CoaguChek XS PT Test

Sample Collection and Preparation

The devices below apply to collecting a fresh sample from a healthy donor. Only healthy donors should be enrolled in your Laboratory Performance Evaluation (LPE) program to ensure the samples are suitable for testing. A personal blood donor may also be used. The CoaguChek XS PT Test kit includes self-contained test strips and a hand-held meter. A test strip and meter are needed for each test.

Procedure

1. Close the container tightly.
2. Wipe the test strip clean with a dry cloth. Allow the patient's finger to dry completely before performing the fingerstick.
3. Perform a fingerstick.
4. Apply 1 drop of blood to the top or side of the target area. You must apply blood to the target area.
5. An hourglass appears as the meter warms up, which takes about 30 seconds.
6. Use the lancet to perform a fingerstick.
7. Use the lancet to perform a fingerstick.
8. Apply 1 drop of blood to the top or side of the target area. You must apply blood to the target area.
9. 10. The result appears in about 1 minute. Record the result.
10. Properly dispose of the used lancet and test strip.
11. If the numbers are different, make sure you are using the correct code chip in the meter. The 3-number code on the test strip contains the information needed to check the code chip.
12. Record the result.
13. If you need to redo a test, use a new lancet, a new test strip, and a different finger.
14. If the result does not match the clinical symptoms, repeat the patient test to rule out a procedural error.
15. Also, changes in the patient's diet can cause unusually low or high results. If you are not sure why the result is different, check the patient's diet.
16. If you are new to the CoaguChek XS System, watch the CoaguChek XS System Video.
17. 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 trend must not be used.
18. If the result is lower than expected, contact your healthcare provider.
19. The physician must determine the best INR level depending on the reason for the test (based on the patient's condition). The INR value depends on the patient's condition. The INR value is determined by the physician. The INR value is determined by the physician.
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The following U.S. patents have been granted or are pending for the CoaguChek XS System (meter and test strips): 6,662,439; 7,073,246; 2005/0103624; 6,881,378; 6,207,000; 2005/0214171; 2005/0123441; 6,645,368; 2004/0157339; 2005/0129574; 2005/0135968

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Accuracy: 700 capillary samples were collected from 357 outpatients at three ex-
ternal sites. Venous plasma samples were measured on a Sysmex Analyzer with Dade Innovin (ISI = 1.02). The results comparison is as follows:

<table>
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<th>Site</th>
<th>N</th>
<th>Slope</th>
<th>Intercept</th>
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<tr>
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<td>-0.10</td>
<td>0.973</td>
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<td>Site 2</td>
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<td>0.032</td>
<td>0.971</td>
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</tbody>
</table>

Precision: Whole blood precision was determined for venous and capillary blood. Eleven sample duplicate collections of three sites. The following charts represent whole blood precision for venous and capillary blood.

Whole Blood Precision for Venous Blood

Whole Blood Precision for Capillary Blood

Precision: Whole blood precision was determined for venous and capillary blood. Eleven sample duplicate collections of three sites. The following charts represent whole blood precision for venous and capillary blood.

Back in Controls and Diagnostics

The CoaguChek XS System has quality control functions integrated into the meter. The meter automatically compares each test result to a series of quality control. The meter automatically confirms its accuracy control test as part of each test. A capillary blood sample is drawn from the single-use quality control, run on the CoaguChek XS System using the manual. The comparison is as follows:

References

1. Moll, S and Ortel, TL. “Metering Warfarin Therapy in Patients with Lupus Anticoagu-
2. Loeliger EA, van den Besselaar AMHP and Lewis SM., “Reliability and Clinical
Impact of the Normalization of the Prothrombin Times in Oral Anticoagulant Control.”

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 put on the shipping carton.

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.

Limited Warranty

Roche Diagnostics warrants that your CoaguChek XS PT test strips will be free from defects in material and manufacture for the period of the time stated in your CoaguChek XS PT Test Strips Warranty. In the event that there is a defect in material or manufacture, Roche Diagnostics will replace the test strips free of charge. Your sole and exclusive remedy with respect to the defects shall be replacement. Any warranty claims should be directed to the Roche Diagnostics Technical Service Center at 1-800-428-4674.

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EXPIRATION DATE OF THE TEST STRIPS.