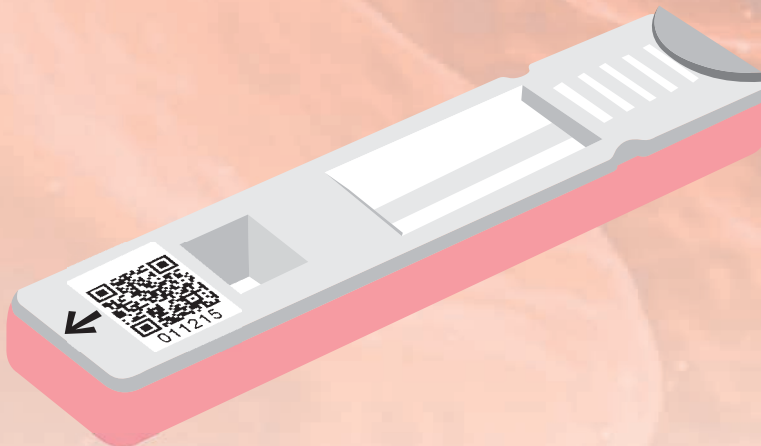




HbA1c Quanti Card

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

.....a vision to serve mankind™



iQuant Analyzer



Developed in partnership with HTIC, IIT Madras

NGSP CERTIFICATION

Result as per NGSP

NGSP Certification Criteria: # within 5% of NGSP Mean	Marks Obtained
36/40	40/40



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
Reagent Lot:
HBQ/XI/030321

Date of Certification: **July 1, 2021**

Certification Expires: **July 1, 2022**

Dink Sarkar
NGSP Steering Committee Chair

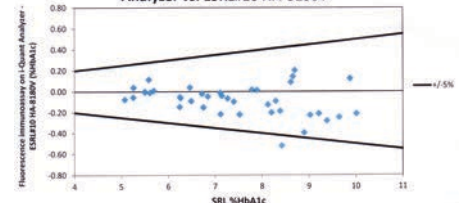
Randee R Little PhD
NGSP Network Coordinator

[Signature]
SRL director/supervisor



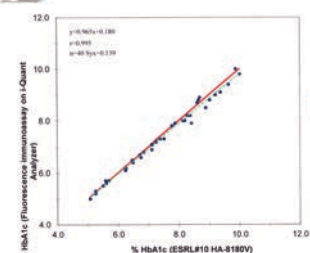
Method Comparison Evaluation Report

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

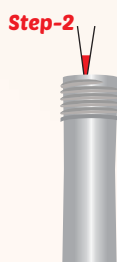
Salient Features:

- 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 15 Minutes
- Long Shelf Life: 24 Months At 2-8°C

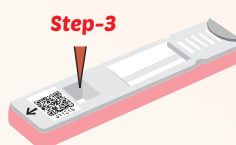
Test Procedure



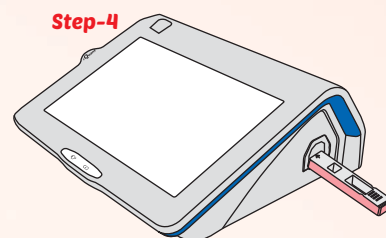
Step-1
Add 200µl of Assay Buffer to HbA1c Conjugate vial & mix it properly on Vortex mixer for 30 seconds



Step-2
Add 10 µl of whole blood to HbA1c Conjugate vial & mix it properly on Vortex mixer for 5-10 seconds



Step-3
Transfer 75 µl of mixture to the test cartridge & insert it into the cartridge slot of dual iHeating Block for 15 minutes.



Step-4
Place test cartridge in the Analyzer and Read Result.*

* 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.

HbA1c Quanti Card comparison with other manufacturers

Parameters	HbA1c Quanti Card	Manufacturer-1	Manufacturer-2
Sample Volume	10 µl	5 µl	5 µl
Sample & Reagent Mixing	By iVortexer (user friendly)	By Hand shaking (not user friendly)	5-6 times mixing by tube
Conjugate	Dried (More Stable)	Liquid (Less Stable)	Dried (More Stable)
Accuracy	Accurate Result less than 5% CV as per NGSP Certification	Results are higher than reference value (CV is more than 6%)	Result are lower than reference value (CV is + 6%)
Measuring Range	4 - 16%	4 - 15%	4 - 15%
Shelf Life	24 months	15 months	18 months
Convenient Packsize	10 Tests & 50 Tests	60 Tests	60 Tests
Price/ test	Economical	Expensive	Expensive

HbA1c Quanti Card is an ideal test kit for quantitative estimation of HbA1c with excellent customer support through iqCloud for pan India.