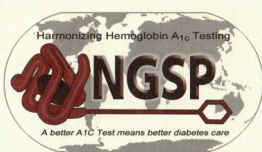


HbA1c Quanti Card

Flourescence based immunoassay (antigen-antibody) for quantitative measurement of HbA1c (glycated hemoglobin) in Human Whole Blood



NGSP CERTIFICATION



Certificate of Traceability

Manufacturer Certification

This certifies that **J. Mitra & Co. Pvt Limited**, using **Fluorescence immunoassay on i-Quant Analyzer** has participated in and successfully completed the NGSP certification for manufacturers and is traceable to the **Diabetes Control and Complications Trial Reference method**. The comparison was performed with: **European Reference Laboratory ESRL#10**

The system evaluated was:

Instrument:
i-Quant Analyzer
Reagent Lot:
HBQ20816

Date of Certification: December 1, 2016

Certification Expires: December 1, 2017

Daniel Sacks
NGSP Steering Committee Chair

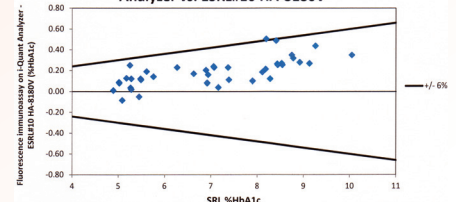
Randee R Little PhD
NGSP Network Coordinator

Chy
SRL director/ supervisor



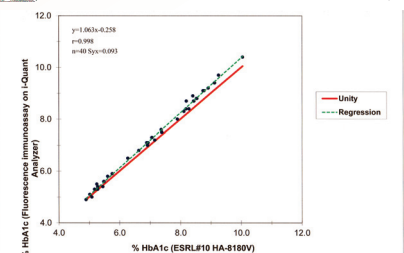
Method Comparison Evaluation Report

Bias Plot: Fluorescence immunoassay on i-Quant Analyzer vs. ESRL#10 HA-8180V



Scatter Plot

J. Mitra & Co. Pvt. Ltd. Fluorescence Immunoassay on iQuant



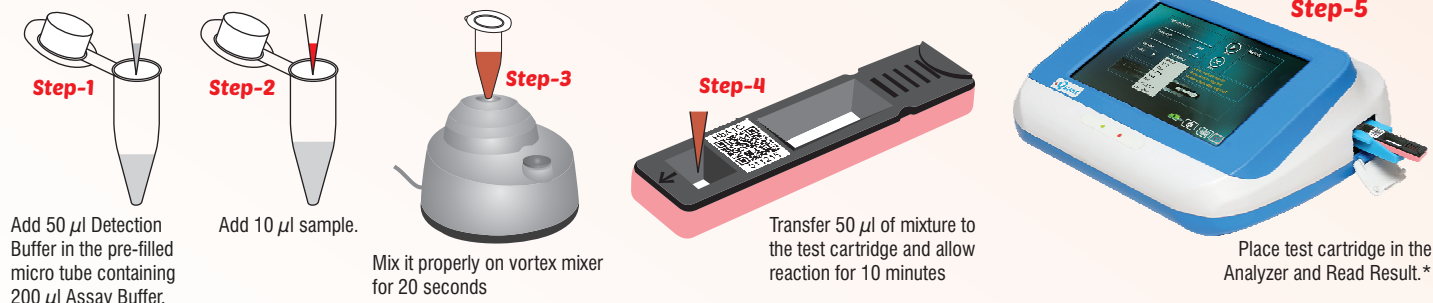
• **ACCURATE** • **EASY** • **FAST** • **RELIABLE**

HbA1c MEASUREMENT TEST KIT

Salient Features:

- ▶ Principle: Based on most advanced fluorescence immunoassay method
- ▶ Certified from NGSP, USA
- ▶ QR Code on each cartridge includes lot specific data, no chip required
- ▶ Individual pouched test cartridge
- ▶ Results within 10 Minutes

Test Procedure



* Result interpretation time, taken by cartridge analyzer for a sample is less than 1 minute, hence more number of tests can be performed in a given time.

Measuring Range

Precision

Within-run and between-run precisions have been determined by testing 10 replicates of 3 HbA1c samples: low, medium & high. The C.V (%) of all the 3 samples was less than 3%.

Accuracy

The HbA1c concentration of 1025 clinical specimens were quantified independently with Quanti HbA1c Card and commercially available NGSP certified kit. The following results were obtained:

Specificity

- ▶ No interference from major hemoglobin variants including HbS, HbC and HbE.
- ▶ No significant interference when other molecules such as Bilirubin (20 mg/ml), Triglyceride (3000 mg/dl) and Glucose (300 mg/ml) were added to the test specimen with much higher



CONVENIENT PACKSIZE:
10 Tests & 50 Tests

For further enquiries, Please contact:

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