Coaguchek Pro II Quality Control

QC is imperative to ensure that the device and consumables are functioning together correctly to provide accurate and reliable patient results. Frequency of QC will be determined by your local POCT team according to New Zealand Best Practise Guidelines for Point of Care Testing 2025 (New Zealand Point of Care Testing Advisory Group).

Stock Control

- Stock must undergo quality control prior to being used for patient testing.
- All levels of QC material must be run on each lot number, per shipment. Multiple boxes of the same stock item with the same lot number do not need to be individually QC'd.

Calibration

A small chip is included with each box of test strips and QC solutions which contains calibration, lot number and expiry information for the device. It must be inserted into the device when a new lot is started to ensure accurate results.

There are two types of code chips. Those that have a 'S' in front of the number indicate this code chip is for test strips. Those that have a 'C' in front of the number indicate this code chip is for control solutions.

If the incorrect code chip is inserted into the device, it will prompt you to change it. Remove the old code chip from the top of the device and insert a new one. Leaving a code chip in the device at all times will protect the internal contacts from dirt and dust.

Internal Quality Control (IQC)

The Coaguchek Pro II has two types of internal quality control; automated quality control and liquid internal controls.

Automated quality controls include the following:

- Automatic check of the electronic components of the device and occurs every time the device is powered on.
- Check of the test strip temperature while a test is in progress.
- Check of the expiration
- An onboard quality control test within every single test strip.

Liquid Controls

- Lyophilized (freeze-dried) and require reconstitution with the supplied liquid dropper
- Stored at 2-8 degrees Celsius
- Stable in the fridge until their stated expiry date

Liquid controls are run on the following schedule:

- Upon each delivery of test strips, prior to patient testing
- Once per month, according to the POCT schedule
- If there is a proposed issue with the device
- If there is an unexpected patient result

Liquid Controls are run by designated Lead Users or laboratory POCT staff.

Reconstitution of Liquid Controls

1. Open the lid of the control bottle.
2. Hold the dropper with the sealed dropper neck pointing upwards, cut off the sealed end with scissors.
3. Apply gentle pressure to the dropper reservoir to transfer the entire contents of the dropper into the bottle.
4. Close the control bottle. Do not discard the dropper.
5. Swirl the bottle to completely dissolve the control plasma inside. Do not shake or invert.
6. Allow to stand for 5 minutes to fully reconstitute. Use within 30 min of reconstitution.

Running Liquid Controls

1. Power on the device.
2. Scan your operator ID.
3. Select Test > Control Test > PT.
4. Remove a test strip from the container and tightly reseal.
5. Slide the test strip into the test strip guide in the direction of the arrows on the strip. Slide the strip in as far as it will go. A beep will indicate that the device has detected the test strip.
6. Ensure the code chip inserted matches the test strip. Change if needed.
7. Select the control code strip for your current control solution or scan the control solution barcode.
8. Select which level of control you are testing (level 1 or level 2).
9. The hourglass icon will show the test strip is warming up. Once warmed, a dropper icon indicates you have 3 minutes to apply the control solution to the test strip.
10. Using the dropper, draw up the dissolved liquid control. Apply 1 hanging drop directly from the dropper to the test strip semi-circular, transparent sample application area.
11. A beep will indicate enough control solution has been applied to the test strip and the test will begin.
12. The result of the control is displayed along wit h the expected range and a pass/fail message.
13. Remove the test strip and dispose of as biohazardous waste.

Liquid control results are recorded in the device and also transmit to the middleware, Aqure. QC is monitored by the local POCT team.

What to do if IQC fails

If a result fails, an up/down arrow is displayed and flashes. A comment may be added.

- Check the expiry date of all consumables.

- Rerun the failed QC ensuring that the correct level of QC has been run and that all QC processes were adhered to.
- DO NOT continue to repeat the control until a PASS has been obtained
- Consult a Lead User for advice
- Consult your local POCT team for advice

External Quality Assurance (EQA)

EQA is provided by the RCPA Point of Care INR programme. Two samples are tested and submitted six times per year.

- Samples arrive lyophilized and require reconstitution.
- They are stored in the fridge between 2-8 degrees Celsius.
- EQA is performed by a Lead User or the POCT team.

Running EQA

1. Select the two vials for the current month
2. Carefully cut off the sealed end of the distilled water dropper (blue label), as close to the tip as possible.
3. Gently transfer all of the distilled water into the lyophilized sample.
4. Replace the lid and gently swirl for approximately 10 seconds.
5. Allow to stand at room temperature for 15min prior to testing. Both samples can be prepared to this stage, but complete the following steps for one sample at a time immediately prior to testing.

6. Run the samples as a patient with the RCPA number as the sample ID.
7. Prepare the device for testing and insert the test strip.
8. Carefully cut the sealed end off the CaCl2 dropper (pink label), as close to the tip as possible.
9. Gently transfer all of the CaCl2 into the reconstituted sample and gently swirl for 10-15 seconds.
10. Within 20-30 seconds of re-calcification, use the supplied plastic pipette to draw the plasma up and down a few times to mix well before applying a drop of plasma to the pre-warmed test strip.

Results are entered onto the RCPA website directly https://myqap.rcpaqap.com.au/login

When RCPA reports are published, they are reviewed by the POCT team and the Chemical Pathologist. Any discordant results are discussed and managed by this team.