Keywords: coaguchek, PT/INR

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Appendix A: CoaguChek XS Plus Operator's Manual

Click Here

I. PURPOSE

This procedure provides instruction for performing PT/INR testing using the CoaguChek® XS Plus System with connectivity to Telcor QML. PT/INR is used for monitoring patients undergoing warfarin therapy.

II. ORDER

A physician's order, standard protocol, or order by other health professional authorized to request laboratory test is required for PT/INR testing.

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III. MATERIALS FOR PATIENT TESTING

<table>
<thead>
<tr>
<th>Reagents</th>
<th>Supplies</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek® XS Plus Test Strips and matching code chip</td>
<td>Latex free gloves</td>
<td>CoaguChek® XS Plus Meter</td>
</tr>
<tr>
<td>CoaguChek® XS Plus PT Controls, diluent droppers and quality control code chip provided</td>
<td>JHMI approved biohazard waste container</td>
<td>AC/DC Power Module</td>
</tr>
<tr>
<td></td>
<td>JHH approved Lancets</td>
<td>Coaguchek® XS Plus Handheld Base Unit (pre-configured by the POCT office)</td>
</tr>
<tr>
<td></td>
<td>Alcohol wipes</td>
<td>4 AA batteries</td>
</tr>
<tr>
<td></td>
<td>Sterile gauze</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Super Sani-cloth® Disinfectant wipes</td>
<td></td>
</tr>
</tbody>
</table>

IV. STORAGE AND STABILITY

<table>
<thead>
<tr>
<th>CoaguChek® XS PT Test Strips</th>
<th>CoaguChek® XS PT Controls</th>
<th>CoaguChek® XS Meter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test strips are stored in their container, with the cap closed at Room Temperature or in the refrigerator (2° - 30° C)</td>
<td>Controls are stored in the refrigerator (2° - 8° C)</td>
<td>Ambient operating temperature is 15° - 32° C (59° - 90°F)</td>
</tr>
<tr>
<td>Test strips are stable until the expiration date printed on the strip container.</td>
<td>Unopened vials stored in the refrigerator are good for 18 months or the printed expiration date, whichever comes first.</td>
<td>Protect from damp or humid conditions.</td>
</tr>
<tr>
<td>Reconstituted controls are stable for 30 minutes.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

V. SPECIMEN

A. Sample required is fresh whole blood collected by finger stick.
B. Sample size required is a minimum of 8 µl.
C. Samples with the following characteristics should be discarded immediately, and a fresh whole blood sample should be collected.
   1. Sample contamination with tissue thromboplastin
   2. Sample contamination with indwelling intravenous solutions
   3. Sample contamination with alcohol cleansing solution
   4. Samples with visible clotting or debris accumulation

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VI. PATIENT PREPARATION
   A. Patient identity should be verified using two unique identifiers prior to sample collection and testing.
   B. Refer to GEN002 Capillary Blood Collection for Point-of-Care Testing procedure for specific instructions on sample collection.
   C. Blood sample should not be collected until the instrument display shows a flashing blood drop symbol indicating that the meter is ready to perform the test.

VII. LOGGING ON AND OFF
   1. Power the meter on by pressing the power button for approximately one second. (Alternatively, the meter can be turned on by inserting a test strip.)
   2. Select your operator name from the list on the meter screen.
   3. Enter your assigned password then touch the check mark.
   4. When testing is complete or another operator will use the device touch the LOGOUT button.

VIII. SAFETY PRECAUTIONS
   1. Follow Standard Precautions and CDC hand washing guidelines when performing this test.
   2. All used test strips should be considered as potentially infectious, handled with care and disposed of by following standard waste facility disposal policy.
   3. Disinfect the meter with a Super Sani-Cloth® Germicidal Disposable Wipes or 70% isopropyl alcohol after each patient test.

IX. QUALITY CONTROL
   1. The CoaguChek® XS Plus System has a number of built-in quality control functions. These assess the electronic components of the meter, temperature, strip expiration and lot information. In addition, a two-level quality control test is run with each patient determination.
   2. External Liquid Quality Controls will be run monthly on each meter in use.

X. LIQUID QUALITY CONTROL TEST PROCEDURE
   A. NOTE: Each box of Quality Control contains 4 bottles each of lyophilized Level 1 and Level 2 plus 8 droppers of diluent. All contents of the box are the same lot# and must be used together with the same code chip.
   B. Have at hand:
      1. the test strip container,
      2. the test strip code chip (if using the lot for the first time),
      3. the freeze-dried control plasma,
      4. the dropper for making the control,
      5. the quality control code chip,
      6. a pair of scissors.
   C. Open the lid of the bottle and remove the rubber cap.
   D. Hold the dropper with sealed dropper neck pointing upward, then cut off the end of the cap with scissors. Do not hold the dropper close to your face.
   E. Caution: Hold the dropper by the stem. Do Not squeeze the bulb of the dropper while cutting the tip.
F. Apply gentle pressure to the reservoir to transfer the entire contents of the dropper to the bottle. Make sure that the dropper does not come in contact with the dried control plasma.

G. Close the container again.

H. Keep the dropper at hand for the next steps. Use this dropper for the current level of QC only.

I. Swirl the bottle using a circular motion to completely dissolve all the control plasma inside.

J. Do not shake the bottle or turn it on its side.

K. The control solution is now ready to be applied to the test strip and is stable for 30 minutes after reconstitution.

L. Repeat the above steps for the second vial of QC.

M. Follow steps 1 - 8 of the patient test procedure below.

N. Touch QC TEST.

O. The test strip symbol prompts you to insert a test strip. Remove a test strip from its container and close the container with the stopper.

P. Holding the strip so the lettering is facing upward, slide it into the strip guide as far as it will go in the direction indicated by the arrows.

Q. A beep tone will indicate that the meter has detected the test strip. If code chip icon appears, insert the test strip code chip.

R. If you are using a new control solution, select NEW CODE, remove the code chip from the meter and insert the code chip that came with the control solution. Otherwise, select the code already stored for your current control.

S. Select the quality control level to be run.

T. A dropper symbol flashes to indicate that the meter is ready for the QC sample to be applied. Sample must be applied within 180 seconds.

U. Using the dropper, draw up the dissolved contents of the vial.

V. Apply a single drop of control solution directly from the dropper to the semicircular, transparent sample application area of the test strip. Do not add more control.

W. The result of the QC test is displayed and automatically saved to memory. The acceptable range of results is displayed below the current result. If a QC test fails and up or down arrow is displayed and flashes.

X. Remove the test strip from the measurement chamber.

Y. Dispose of the used test strip and clean the meter, if necessary.

Z. Repeat the process for the next level of QC. When testing is complete, remove the quality control chip from the meter and store it with the controls.

AA. If any result falls outside the acceptable range refer to the procedure steps listed below for corrective action.

AB. When successful with each level of QC, discard the used vial and associated dropper. Do not reuse the dropper for another level of QC or a patient.

AC. When QC is complete, return the meter to the docking station.

AD. Note the appearance of the blinking data transmission symbol.

AE. If any result falls outside the acceptable range refer to the procedure steps listed below for corrective action.

Note: The QC solution contains animal material, which should be considered potentially infectious and should be disposed of as per hospital policy.

XI. LIQUID QUALITY CONTROL CORRECTIVE ACTION

If results fall outside the acceptable range:

1. Check control material and test strip expiration dates
2. Repeat test if still within 30 minutes since reconstitution.
3. If repeat fails, reconstitute a new vial of QC and repeat test.
4. After 2 successive QC failures, discontinue testing and contact POCT office (5-2645) for assistance

XII. PATIENT TEST PROCEDURE

1. Have the test strip container and the associated code chip at hand. If a code chip is already inserted into the meter, make sure that the number matches the number on the label of the test strip container in use.
2. If the code chip needs to be replaced because the code does not match, remove the chip by gently sliding it out of the chip slot.
3. Slide the new code chip into the code chip slot until it snaps into place.
4. Place the meter on a level, vibration-free surface or hold it in your hand roughly horizontal.
5. Turn the meter on by pressing the ON/Off button and holding until the meter turns on. Alternatively, the meter can be turned on by inserting a test strip or connecting the power adaptor.
6. If running the meter without the power adapter, check the battery level. If there are no bars left in the battery symbol, change the batteries before proceeding. Consult the operator’s manual to change the meter batteries.
7. Check that the date and time are correct. Consult the operator’s manual to correct any incorrect entries.
8. If a QC lockout is displayed instead of PATIENT TEST, run liquid quality control before performing a patient test.
9. Touch PATIENT TEST.
10. Enter the Patient ID as the 10-digit CSN (Contact Serial Number). Then press (Check) OK to move to the next screen.
11. The test strip symbol prompts you to insert a test strip. Remove a test strip from its container and close the container with the stopper.
12. Holding the strip upward, slide it into the strip guide as far as it will go in the direction indicated by the arrows.
13. A beep tone will indicate that the meter has detected the test strip. If code chip icon appears, insert the test strip code chip.
14. The hourglass symbol shows that the test strip is warming up. When the warm-up is complete, a beep tone will occur. The blood drip symbol flashes to indicate that the meter is ready to perform the test and is waiting for the blood to be applied. Blood must be applied within 180 seconds.
15. Perform a finger stick as described in procedure GEN002 Capillary Blood Collection for Point-of-Care Testing, wiping away the first drop of blood.
16. Apply the blood directly from the finger to the semicircular, transparent application area of the test strip within 15 seconds of lancing the fingertip. An audible beep tone indicates that enough blood has been applied and the blood drop symbol disappears and the test starts.
   Do not add more blood. Do not touch the test strip until the result is displayed.
17. Remove the test strip from the measurement chamber as indicated by the REMOVE icon displayed on the screen.
18. Dispose of the used lancet and test strip according to waste disposal protocol.
19. Disinfect the meter.
20. Return the meter to the docking station if it has been removed for patient testing.

XIII. REFERENCE/INTERVENTIONAL RANGES

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<th>Reference Range</th>
<th>INR</th>
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<tbody>
<tr>
<td>Reference Range</td>
<td>0.9 - 1.1</td>
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<tr>
<td>Therapeutic: Standard</td>
<td>2.0 - 3.0 **</td>
</tr>
<tr>
<td>Therapeutic: Heart Valve</td>
<td>2.5 - 3.5 **</td>
</tr>
<tr>
<td>Critical Action Value</td>
<td>&gt; 5.0</td>
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**Dependent on physician’s order

XIV. MEASURING RANGE
The CoaguChek® XS Plus System has a measuring range of 0.8 to 8.0.

XV. CRITICAL ACTION VALUE
1. Any INR >= 5.0 is a Critical Action Value.
2. Repeat testing is recommended with a new finger stick on the CoaguChek® or as a venipuncture in the Core Laboratory as per the discretion of the clinic provider.
3. When the operator is also the care provider and is responsible for warfarin dosing, no further communication is required. The following comment is automatically attached to the result: “Performed by authorizing and/or prescribing provider.”
4. If the operator suspects that the initial value is inaccurate due to problematic capillary puncture that result should be canceled and documented as such by the POCT office. Initial values of 5.0 or greater that match the repeat value within +/-2.0 of the core lab value or within 10% of the CoaguChek® repeat are considered to be valid repeats.
5. Discrepant repeats on the CoaguChek® that cannot be explained should be checked a third time by a venipuncture sample sent to the Core lab. When a discrepancy occurs between the Core Laboratory and the CoaguChek®, the Core lab result should be reported.

XVI. RESULTS INTERPRETATION
Test results should be scrutinized in light of a specific patient’s condition and anticoagulant therapy. Any results exhibiting inconsistency with the patient’s clinical status should be repeated or supplemented with additional test data.

Patients who are under treatment with Warfarin in combination with antibiotics and/or chemotherapeutics, which could potentially lead to extremely high coagulation times (>10 INR), may in rare cases receive repeated “ERROR 6” messages instead of an INR value. If the operator suspects this error is occurring due to the described conditions, a sample should be sent to the Core Laboratory for confirmation.
Subject
PT/INR, Prothrombin Time (PT)/INR Test Procedure Using the CoaguChek XS Plus System

XVII. DOCUMENTATION
A. When connectivity is running, all results are transmitted to Telcor QML and Epic when the Coaguchek meter is connected to the docking station.
B. When the meter is connected to the docking station, verify that information is transmitting by the presence of a flashing icon in the lower right of the meter display screen next to the battery icon.
C. During computer system downtime, decisions on the back-up plan will be made based on the anticipated length of the downtime. Patient testing on the Coaguchek can continue during system downtime.

XVIII. METHOD LIMITATIONS
1. Samples with hematocrits less than 25% or greater than 55% may affect the accuracy of the test result and should not be tested on the CoaguChek® XS system.
2. The CoaguChek XS® System should not be used patients being treated with any direct thrombin inhibitors including Hirudin, Lepirudin, Bivalirudin and Argatroban.
3. The presence of anti-phospholipid antibodies (APA’s) such as Lupus antibodies can lead to prolonged clotting times, i.e., elevated INR values. A comparison to an APA-insensitive laboratory method is recommended if the presence of APA’s is known or suspected.
4. As stated in the CLSI document H49-A, “clinically important discrepancies of INR are often observed among different laboratory-based PT test systems as well as point-of-care test systems”.
5. The CoaguChek® XS System PT system is not recommended for use measuring INR values >= 2.9 when heparin is administered simultaneously in doses which yield the plasma concentrations of unfractionated heparin concentrations above 0.8 U/ml and of low molecular weight heparins (LMWH) above 2 IU/ml.
XIX. PROCEDURAL NOTES

A. Always...
   1. Close the container immediately after removing a test strip
   2. Operate the meter at an ambient temperature between 59 °F and 90 °F (15 °C and 32 °C)
   3. Place the meter on a level, stable surface or hold it roughly horizontal
   4. Follow the information on correct handling of test strips in the package insert
   5. Keep the strip guide and housing clean.

B. Never…
   1. Store the meter at extreme temperatures.
   2. Store the meter in damp or humid conditions without protection
   3. Remove or insert the code chip while the meter is performing a test
   4. Use the code chip from a pack other than the one in use.
   5. Touch or remove the test strip during a test.
   6. Wait more than 15 seconds after lancing the fingertip before applying the blood.
   7. Add more blood after the test has begun.
   8. Perform a test with a drop of blood from a previous puncture.

XX. "C" FLAG

A “C” flag displayed next to a result could indicate a very low patient hematocrit (<25%), contamination with alcohol, or the patient's finger was excessively squeezed to obtain the sample, diluting the blood, and resulting in a low hematocrit. The result must be verified with a repeat sample using a different finger, ensuring the patients' hands are both completely dry and the finger is not excessively squeezed after the finger stick. If you still get a “C” flag with the repeat, the result is not accurate and will not transmit to Epic. It is recommended to use a method other than the CoaguChek® system to check the patient's INR value.
XXI. CLEANING

1. Care must be taken to properly clean the meter housing and the test strip guide. Incorrect cleaning with certain cleaning agents or allowing liquid to enter the meter’s housing can result in incorrect operation and possible failure of the system.
   1. Cleaning the meter housing:
      1. Use only a soft lint-free cloth moistened with 70% isopropyl alcohol or ethanol or Super Sani-cloth® Germicidal Disposable Wipes.
      2. Clean the housing daily at the start of each shift, when it becomes visibly soiled and after each patient encounter.
      3. Ensure that the blue test strip guide cover remains tightly closed while cleaning the housing.
      4. Make sure that no liquid enters the meter or accumulates near any opening.
      5. With the meter turned off, clean the outside of the meter with a lightly moistened cloth.
      6. Wipe away residual moisture and fluids after cleaning the housing.
      7. Allow wiped areas to dry for at least 15 minutes before performing a test.
   2. Cleaning the test strip guide:
      1. Use only 70% alcohol to clean the test strip guide. Clean the test strip guide when it becomes visibly soiled.
      1. Remove the test strip guide cover by pressing upwards from the front.
      2. Hold the meter upright with tests strip guide facing down.
      3. Clean the easily accessible white areas with a lint-free swab or a moistened cotton swab. Ensure the swab is only damp, not wet.
      4. Apply cleaning agent for the minimum required contact time. Wipe away residual moisture and fluids. Make sure that no liquid enters the meter.
      5. Let the inside of the test strip guide dry for at least 15 minutes before re-attaching the test strip guide cover and testing again.
      6. Re-attach the test strip guide cover to the housing. Make sure it snaps into place ensuring it is properly closed.

XXII. INSTRUMENT DOWNTIME

When a particular CoaguChek® XS Plus meter cannot be used for patient testing due to QC failure or mechanical or electronic instrument failure that cannot be resolved by the operator, contact the Point-of-Care Testing Program office at 5-2645, CMSC-SB Room 207, or email POCT Group (POCTGroup@exchange.johnshopkins.edu).

Utilize the Core Laboratory by sending venipuncture samples during meter downtime.
XXIII. CORRELATION SAMPLES

It is the responsibility of operators in the INR clinics to initiate random correlation with Core Lab. Refer to PTINR001 PT/INR Patient Correlation Procedure Procedure for specifics, including the recommended minimum frequency.

XXIV. OPERATOR TRAINING AND COMPETENCY

Initial training and competency will include the following:

<table>
<thead>
<tr>
<th>Initial Testing</th>
<th>Ongoing Competency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overview of the meter</td>
<td>Assess competency twice the first year after initial training and annually thereafter.</td>
</tr>
<tr>
<td>Successfully perform the QC</td>
<td></td>
</tr>
<tr>
<td>Complete training checklist</td>
<td></td>
</tr>
<tr>
<td>Successful completion of the online My Learning module and quiz</td>
<td></td>
</tr>
</tbody>
</table>
XXV. RELATED DOCUMENTS
PTINR001  PT/INR Patient Correlation Samples Procedure
GEN002 Capillary Blood Collection for Point-of-Care Testing

XXVI. REFERENCES
CoaguChek® XS Plus System Operator’s Manual, Roche Diagnostics. See Appendix A.

XXVII. SPONSORS AND DEVELOPERS
Sponsor:
Pathology Performance Improvement

Developer:
Point of Care Testing Office

Review Cycle: Two (3) years

XXVIII. SIGNATURES

<table>
<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>William Clarke</td>
<td>11/17/2022</td>
</tr>
<tr>
<td>Doctor of Philosophy, Clinical Lab Scientist</td>
<td></td>
</tr>
</tbody>
</table>

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