

Representation of the expected values on the Quo-Test A1C Control Data Card

LEVEL 1				LEVEL 2			
Unit	LOWER LIMIT	TARGET	UPPER LIMIT	Unit	LOWER LIMIT	TARGET	UPPER LIMIT
DCCT (%)				DCCT (%)			
IFCC (mmol/mol)				IFCC (mmol/mol)			
JDS (%)				JDS (%)			

Level 1 = normal

Level 2 = abnormal

Calibration

Quality Control values are assigned using equipment calibrated using samples provided by the European Reference Laboratory, via the NGSP network. They are traceable to the IFCC reference method.

Troubleshooting

If the result of either control fails then review the Instructions For Use and repeat the control again. If the repeat test also fails then contact your local distributor or call EKF-diagnostic GmbH customer support on +49 39203 511 414 or support@ekf-diagnostic.de.

You must not use the analyzer or report any test results until the problem has been resolved.

Storage and Stability

Store unopened control kits in a refrigerator at 2 to 8°C (36 to 46°F). The expiry date is printed on the outside of the pack. The controls cannot be used after this date.

Once controls have been reconstituted they can be used for up to 15 days, when kept in their package in a refrigerator at 2 to 8°C (36 to 46°F).

Protect the controls from sunlight. Always store the controls and the reconstituted controls within their original box.

Limitations of Use

For use with the Quo-Test Analyzer and Quo-Test A1C Test Cartridges only.

Quo-Test A1C Control Kit

REF 0061

Instructions For Use



Read and familiarize yourself with the contents of the Instructions for Use before using the controls.

Consult the Quo-Test A1C Control Data Card for the expected values.



Please regard the hints for the modified storage conditions of the controls. Protect the controls from sunlight.

	MEANING
	Read the instructions for use
	In-vitro-Diagnostic Medical Device
	Batch or lot number
	Calibration Barcode
	Product Reference
	Control
	Storage Temperature
	Contents sufficient for <n> Number of Tests
	Expiry date
	Manufacturer
	Caution
	CE mark
	Biological Hazard
	Keep away from sunlight



WARNING! POTENTIALLY BIOHAZARDOUS MATERIAL

Human sourced materials were used in the manufacture of this product. Each donor unit was tested for hepatitis B surface antigen (HbsAg), antibodies to hepatitis C (HCV), and antibodies to Human Immunodeficiency Viruses (HIV-1 and HIV-2), HIV-1 Antigen and Syphilis and found to be negative. **CAUTION!** Because no test method can offer complete assurance that HIV, Hepatitis B or C viruses, or other infectious agents are absent, these products must be handled as potentially infectious. Handle the Hemoglobin A1c Control with the same precautions used with patient specimens.



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Intended Use

The Quo-Test A1C Control Kit is intended to check the general functionality and accuracy of the Quo-Test A1C Test system.

Description of the Quo-Test A1C Control Kit

The kit contains two controls: Level 1 (in the normal value range) and Level 2 (in the abnormal value range) controls. **Both** controls, **Level 1 and Level 2** should be used when Quality Control is being carried out.

Quality controls should be run:

- With each new lot of Test Cartridges.
- With each new shipment of Test Cartridges.
- At any time there is concern that the test result may be wrong, the Test Cartridges may not have been stored correctly, the user is unfamiliar with the test procedure or there is concern that a user may be performing the test incorrectly.

Use the controls according to the quality standards set by your organization or laboratory. Refer to the **Expected Values** on the **Quo-Test A1C Control Data Card** to check the results obtained.

Only Quo-Test A1C controls are suitable for use with the Quo-Test A1C Test System. Preservatives and additives used in third party controls may interfere with the running of the A1C test and EKF-diagnostic GmbH cannot guarantee the results obtained with third party controls.

In addition to running the Quo-Test A1C controls, it is recommended that laboratories regularly participate in an external quality control scheme.

Quo-Test A1C Control Kit Contents

2 bottles of Level 1 Control with white lids.

2 bottles of Level 2 Control with black lids.

1 dropper bottle containing reconstitution solution for reconstituting the controls.

4 color coded dropper caps (2 white, 2 black).

16 plastic trays.

1 Quo-Test A1C Control Data Card.

1 Instructions For Use.

Accessories Required (not included)

Quo-Test Analyzer
Quo-Test A1C Test Kit

Preparing the Controls

Follow these instructions to reconstitute the controls prior to use:

- Place the Level 1 control and the dropper bottle on to a clean, dry surface.
- Unscrew the cap of the control bottle. Unscrew the cap of the supplied dropper bottle. Invert the dropper bottle over the control bottle and add 6 drops of reconstitution solution to the control by gently squeezing the dropper bottle. **To avoid cross contamination make sure that dropper bottle and control bottle don't touch each other.**
- When the reconstitution solution has been added, put the caps back on both bottles.
- Leave the control bottle to stand for 15 minutes. At the end of this time, gently swirl the contents to ensure that they are completely reconstituted. **Avoid** vigorously shaking the bottle as this will create bubbles.
- Leave the control bottle to stand for a further 15 minutes before use.
- Remove the control bottle cap and replace it with the white dropper cap.
- Write the date prepared on the control label. The control can be used for up to 15 days when stored at 2 to 8°C (36 to 46°F).
- Follow the above instructions to prepare the Level 2 control using the black dropper cap.
- **The controls are now ready. Refrigerate immediately until required for use. Always store the controls within their original box.**

Using the Controls

Refer to the Quo-Test Analyzer User Manual for setting up the analyzer and the Quo-Test A1C Test Kits Instructions for Use for preparing test cartridges for use.

Follow these instructions to run the controls on a Quo-Test analyzer:

- Place the Level 1 Control, a Quo-Test A1C test cartridge, a blood collector, a small plastic tray (provided in the control kit) and the Quo-Test analyzer on to a clean, dry, level surface.

- The Quo-Test analyzer and test cartridge **must** be at the same working temperature before use.

- The **reconstituted A1C controls can be used straight from the fridge** and do not need to be at room temperature before use.

- Again swirl the bottle with the reconstituted control before use.

- Point the barcode scanner at the Level 1 control barcode, which is printed on the control data card. Press the barcode scanner button until you hear a beep.

- The analyzer screen will now show "Run Level 1 Control".

- Unscrew the dropper cap. Expel any control material in the dropper into the bottle. Refit the dropper cap and gently swirl the contents before use. **Avoid taking up bubbles.**

- Unscrew the dropper cap, gently squeeze the bulb on the control cap, place the tip of the dropper into the control material in the bottle and gently release the bulb on the control cap. Some of the solution will be drawn into the glass dropper. **Avoid taking up bubbles.**

- Put a drop of the control solution on to the small plastic tray by gently squeezing the bulb.

- Screw the dropper cap back on the control bottle.

- To run the control, touch the blood collector to the drop of control solution on the plastic tray, like a finger-prick sample **avoiding bubbles.**

- Put the blood collector into the test cartridge and put the cartridge into the analyzer.

- Pull the red slide forward and close the analyzer door. The test will start automatically.

- When the test is finished, the result will be shown on the screen. If the result is within the acceptable range, the screen will show "Level 1 Control OK". If the result is outside the range then the screen will show "Level 1 control Fail". The measured A1C value is also displayed. The result will remain on screen until the door is opened.

- Now run the Level 2 Control in the same way, making sure that you scan the Level 2 Control Barcode.

- Refer to the **Expected Values on the Quo-Test A1C Control Data Card.**

- **Return the control material to the refrigerator immediately after use. Always store the controls within their original box.**

- Quality control results are stored in the analyzer memory as control samples. Control sample data files include the test lot number, control lot number, whether the control was run as a Level 1 or Level 2 control, the A1C value and if the control passed or failed. Refer to the Quo-Test Analyzer User Manual to access results held in the memory.

To exit control mode, close the analyzer door with no cartridge present in the test chamber and wait for the system to return to the home screen.



Warnings and Precautions

For *in vitro* diagnostic use only.

Do not use an unopened control kit after the expiry date or if the control kit has not been stored in accordance with the recommendations.

Do not use controls beyond 15 days once reconstituted or if the reconstituted controls have not been stored in accordance with the recommendations.

Do not use the control kit if the vials containing the control material or dropper bottle containing the reconstitution solution are damaged.

Use gloves - Used Test Cartridges, sampling equipment and controls are potentially infectious.

Used Test Cartridges should be disposed of **immediately** as **clinical waste** in accordance with local / national regulations.

Protect the controls from sunlight by storing within their original box, whether unopened or in reconstituted form.