Sample Collection and Preparation
The strips must be applied to a clean, dry, and intact finger. Gently press the capillary tube to collect a drop of blood. Before the meter is warmed up, a flashing test strip and blood drop symbol appear in the meter display. If the result does not match the clinical symptoms, repeat the patient test to rule out procedural error.

Storing the Test Strips
These test strips are for use outside the body only. Do not eat the test strips. If for any reason you get an error message and you will have to repeat the test.

1. Insert the meter into the charger. The CoaguChek XS Meter will perform a software test. The meter will display the test result in units equivalent to laboratory units. The meter displays test results in units of International Sensitivity Index (ISI). The meter will display the following text: "Testing performed with the following CoaguChek XS System. A certificate of CLIA waiver is required to perform the test in a waived setting."

Step 1: Getting Ready to Test
CoaguChek XS Meter

1. Insert one test strip to the meter. (See page 12 for instructions to prepare the lancet.)
2. If you are testing strips from a previous, unopened strip pack, you will need to change the code chip that came with the test strip pack and test the code chip to confirm it is functioning correctly. If the meter displays an unusual test result (other than error messages), follow the instructions to confirm that the code chip is functioning correctly before proceeding to test. (See page 14 of CoaguChek XS System User Manual.)
3. The test strip will appear in the meter display for 4 seconds before the meter displays the test result.

Step 2: Testing Blood from a Fingerstick
Getting a Good Drop of Blood
Patients may have different techniques for getting a good drop of blood.

1. While picking up the lancet, it is recommended to pick up the lancet from the bottom (base) to avoid using the cutting edge. When the lancet is inserted into the finger, it should be at a slight angle. The lancet should not be inserted more than 1/8 inch (3 mm) into the skin. After picking up the lancet from the bottom, hold it close to the skin to collect the blood sample. After collecting the blood sample, remove the lancet from the skin and place it back into the lancet pocket or cover the lancet wound with a dry gauze pad. Before inserting the lancet back into the lancet pocket or removing the lancet from the skin, the lancet must be discarded in the trash or medical waste bin.

Procedure
1. Use the lancet to make a small cut on the side of the finger. After the lancet is removed, press firmly with a gauze pad or dry cloth. Before inserting the lancet back into the lancet pocket or removing the lancet from the skin, the lancet must be discarded in the trash or medical waste bin.

2. Gently rub the finger from its base.
3. Inspect the thumb already used. Repeat the procedure if the blood is not coming out. Do not add more blood. Do not touch or remove the test strip when a test is in process. The result appears in about 1 minute. Record the result.

4. Is the correct code chip in the meter? The 3-number code on the test strip container, then press M in the meter display. If this error message appears again when the test is repeated, the result should be checked as performed with a different code chip. Also, changes in the patient's diet can cause unusually low or high results.

5. Lipemic samples containing up to 500 mg/dL of triglycerides

6. The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL.

7. The CoaguChek XS PT Test uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used.

8. The patient's INR must be determined by a coagulation laboratory. The results, as seen in the graph below, represent the performance of the CoaguChek XS PT Test compared to the INRs measured on a Sysmex Analyzer using Dade Innovin (ISI = 1.02). The patient clinical conditions included (number of patients): normal - not on warfarin (62), atrial fibrillation (8), other (13). The INRs measured on a Sysmex Analyzer using Dade Innovin (ISI = 1.02). The patient clinical conditions included (number of patients): normal - not on warfarin (62), atrial fibrillation (8), other (13).

9. The CoaguChek XS PT Test is sensitive to various clotting factors as determined by the presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (1), antithrombin III (1), Protein C (1), Protein S (1), Fibrinolytic inhibitors (2), D-dimer (1), disseminated intravascular coagulation (1), infection (5), other (46).

10. Do not read more than one test strip per meter. The result should be checked as performed with a different code chip. If the result does not match the clinical symptoms, repeat the patient test to rule out procedural error.

11. The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL.

12. When a patient is on intravenous infusion therapy, do not collect sample from arm receiving the infusion line.

13. The CoaguChek XS PT Test uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used.

14. Bilirubin up to 30 mg/dL

15. The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL.

16. When the meter is warmed up, a flashing test strip and blood drop symbol appear in the meter display.
Whole Blood Precision for Venous Blood

- Site 3
- Site 2
- Site 1

Capillary Data:
Analyzer with Dade Innovin (ISI = 1.02) The results comparison is as follows:

<table>
<thead>
<tr>
<th>CoaguChek XS INR</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correlation</td>
<td>0.971</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slope Cl</td>
<td>0.990, 1.023</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>y = 1.006x + 0.032</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
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</table>

Whole blood precision was determined for venous and capillary blood. 700 capillary samples were collected from 357 outpatients at three external sites. Capillary blood samples were assayed on the CoaguChek XS meter with Dade Innovin PT Test Strips. The results comparison is as follows:

<table>
<thead>
<tr>
<th>CoaguChek XS PT Test Strip</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>Slope Cl</td>
<td>0.990, 1.023</td>
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</tr>
<tr>
<td>y = 1.006x + 0.032</td>
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<td></td>
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</tr>
</tbody>
</table>

The CoaguChek XS System has quality control functions integrated into the meter. These functions include daily quality control, weekly quality control, and monthly quality control. The meter automatically runs its quality control test as part of every test procedure. The CoaguChek XS quality control functions are also graphically represented in the CoaguChek XS System User Manual.

References

The CoaguChek XS PT Test Strips shall be replacement. Any warranty claim should be directed to the Roche Diagnostics Technical Service Center at 1-800-428-4674. You will need to return a complete package (including manual and test strips) for replacement. The strips shall be replacement. Any warranty claim should be directed to the Roche Diagnostics Technical Service Center at 1-800-428-4674. You will need to return a complete package (including manual and test strips) for replacement.

Additional Information
The CoaguChek XS System has a built-in quality control function. If you have questions, contact Roche Diagnostics Technical Services Center at 1-800-428-4674, or 1-877-ROCHETEST.

Limited Warranty
Roche Diagnostics warrants that your CoaguChek XS PT Test Strips will be free from defects in material and manufacture and will be in perfect operating condition when shipped to the purchaser. Roche Diagnostics, at its option, will replace the entire lot of the test strips, or replace the test strips free of charge. You have the option of returning the entire lot or replacing the defective test strips. Any warranty claim should be directed to the Roche Diagnostics Technical Service Center at 1-800-428-4674.

The CoaguChek XS System (meter and test strips) is warranted to be free from defects in materials and manufacture until the expiration date printed on the package. The warranty period shall extend for a longer duration than the expiration date of the test strips.


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Manufactured by: Roche Diagnostics GmbH
Distributed in the U.S.A. by: Roche Diagnostics
2117 Robin Road
Indianapolis, IN 46268
www.coaguchek.com
www.roche.com

The following U.S. patents have been granted or are pending for the CoaguChek XS System:

Roche Diagnostics makes no other warranties, express or implied, including but not limited to the implied warranty of merchantability or fitness for a particular purpose in the CoaguChek XS System (meter and test strips). All other uses are strictly prohibited. The CoaguChek XS System is intended for use by trained users in conjunction with the CoaguChek XS PT Test Strips for in vitro diagnostic purposes. Roche Diagnostics makes no other warranties, express or implied, including but not limited to the implied warranty of merchantability or fitness for a particular purpose, in any event.