CoaguChek XS PT Test

Place the meter on a flat surface (like a table or counter top) and hold it roughly horizontal so that it will provide accurate results during testing. Vibrations or other movement can result in an error message.

Step 1: Getting a good drop of blood
Increasing the blood flow in the finger will help you get a good drop of blood.

1. Press the lancet firmly onto your finger to create a blood droplet and then stop pressing it.
2. Place the test strip into the meter’s test site. The meter will display the result.

Step 2: Confirming the test result

1. The meter will display the result when the test is complete. The result will remain on the display for 30 seconds.
2. Record the result.
3. Dispose of the used lancet and test strip according to local waste disposal regulations.

Step 3: Repeating the test

1. If the result is not within the normal range, repeat the test according to the directions on the test strip.
2. Record all results and any changes in patient’s condition.

Example of expected performance

- Sensitivity: 0.8 U/mL
- Specificity: 0.974
- Accuracy: 1.034

Calibration

- The CoaguChek XS Meter uses a photo-optical method to test the patient’s blood for prothrombin time.
- The result is displayed in seconds, which is the time it takes for the patient’s blood to clot.

Factors affecting prothrombin time

- Hematocrit
- Platelet count
- Temperature
- Drugs (e.g., warfarin, aspirin, heparin)
- Other medical conditions (e.g., liver disease, renal failure)

Testing performed with the following in vitro spiked samples or native blood samples were compared to standard test results for CoaguChek XS PT Test:

- Biplubin up to 30 mg/dL
- Lipemic samples containing up to 50 mg/dL of triglycerides
- Hemolysis up to 1000 mg/dL
- Heparin concentrations up to 0.8 U/mL
- Low molecular weight heparin (LMWH) up to 2 IU anti-factor Xa activity/mL
- Dipyrismid up to 20 mg/dL
- Fondaparinux up to 5 mg/dL

Note: Samples of patients treated with protease cannot be tested with this system.

- The presence of anti-phospholipid antibodies (APAs) such as LUPUS antibodies (LA) can potentially lead to prolonged clotting times, i.e., elevated INR values. A comparison to an APA-instructive laboratory method is recommended if the INR is known or suspected.

- When measuring “ERROR 4” Sporadically occurring “ERROR 4” are generally due to an interaction of the system state safety mechanisms that are designed to prevent the release of wrong measurement results. However, in rare cases, “ERROR 4” may be received by patients under normal conditions leading to extremely high coagulation times (10 × INR, < 1.5 δ), e.g., treatment with warfarin (vitamin K antagonists) in combination with anticoagulants and/or antiplatelet medications.

- The meter should be checked immediately after changing the test strip. If an error message appears when the test is repeated, the result must be checked using another method.

- The results obtained cannot be used for the determination or the assessment of a therapy with factor II or factor X antagonists.

Expected results

- The CoaguChek XS Meter displays test results in units equivalent to laboratory blood plasma measurements. Results may be displayed in the International Normalized Ratio (INR) or the CoaguChek XS PT Test. A unit used most often in Europe by healthcare professionals in Europe.

Other factors affecting prothrombin time

- Diet
- Alcohol
- Physical activity

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Additional information
The CoaguChek XS System User Manual contains more information. If you still have questions, call Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to 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/forms.htm) by mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787 or fax (1-800-FDA-0178).

Return policy
If there is a problem with the CoaguChek XS PT Test Strips, you may be asked to return them, along with the test strip code chip, to Roche Diagnostics. Before returning, call Roche Diagnostics Technical Service Center at 1-800-428-4674. You will be mailed a return authorization label which must be placed on the shipping carton.

References

Symbols
Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

FOR US CUSTOMERS ONLY: LIMITED WARRANTY
Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

Customer Service
Roche Diagnostics GmbH
Sandhöfer Strasse 115
85607 Munich
www.roche.com

Roche Diagnostics
3002 Sandhofer Strasse
Mannheim, Germany

Roche Diagnostics US
Customer Service: 1-800-428-4674
www.coaguchek-usa.com

Additional information for customers
If you have questions about Roche products, please call the appropriate number provided in the Roche Diagnostics customer service directory. If you have questions about the CoaguChek XS PT Test Strips, please call 1-800-428-4674.

Quality control
CoaguChek XS PT Test Strips include quality control functions integrated into the meter and test strips, so you do not have to run quality control tests with liquid quality controls. The meter automatically runs its own quality control test as part of every blood test. For more information about the built-in quality control functions, see the CoaguChek XS System User Manual.