

Primary Care Quality Control of Roche Coagucheck machines

Quality Assurance

Quality assurance is the means by which we assure ourselves that the results that our Coagucheck machine gives are accurate and therefore are safe for treating patients.

When the instrument is used for a patient sample it performs an automatic Quality control check and if this is successful a √ appears on the screen. This means that the patient result is Ok to accept.

The Roche QC should also be run regularly to make sure that the machine is working properly.

Roche QC should be performed by designated staff in the clinical area

a) ROCHE QC samples:

- i) QC should be run:
 - At least monthly and whenever the monitor has not been used for a considerable time.
 - If you suspect incorrect storage and handling of the test strips
 - If you start to obtain several implausible results
 - If you drop the meter
 - At a change of strip code or lot number.
- ii) Allow the control material and test strip to come to room temperature for 5 minutes before use
- iii) The control box contains freeze-dried control material, pipettes containing liquid and a code chip
- iv) Open the lid of the control vial and remove the rubber cap
- v) Hold the pipette with the sealed neck pointing upward, and then cut off the end of the cap with scissors
- vi) Apply gentle pressure to the reservoir and transfer the entire contents of the pipette to the vial, making sure the tip does not touch the dried plasma
- vii) Replace the rubber cap
- viii) Swirl the vial gently in a circular motion to completely dissolve all the control plasma. Do not shake the vial or put it on its side
- ix) Switch on the monitor and touch the QC TEST button
- x) Insert a test strip until the bleep sounds
- xi) Select the QC code that matches the control solution. If it is a new batch then press NEW CODE and insert the code chip into the monitor

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NOTE: test strip chips start with a letter S, control code chips start with a letter C

- xii) Select the level of control
- xiii) The hour-glass icon indicates the strip is warming up
- xiv) When the beep sounds, the pipette icon will appear indicating the control should be applied. This must be done within 120 sec
- xv) Use the pipette to draw up the dissolved contents of the vial
- xvi) Apply a drop to the strip target area. A bleep will sound
- xvii) The result will be displayed together with the acceptable range. The result is automatically saved to memory. If the QC fails then an arrow will be displayed, up arrow is too high, and down arrow is too low
- xviii) Remove and dispose of the strip and discard the control material into biohazard bin
- xix) Previous QC result can be viewed by using the scroll button

Results:

All results should be logged on a QC results log with date and time and control result and initials of person that ran the control...

The monitor is working correctly if the result is within range. If the result is out of range then repeat with a fresh vial. If still out of range then check the following:

Sources of error:

- a) Have you used the wrong code chip? The lot number of the test strip must match the number on the code ship
- b) Have you used correctly stored QC material and test strips? (storage conditions are on the side of the box)
- c) Are the strip guide and door clean (refer to maintenance)?
- d) Have you followed the correct procedure as above?

If all these check out and control is still out of range do **do not use the monitor** (Use a monitor that is working correctly or send a coagulation sample to the laboratory) and contact Roche technical support. (0808 100 19 20)

b) Some form of EQA is essential.

The recommended option is to participate in an accredited EQA programme such as the UK National External Quality Assessment Scheme (NEQAS) or the Welsh External Quality Assessment Scheme (WEQAS)

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Anticoagulation External quality providers.

NEQAS

Cost per annum 2014 = £100 per monitor covered.

Ease of use; Add contents of solution 1 to sample bottle mix and wait 10 mins, add solution 2 mix x 3 and put one drop on to Accu-Check strip in instrument.

Number of distributions per year = 4

Number of samples per distribution = 2

Costs for repeat samples = No cost

Results report back = on line entry and access to results.

www.coageqa.org.uk

Please contact the Manager (Tim Woods: Tim.Woods@coageqa.org.uk) for information on participation fees in all UK NEQAS for Blood Coagulation programmes.

WEQAS

Cost per annum 2014 = £45 per monitor covered.

Ease of use Solution is ready to use – mix and apply to the strip.

Number of distributions per year = 4

Number of samples per distribution = 1

Costs for repeat samples – No Cost

Results report back = online entry and access to results.

www.weqas.com.

Telephone: +44 2920 748186. E-mail: weqas.poct@wales.nhs.uk

Method for External QA scheme (NEQAS)

External QC (NEQAS) should be performed by designated staff.

Samples are received from the scheme organisers and processed according to their instructions.

The results are returned to the organiser who will then issue a report on your performance compared with all the other Coagucheck users who are registered around the country.

It is highly recommended by the MHRA to participate in a suitable scheme.