Roche CoaguChek XS Plus INR

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Location:
Country Health SA – Integrated Cardiovascular Clinical Network (iCCnet CHSA)
1. PURPOSE AND SCOPE

This method is to be used for the determination of prothrombin time (PT) in capillary and venous whole blood using the Roche CoaguChek XS instrument.

2. HAZARDS

Patient Samples
All patient samples should be treated as potentially infectious and handled appropriately. Personal protective equipment (e.g. gloves and safety glasses) should be worn when processing samples and performing maintenance.

Quality Control
As quality control samples are derived from human source material, they should be treated as potentially infectious. Although having been tested for HBsAg and HIV, this does not guarantee that all infective units have been detected. Personal protective equipment (e.g. gloves and safety glasses) should be worn when processing samples.

Suspected contamination should be reported to your section safety officer or supervisor.

3. CLINICAL

Oral anticoagulation therapy is the established treatment for patients suffering from a range of conditions in which it is necessary to inhibit the formation of blood clots within the circulation.

The major indications for anticoagulation include:
- Prevention of thrombosis in patients with prosthetic heart valves/stents
- Treatment and secondary prevention of venous thromboembolism
- Primary prevention of venous thromboembolism in high risk patients
- Primary prevention of stroke in patients with atrial fibrillation

Oral anticoagulant drugs antagonize the effects of Vitamin K, reducing the blood’s ability to form a clot. This effect can be measured by determining the prothrombin time in a patient’s blood and comparing it with a standard figure. The resulting ratio is called the International Normalised Ratio (INR).

INR is a good indicator of effectiveness of therapy and risk of bleeding during warfarin therapy. Regular INR testing is required to adjust the warfarin dose in patients to maintain their INR as close to the appropriate target INR as possible. Optimum target INR figures have been established for different diagnoses.

Warfarin is a potentially hazardous drug causing major bleeding in 1-2% of people treated, and intracranial bleeding in about 0.1-0.5% during each year of therapy (Gallus A et al MJA 2000; 172: 600-605). Patients on therapy should be monitored closely.

4. INSTRUMENT

The CoaguChek XS Plus instrument uses a rechargeable battery pack which is supplied with the instrument. The instrument also has a direct power supply via a power cord or the docking station. The instrument should be regularly charged to ensure that the instrument has enough battery power for testing.

**Operating and technical conditions**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>15 - 32°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>10 - 85% (no condensation)</td>
</tr>
<tr>
<td>Position</td>
<td>Place meter on a level, vibration-free surface or hold so it is roughly horizontal</td>
</tr>
<tr>
<td>Memory</td>
<td>1000 patient and 500 QC results with date and time</td>
</tr>
<tr>
<td>Weight</td>
<td>311g without batteries</td>
</tr>
</tbody>
</table>
5. **PRINCIPLE**

**Test Strips**
The CoaguChek XS PT test strip has a test area containing a prothrombin reagent. When blood is applied, the reagent is solved and an electrochemical reaction takes place creating an electrochemical signal.

**CoaguChek XS Plus**
The electrochemical signal and the time taken to generate the signal are measured and converted by means of an algorithm into customary coagulation units (INR). The result is then displayed on the screen.

6. **CONSUMABLE STORAGE**

CoaguChek XS PT test strips should be stored at room temperature when not in use (15-30°C). Test strips may be stored in the refrigerator (2-8°C), but must be brought to room temperature for use. Once a test strip is removed from the container, immediately replace the stopper to prevent the remaining strips from deteriorating. Test strips must be used within 10 minutes of removal from the container.

Lyophilised quality control material and red diluents should be refrigerated until use.

7. **SAMPLE COLLECTION AND STORAGE**

Fresh capillary or venous whole blood can be used. Anticoagulated blood must not be used (heparin, EDTA, citrate, oxalate or other substances).

**Capillary Puncture**

Make sure the finger is clean, warm and dry. Use a lancing device that provides a deep puncture so that blood flows freely. Immediately after lancing, massage gently along the side of the finger to obtain a large drop of blood without pressing or squeezing too hard. Immediately apply the first drop (a large well-rounded drop) without air bubbles to the application area or side of the sample application area. Do not apply more blood to the test strip.

**Venepuncture**

Blood must be collected in a plain plastic syringe without anticoagulant. Use a 23-gauge needle (approx 0.65 mm) or larger. Blood sample must be tested within 15 seconds of collection. Discard the first 4 drops of blood and apply 5th drop to the application well. Ensure no bubbles are present.

8. **LIMITATIONS AND KNOWN INTERFERENCES**

- Point of care INR testing should not be used for snake bites
- Samples should not be taken from an arm receiving an intravenous infusion
- Poor blood flow due to poor capillary or venepuncture technique may cause erroneous results
- Anti-phospholipid antibodies (APA) such anticardiolipin antibodies or lupus antibodies may falsely prolong coagulation times using the CoaguChek XS Plus system. Where APA are known to be present, it is imperative that a result be obtained from a laboratory using an APA insensitive method
- Results are not affected by heparin concentrations up to 0.8 U/mL
- The CoaguChek XS PT test is insensitive to low molecular weight heparins (LMWH) up to 2 IU/mL antifactor Xa activity

No significant interference was observed by the following at the concentrations indicated:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>513 µmol/L</td>
</tr>
<tr>
<td>Haemolysis</td>
<td>0.62 mmol/L</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>5.7 mmol/L</td>
</tr>
<tr>
<td>Haematocrit</td>
<td>25 – 55%</td>
</tr>
</tbody>
</table>
9. STANDARDS

Each lot of test strips is calibrated to a reference lot that is traceable to the WHO International Reference Preparations. For the purpose of providing universal INR results, the Mean Normal Prothrombin Time (MNPT) has been established as 12 seconds for healthy volunteers and the International Sensitivity Index (ISI) for the system has been established as 1.

The calibration data is stored in a lot-specific code chip. The code chip contains programming information about the test strip, lot number and expiration date. Each code chip is specific to one lot of test strips. A new code chip is supplied in each box of test strips.

10. TEST PROCEDURE

1. Turn the instrument on by pressing the On/Off button for longer than 5 seconds.

   ![Main Menu](Image)

   Note: check the charge level of the instrument, if no bars are left, you cannot perform a test.

2. Clean the finger with an alcohol wipe or soap and warm water and dry thoroughly. Warming fingers promotes blood flow.

3. Touch the Patient Test button and enter the Patient’s UR number as the Patient ID. If a UR number is not available, enter the Patient’s Surname followed by their date of birth (i.e Smith 311255). The display will prompt you to insert the test strip.

4. Remove a test strip from the container and insert it into the test strip guide as shown below. Ensure the correct code chip is inserted. Test strips must be used within 10 minutes of removing them from the container. Immediately after removing a test strip close the container again with the stopper.

   ![Test Strip Insertion](Image)

   The hourglass symbol indicates that the test strip is warming up.
5. A beep will indicate the warming up process is complete. When the device is ready to perform the test, the blood drop symbol will flash with a 180 second countdown. Blood must be applied to the test strip within this time.

![Image of CoaguChek XS Plus INR device](image1)

6. Lance the side of a fingertip with a lancing device. The side of a fingertip is recommended as it causes the least pain. Gently squeeze the finger to obtain a hanging drop of blood.

7. Apply blood directly from the finger to the clear sample application area. Blood must be applied to the test strip within 15 seconds of lancing the finger. Applying the blood after this period will falsify the result. When the blood drop is detected, the device will beep and the test begins.

![Image of blood application](image2)

Note: Blood may be applied to the side of the sample application area as shown by obtaining a drop of blood and holding the drop of blood to the side of the test strip, until the meter beeps.

8. The instrument performs an automatic internal check on the strip before the result is displayed.

9. The INR result is displayed on the screen and automatically stored in the memory. Remove the test strip and dispose of appropriately. If finished testing, turn the instrument off.

**Important:** If the test results do not fit the clinical picture of the patient, repeat the test using a new sample and ensure you follow the testing procedure correctly. If the repeated result still does not fit the clinical picture, you should send a sample to the laboratory for confirmation, check that the quality control results are within target limits and notify your medical officer.
11. QUALITY CONTROL

Internal Quality Control
Quality control samples consist of a lyophilised material of human origin. Internal quality control samples should be tested a minimum of once per month.

1. Open the bottle of control very carefully, avoiding loss of any powdered material
2. Using scissors, cut off the tip of the dropper (long skinny part) and carefully add **ALL** the red diluent to the bottle
3. Gently swirl the bottle 2 to 3 times to dissolve the powder and allow mixing for one minute. Ensure the sample is tested **immediately** (within 5 minutes).
4. Select patient test and enter the ID as ‘QC’ followed by the lot number of the control (i.e. QC20220) then insert the test strip into the machine when prompted.
5. Draw the solution into the larger dropper by gently squeezing the bulb and releasing it whilst in the solution. Apply a couple of drops to the test strip when prompted by the instrument.

If the result falls outside the expected range, repeat the test using a new bottle of control. If the result is outside the expected range again, contact the iCCnet CHSA technical support on (08) 7117 0600.

Results are to be recorded on the 'INR Internal QC Results Sheet' in your CoaguChek XS Plus folder and faxed to iCCnet CHSA office (08) 7117 0635.

External Quality Controls
External quality controls for the year will be sent to each site in January/February along with a reporting schedule and result sheets. The information provided with the external quality controls samples will indicate which samples should be run each month and the due date. Quality control samples consist of a lyophilised sample based on human sera.

1. Select the corresponding sample, as indicated by the label on the bottle
2. Open the bottle of control very carefully, avoiding loss of any lyophilised material
3. Using scissors, cut off the tip of the dropper (long skinny part) and carefully add all the red diluent to the bottle
4. Gently swirl the bottle 2 to 3 times to dissolve the powder and allow mixing for one minute. Ensure the sample is tested **immediately** (within 5 minutes).
5. Once dissolved, select patient test and enter the sample number as the patient ID (i.e. EQA I17-01)
6. Insert the test strip into the machine when prompted
7. Draw the solution into the larger dropper by gently squeezing the bulb and releasing it whilst in the solution. Apply a couple of drops to the test strip when prompted by the instrument.
8. Once analysis is complete, fill out this sheet and fax results to the iCCnet CHSA office (08) 7117 0635
9. Discard the bottle of control

12. RESULTS

Measuring Range and Interpretation
The instrument has a measuring range of 0.8 – 8.0 INR. The CoaguChek machine has been configured to report results as International Normalised Ratio (INR).

Unusual Results
An unexpected result may include any result that falls outside the therapeutic range, or a result that falls inside the therapeutic range but is not consistent with the clinical symptoms (e.g. bleeding or bruising).
Causes of unexpected results
- Changes in diet, lifestyle or taking nutritional supplements
- Certain prescription drugs and over the counter medicines (e.g. antibiotics)
- Anti-phospholipid antibodies (APA) such as anticardiolipin antibodies or lupus antibodies may falsely prolong coagulation times using the system. Where APA are known to be present, it is imperative that a result be obtained from a laboratory using an APA insensitive method.
- Liver disease, congestive heart failure, thyroid dysfunction, and other diseases or conditions can affect the action of oral anticoagulants and the INR value

What to do when you get an unexpected result
- If the result is outside the therapeutic range, follow your clinic’s steps for re-testing
- If, after re-testing, the result is still outside the therapeutic range, consider the above causes
- If you get an INR ≥4 on the CoaguChek XS Plus instrument a laboratory test should also be done to confirm the result. If a laboratory test is not available, retest on the CoaguChek XS Plus

If the result falls within the therapeutic range, but there is reason to believe the INR could be significantly different (e.g. bleeding or bruising), testing by an alternative method should be arranged immediately.

Accessing Previous Results
The CoaguChek XS Plus instrument is able to store up to 1000 patient results in its memory. To access results in the memory, touch Review Results, Patient Result and select the result you are looking for.

13. DOWNLOADING RESULTS
The results can be downloaded into iPOCCS by connecting the white downloader to a power supply and a network point via a network cable. Light on the top of the downloader should turn a constant green.

Place the CoaguChek instrument into the downloader, ensuring it is firmly in place. It will display flashing symbol or ‘Connecting to the DMS’.

Once finished, the symbol stops flashing or ‘Docked’ will appear on the screen and press ✓. Downloading of results usually takes a few minutes to complete.

14. REFERENCE RANGE
The anticoagulant effect of Warfarin should be kept at an International Normalised Ratio (INR) of about 2.5 (desirable range, 2.0 – 3.0), although a higher level may be better in a few clinical conditions.

The risk of bleeding increases exponentially with INR and becomes clinically unacceptable once the INR exceeds 5.0.
15. MAINTENANCE

Monthly or as needed. Ensure the instrument is turned off when performing any maintenance procedure.

Suitable cleaning agents include:
- 70% ethanol or isopropyl alcohol
- A mixture of 1-propanol (400mg/g), 2-propanol (200 mg/g) and glutaraldehyde (1.0 mg/g)
- 10% sodium hypochlorite solution (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours)
- Quaternary ammonium compounds up to 0.5 % (single compound or mixture) in isopropyl alcohol (isopropanol) up to 55 %.

Cleaning the outside of the instrument
- Ensure the blue chamber cover remains tightly closed when cleaning
- Wipe any blood off the instrument using an appropriate alcohol or detergent wipe
- Do not use alcohol wipes on the display screen
- Do not let liquid accumulate near or enter any opening
- Allow the area 10 minutes to dry before performing a test

Cleaning the instrument’s test strip guide (measurement chamber)
- Use gloves while cleaning
- Remove the blue test strip guide cover by unclipping it and pulling it up
- Rinse the cover with warm water or wipe it clean using the solutions recommended above. Let the test strip guide cover dry for at least 10 minutes before reattaching it.
- Hold the instrument upright with the test strip guide facing down
- Clean the easily accessible white areas with a moisten cotton swab/wipe. Ensure swab/wipe is only damp, not wet.
- Apply cleaning agent for a contact time of >1 minute then wipe away any residual liquid following cleaning
- Let the inside of the test guide dry for 10 minutes before replacing cover and restart testing.

16. USER ACCREDITATION

PoCT operators must complete the online competency for the device at: www.iccnetsa.org.au and receive a certificate before using the device. This accreditation is valid for 1 year, after which the user must retake the competency.

17. TECHNICAL SUPPORT

For technical support during office hours (Monday to Friday 9:00am – 5:00pm), contact iCCnet CHSA on (08) 7117 0600. For after-hours technical support (24hrs/7 days a week), please page (08) 8378 2208.

For online resources, please visit the website: www.iccnetsa.org.au

18. REFERENCE SOURCE OF METHOD

Adapted from the method described in the Roche CoaguChek XS Plus operator’s manual (January 2014) and Roche CoaguChek PT Test kit insert (2015).