# Quality Control (QC)

QC must be run to ensure that accurate and reliable results are being produced by the instrument and the discs. Roche sell commercially available control solution.

- The QC must be keep in the fridge (2-8 degrees) up to the stated unopened expiry date.
- Each QC vial has an open expiry of 90 days.
- Ensure the opened date is printed on the bottle, as well as its 90 day expiry.
- Yellow stickers are available for the opened and expiry dates.

Each new lot of QC material has an information disc which needs to be loaded first, this will update the lot specific QC target value. The manufacturer control range is calculated as the target value ±3SD. This has been deemed as too wide, therefore it is now set in the analyser as target value ±2SD.

QC must be performed:

- Each time a new lot or delivery of discs arrive – level 1 and 2
- Once per month – alternating between level 1 and 2
- If an unexpected result is obtained for a patient

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## Stock Control

All new shipment of discs and QC material needs to be dated on arrival. Once both levels of QC has been run successfully on the shipment lot, add a completed 'QC' sticker to the box. This ensures that users know the box is ready to use. Ensure that QC information is recorded on Cartridge QC sheet within the patient results folder.

## Performing a QC test

1. The control is supplied ready to use
2. Gently mix the vial before testing to ensure homogeneity
3. Select **Control Test** from the main menu
4. Select **QC test**
5. For a new QC lot select **New QC Lot**. Insert QC info disc and close the lid. The QC information will be saved into the system.
6. The QC target value and range are displayed. Validate by selecting ✔
7. Select level of QC test (Level 1 or 2)
8. Remove the cap and add the corresponding colour dropper. Carefully apply a drop of QC solution to the suction point. Ensure that the blue marked area in completely full
9. Open analyser lid and remove QC info disc, if used, then insert the test disc.
10. Verify that the QC solution lot number matches the lot number displayed on the screen. ✔ to continue.
11. The QC test takes just over 5 minutes.
12. The results will be displayed along with the lot number and PASS or FAIL.
13. If the QC fails, go through the checklist in the box below to try to fix the problem. Add a comment by pressing the comment box.  Include what went wrong and how it was fixed.
14. Accept and remove disc.
15. The QC results are stored in the instrument and can be found retrospectively for review. They can be found by **Results Review > Control Results > QC Test > Select Test**. These can be found by date and time.

## What to do if a QC test fails

Check the following:

1. Have the controls have been opened for more than 30 days?
2. Was the correct control level tested?
3. Were the controls stored in the fridge?
4. Were the controls applied to the disc without air bubbles?
5. Was the correct QC information disc used ie: was a disc from a different kit lot number used?
6. Does the machine pass the optical check?

Troubleshoot using the above box to rule out potential errors, then repeat the QC test. In the meantime, STOP testing any patient samples until the issue is resolved and the QC is within range.

If the QC still FAILS. Contact POCT Quality Manager on 2453 or contact the Roche Techline 0800 36 36 22

## External Quality Control (EQA)

A monthly comparison sample is run between the B101 and Hastings Laboratory Bio-Rad D100. This ensures that results being obtained by POCT are within acceptable limits. The D100 is enrolled in the Waikato Hba1c comparison.
These samples are run as **Control Test > Proficiency Test**.
Data entry and results can be found at: ..\..\..\POCT\QC\B101 HbA1C – Diabetes Clinic.xlsx

## Optical Check

An optical check uses a special disc that is supplied with the instrument. It is designed to test the optical unit of the instrument. This needs to be run weekly or, if the analyser has been moved, before a patient test is performed.




## Performing an Optical Check

1. From the Main Menu choose **Control Test > Optical Check**
2. Load Optical check disc and close the lid
3. The test runs and when complete will beep and will display on the screen if the test has passed or failed.

*If the optical check fails, clean the inside of the instrument and repeat the test*
Again if the test fails; Contact POCT Quality Manager on 2453 or contact the Roche Techline 0800 36 36 22

## Calibration

The instrument automatically reads the lot-specific calibration data from the barcode printed on the disc, eliminating the need for calibration by the user.

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