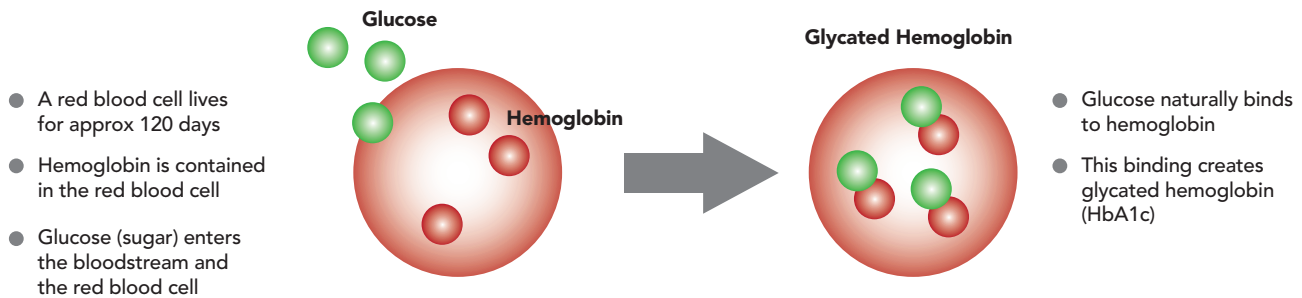


FLUORESCENT QUENCHING TECHNOLOGY

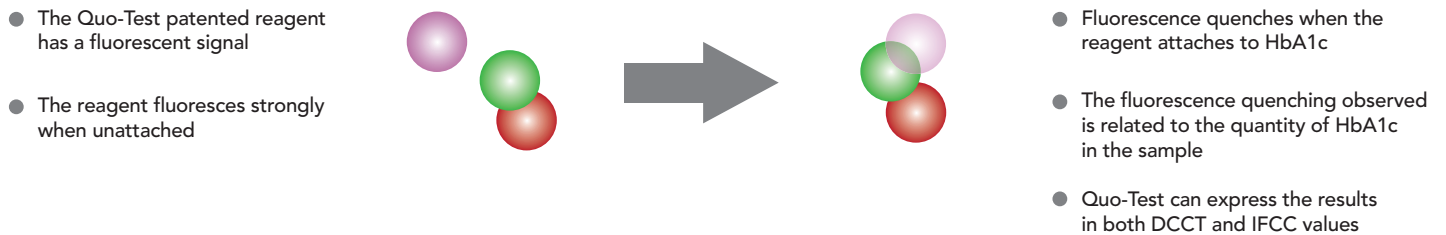
- Quo-Test uses fluorescence quenching combined with boronate affinity technology to measure glycated hemoglobin (HbA1c)
- The glycated hemoglobin binds to a boronate fluorescent conjugate causing quenching of the signal
- Quenching is measured by a sensitive fluorimeter



GLYCATED HEMOGLOBIN (HbA1c) EXPLAINED



QUO-TEST TECHNOLOGY



IMPRECISION STUDIES

- 20 day imprecision study
- CLSI guidelines
- High and low sample run in duplicate every day for 20 consecutive days

	Low sample % CV	High sample % CV
TOTAL IMPRECISION	2.82%	2.49%
WITHIN RUN IMPRECISION	2.64%	1.89%
BETWEEN DAY IMPRECISION	1.40%	0.86%
BETWEEN RUN IMPRECISION	0.00%	1.37%



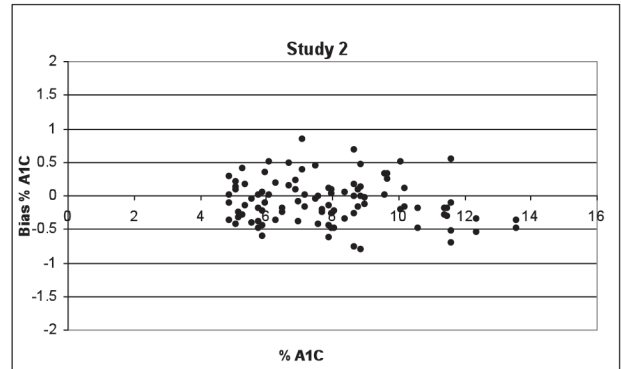
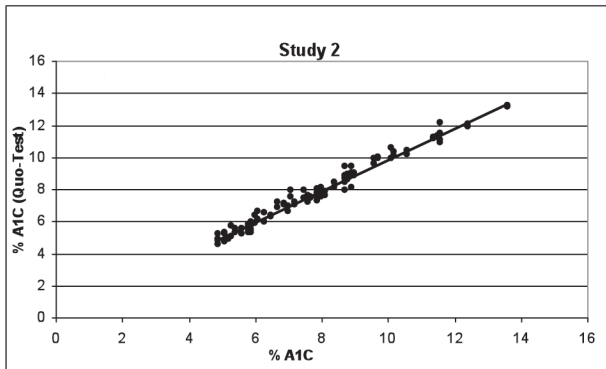
CORRELATION STUDIES

Summary of the results for testing 98 patient samples on the Quo-Test A1c assay, a competitor desktop analyser and a reference laboratory auto-analyser.

	Predicate device	Sample N =	Quo-Test A1c Correlation R =	Quo-Test Bias % A1c (DCCT)	Quo-Test A1c Precision % CV
STUDY 1	Desktop analyser	50	0.971	-0.03	2.80
	Laboratory auto-analyser	50	0.984	-0.30	2.80
STUDY 2	Desktop analyser	48	0.980	-0.09	2.90
	Laboratory auto-analyser	48	0.989	-0.10	2.90

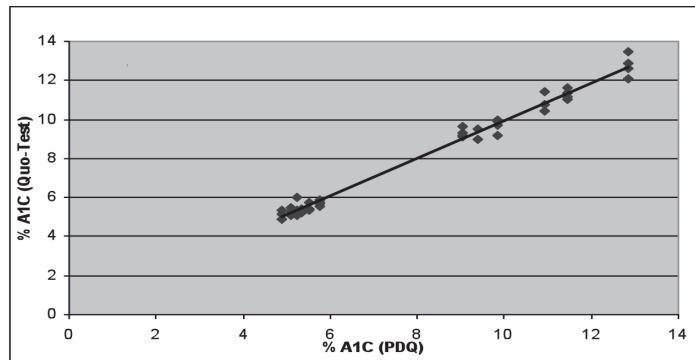
CLSI Clinical and Laboratory Standards Institute

QUO-TEST VS LABORATORY AUTO-ANALYSER



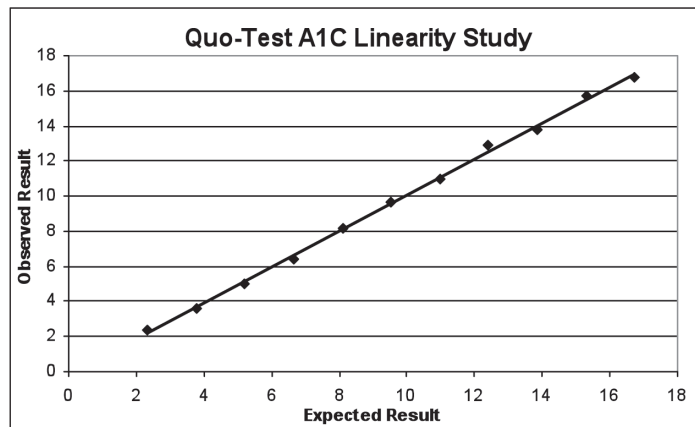
$y = 0.9772x + 0.0801$ $R^2 = 0.9772$ $r = 0.989$

QUO-TEST VS BORONATE AFFINITY HPLC ANALYSER



$y = 0.9699x + 0.2551$
 $R^2 = 0.9885$
 $r = 0.994$

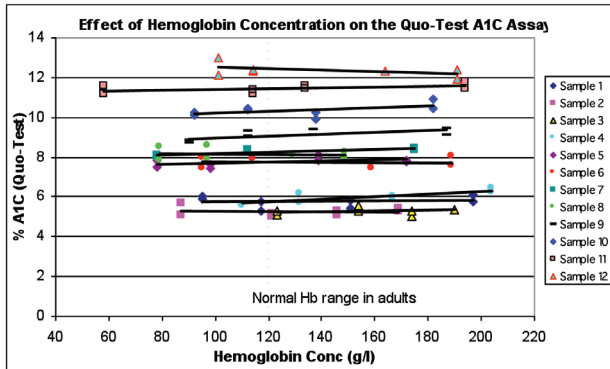
QUO-TEST LINEARITY



$y = 1.0275x - 0.2269$
 $R^2 = 0.9983$
 $r = 0.999$

NO EFFECT OF HEMOGLOBIN CONCENTRATION

- 12 venous samples
- Hemoglobin range from 58 to 204 g/l

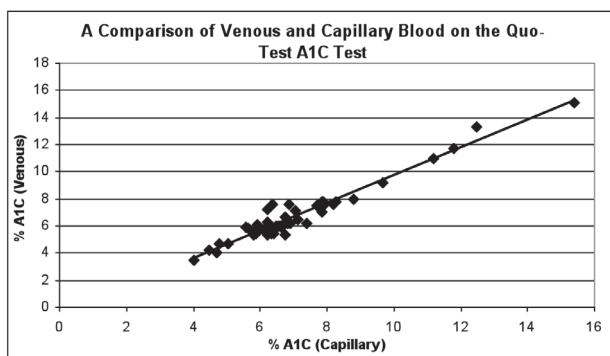


HEMOGLOBIN VARIANTS

The Quo-Test A1c test was found to be unaffected by the following hemoglobin variants:

- Hb S, also known as sickle cell anemia (heterozygote and homozygote)
- Hb AC, Hb AD, Hb AE, Hb AJ, Hb CC, Hb SC, Hb EE
- B-thalassemia
- Elevated fetal hemoglobin: Up to 30%

CAPILLARY VS VENOUS BLOOD



$$y = 1.0235x - 0.4811 \quad R^2 = 0.9431 \quad r = 0.971$$