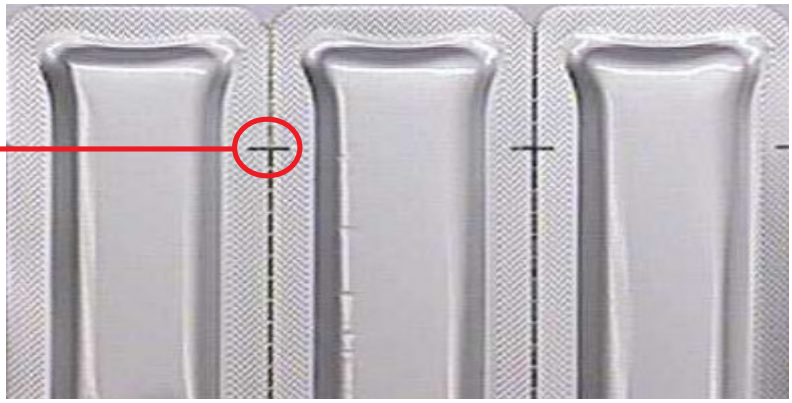
Issue, cont.

This is an example of the back side of an acceptable pouch. Please note the ***correct*** *placement of the "easy open" notch.*



Clinical Significance

Warning

The false results can be either higher or lower than they should be and will vary from sample to sample. In some cases, a "Test Error" reading may be obtained, but this will not always occur.

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

Any unexpected result should always be followed up with appropriate studies and inquiries to define the cause of the unusual result. Patient medication should never be changed without confirming the accuracy of results.

Precautions

The seal of the CoaguChek PT test strip foil pouch is very important to ensure accurate results. You must inspect each test strip foil pouch before use to verify that it has a good seal, regardless of the lot number. Pouches that look like they have a good seal may still be used, but you must still run each patient sample twice using two different CoaguChek PT test strips. The overall estimated defect rate is currently calculated to be extremely low. If the foil pouch appears to be bad, do not use any of the strips from that box and open a new box for use. Please contact Point of Care Technical Service at 1-800-428-4674 if you have any pouches that are defective.

NOTE

As stated in the CoaguChek PT test strip package insert, unusual results can also be attributed to the following:

- The expiration date on the control has passed.
- It has been more than four minutes since you opened the pouch.
- The foil pouch was stored in an area that was too hot.
- The foil pouch does not have an airtight seal or has a hole in it.
- The monitor has not been cleaned or serviced as it should have been.

Product Replacement for CoaguChek PT Test Strips

Roche Diagnostics is taking corrective actions to eliminate this problem with future lot numbers. However, even with the new lots, this product is sensitive to moisture and you should always inspect each foil pouch before use to verify pouch integrity, regardless of the lot number. To receive replacement product for any boxes of CoaguChek PT test strips that contain bad pouches, please contact Point of Care Technical Service at 1-800-428-4674. Beginning with CoaguChek PT test strip lot number 669, you will no longer be required to perform duplicate testing with each patient sample.

Actions Required

- **You must inspect each test strip foil pouch before use to make sure the pouch is sealed properly, regardless of the lot number.** If the foil pouch appears to be bad, do not use any of the strips from that box and open a new box for use. Please contact Point of Care Technical Service at 1-800-428-4674 if you have any pouches that appear to be bad.
- **Even when you visually inspect each pouch you may not be able to determine if the pouches are affected; therefore, you must run each patient sample twice using two different CoaguChek PT test strips.**
- **Consult with the physician or pathologist at your facility to determine specific clinical implications for your patients.**
- Make sure all testing locations and personnel at your facility are aware of this situation.
- To receive replacement product for boxes of bad test strips in your inventory, please contact Point of Care Technical Service at 1-800-428-4674.
- File this Urgent Product Recall Update for future reference.

Questions

We apologize for any inconvenience this situation may cause. This Urgent Product Recall Update is being made with the knowledge of the Food and Drug Administration (FDA). If you have further questions about the information contained in this Urgent Product Recall Update, please contact Point of Care Technical Service at 1-800-428-4674, 24 hours a day, 365 days a year.