



URGENT RECALL

03-195
09/30/03

Product Alert Update On Your CoaguChek™ PT Test Strips

Issue

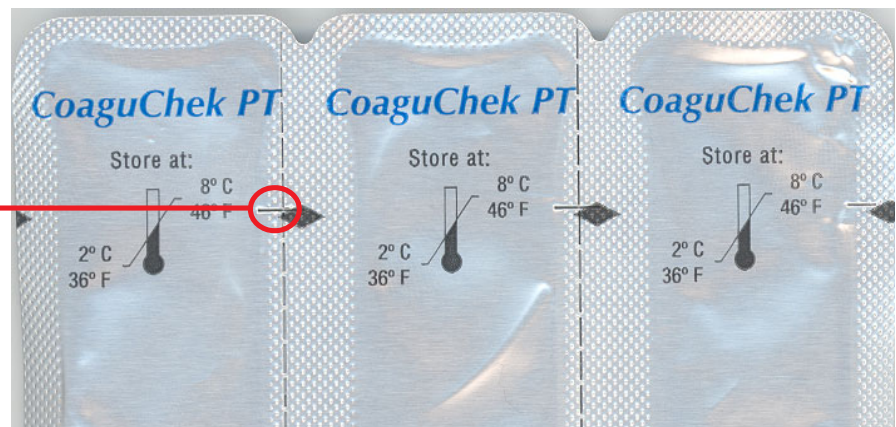
Roche Diagnostics recently notified you of the potential for erroneous patient results or “Test Error” readings with CoaguChek PT test strips, catalog number 3116247, lot numbers 591 and 619. We now know that some of the pouches were not properly cut by the machine. Because of this, the “easy-open” notch on the side of the pouch cuts into the seal of the pouch. This will let moisture into the pouch and ruin the test strips.



Roche Diagnostics has now determined that all lot numbers of catalog numbers 3116247 (professional use) and 3116239 (patient self testers) with a lot number before 669 may have this problem. You may continue to use the CoaguChek PT test strips; however, to be sure that your CoaguChek PT test strip results are correct, please follow the steps provided below for all lots before lot number 669:

- **It is important that your pouch has a good seal. You must look at each pouch before you use the test strips to make sure the “easy open” notch is in the correct position. The pictures below will help you.**
- **The line in the middle with the circle around it is the “easy-open” notch to help you open the pouch.**
- **If the notch cuts into the part of the pouch with the test strip in it, do not use any of the test strips from that box. Get another box of test strips before doing your next test.**
- **Pouches that look like the “easy open” notch is in the correct position can be used, but you must run two tests to be sure the seal was good. This is to compare the two results in case there was a defect that you could not see.**
- **If your two test results are within 1.0 INR, you can trust this result. If your two test results are not within 1.0 INR, are higher than 4.5 INR, or are outside of the range provided by your doctor, call your doctor.**

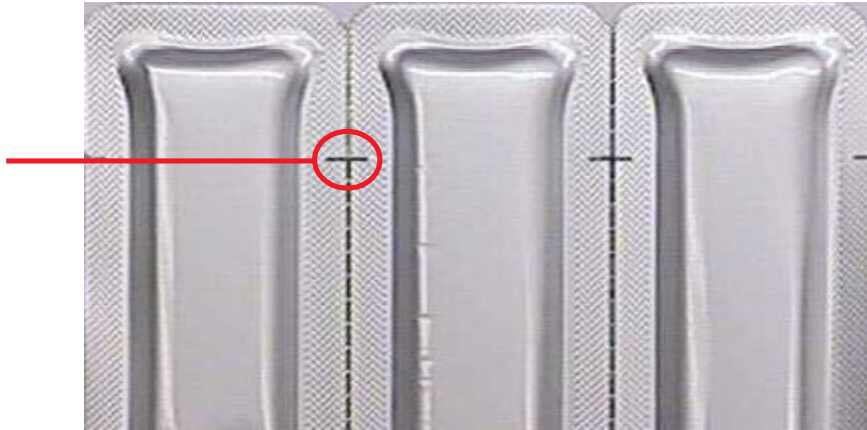
This is an example of an affected pouch. Please note the **incorrect** placement of the “easy open” notch. The printed diamond should not be used as an indicator of the defect.



over...

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.

Please tell your doctor about this problem with the test strip pouches because it could affect your treatment.

Precautions _____

An airtight seal on the CoaguChek PT test strip foil pouch is very important. You must inspect each test strip foil pouch before each use to make sure the “easy open” notch is in the correct position. Pouches that look like the “easy open” notch is in the correct position can be used, but you must run two tests to be sure the seal was good. If the notch cuts into the part of the pouch with the strip in it, do not use any of the test strips from the box that contained the bad pouch and get a new box of CoaguChek PT test strips before you do any testing. Please call Point of Care Technical Service at 1-800-428-4674 if you see any bad pouches.



NOTE

As stated in the CoaguChek PT test strip package instructions, you should not trust your results in the following cases:

- 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.
- You did not mix the control solution well.
- You did not follow test instructions.
- The monitor has not been cleaned or serviced as it should have been.

If you do have an unexpected result, please contact your doctor.

Product Correction for CoaguChek PT Test Strips

Roche Diagnostics is fixing the problem for new lot numbers, but it will be a few weeks before these lots are available. Even with the new lots, you should inspect each foil pouch before you use the test strip to make sure they are airtight, just in case the pouch is damaged in some way. 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

- **Review this information carefully.**
- **Share this Product Alert Update with your doctor.**
- It is important that your pouch has a good seal. You must look at each pouch before you use the test strips to make sure the “easy open” notch is in the correct position.
- If the notch cuts into the part of the pouch with the test strip in it, do not use any of the test strips from that whole box. Get another box of test strips before doing your next test.
- Pouches that look like the “easy open” notch is in the correct position can be used, but you must run two tests to be sure the seal was good. This is to compare the two results in case there was a defect that you could not see.
- If your two test results are within 1.0 INR, you can trust this result. If your two test results are not within 1.0 INR, are higher than 4.5 INR, or are outside of the range provided by your doctor, call your doctor.
- File this Product Alert Update for future reference.

Questions

We apologize for any inconvenience this situation may cause. This Product Alert 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 Product Alert Update, please contact Point of Care Technical Service at 1-800-428-4674, 24 hours a day, 365 days a year.

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