

FREQUENTLY ASKED QUESTIONS

Q: How long does it take to perform a glycated hemoglobin (HbA1c) test?

A: Once a blood sample has been introduced into the Quo-Lab the obtained results are reported within 4 minutes.

Q: How much blood is required?

A: Just 4µL is required from a finger prick, capillary or venous sample.

Q: What technology is being used?

A: Quo-Lab uses a patented Boronate Fluorescence Quenching Technology (BFQT) associated with simple yet powerful multiple optical measurements.

Q: What is the benefit of BFQT?

A: Based on well documented boronate affinity for glycated hemoglobin, BFQT has similar performance to the boronate affinity chromatography systems used in reference laboratories. Because BFQT does not require chromatographic separation, the methodology allows for fast, simple and accurate point of care HbA1c measurement.

The Quo-Lab system using the BFQT has the advantage of not being affected by hemoglobin variants (which do not result in reduced erythrocyte life span), labile glycated hemoglobin or hematocrit levels.

Q: How are results reported?

A: Results are displayed using dual reporting with user selectable units % DCCT, mmol/mol IFCC, % JDS, eAG mg/dl and eAG mmol/l

Q: Does Quo-Lab store patient results?

A: Yes, the Quo-Lab can store up to 7,000 results which can be downloaded to a PC via a USB cable.

Q: Are Quo-Lab systems traceable to the NGSP and IFCC schemes?

A: Quo-Lab analysers and A1C tests are calibrated and quality controlled using NGSP European Reference Laboratory supplied materials and are traceable to the IFCC reference method.

AACC American Association for Clinical Chemistry

- BFQT Boronate Fluorescence Quenching Technology
- DCCT Diabetes Complications and Control Trial
- IFCC International Federation of Clinical Chemistry
- NGSP National Glycohemoglobin Standardization Program

Q: What is NGSP and IFCC certification?

A: In an effort to standardize glycated haemoglobin results the AACC established the "National Glycohemoglobin Standardization Program" (NGSP) in 1996. In parallel the International Federation of Clinical Chemistry (IFCC) developed reference methods for glycated hemoglobin. In 2006 and 2007, an international consensus between IFCC and AACC was agreed upon.

The calibration and certification of laboratories and manufacturers to the same standards have improved the conformity of the results.

However, in practice differences can still be observed between technologies as well as between individual systems either because of the heterogeneity of hemoglobins, underlying different technologies (e.g. ion exchange, boronate affinity, immunoassay) due to calibration drifts, or lot to lot variability. This may result in differences in reported values.

EKF Diagnostics follows the recommendations of the IFCC and NGSP to ensure that EKF instruments and reagents are accurately aligned and traceable to the reference method. See www.ngsp.org for more information.

Q: Can the Quo-Lab be used in laboratories?

A: Yes, although the Quo-Lab has been developed to be used in a point of care setting, it is a professional product providing laboratory level accuracy.

Q: Is there a warranty period?

A: Yes, all Quo-Lab analysers carry a 12 month worldwide warranty.

Q: What languages are featured on the device?

A: Quo-Lab can be set up can be set up in English, Czech, Danish, Dutch, Finnish, French, German, Italian, Spanish, Russian, Polish, Romanian, Portuguese, Bosnian, Bulgarian, Croatian, Estonian, Greek, Kazakh, Latvian, Lithuanian, Serbian, Slovakian, Swedish, Turkish, Chinese and Japanese. Other languages may be added. Ask your EKF representative for details.

Q: Where is the EKF Quo-Lab HbA1c analyser produced?

A: It is assembled at EKF Diagnostics' ISO 13485:2012/2003 accredited manufacturing facility in Germany.

