

### 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-Test results are reported within 4 minutes.

### Q: How much blood is required?

A: Just  $4\mu L$  is required from a finger prick, capillary or venous sample.

### Q: What technology is being used?

A: Quo-Test 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, the BFQT has similar performances as the boronate affinity chromatography systems used in reference laboratories. However, as it does not require physical separation it assures a simple, fast and accurate measurement.

The Quo-Test 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 on the digital display and reported in mmol/mol IFCC, % DCCT, % JDS, eAG mg/dl and eAG mmol/l values.

### Q: Does it store patient results?

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

### Q: Does the instrument have a NGSP and IFCC certification?

A: Yes, the Quo-Test analyser has been certified to the NGSP and IECC standard.

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 has set up the "National Glycohemoglobin Standardization Program" (NGSP) in 1996. In parallel the International Federation of Clinical Chemistry (IFCC) developed reference methods for glycated haemoglobin. 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 among technologies as well as between individual systems either because of the heterogeneity of haemoglobines, 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 our instruments and reagents are accurately aligned and traceable to the reference method. See www.ngsp.org for more information.

#### Q: Can the Quo-Test be used in laboratories?

A: Yes, although the Quo-Test 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-Test analysers carry a 12 month worldwide warranty.

### Q: What languages are featured on the device?

A: Quo-Test 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, and Chinese. Ask your EKF representative for details.

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

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

