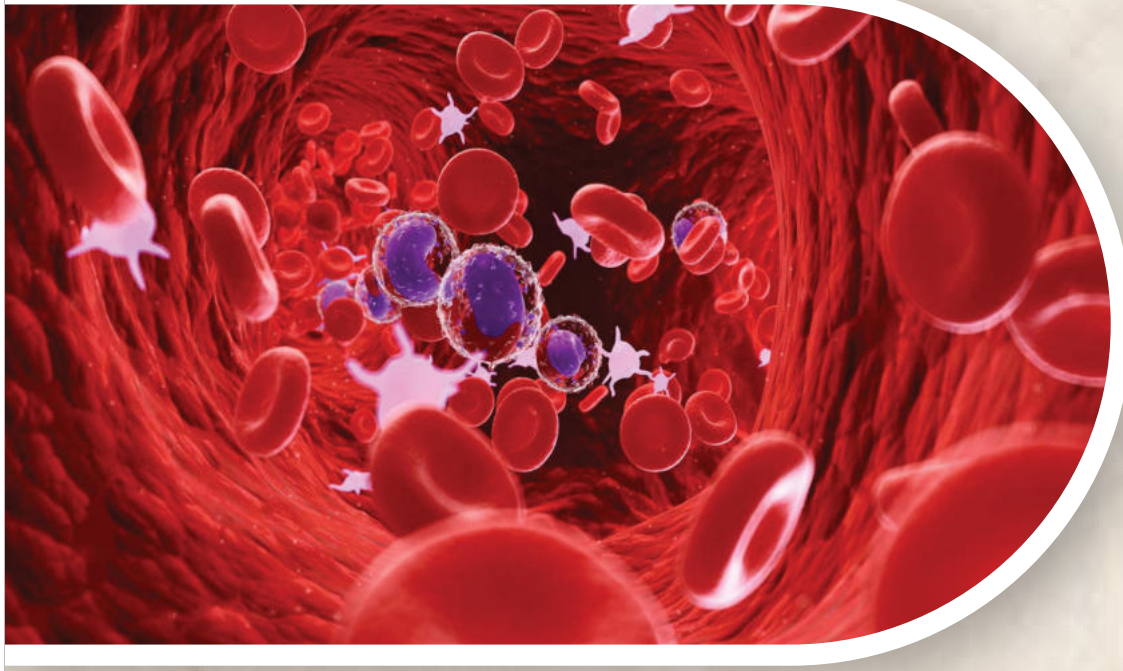




KIVO HBA1C Assay

(Latex Enhanced Turbidimetric Immuno Assay)
(LETIA)



Product Attributes :

- Two Liquid Reagents (3 Parts R1+ 1 Part R2).
- Latex Enhanced Turbidimetric Immuno Assay. (LETIA)
- Available with 4 Level Calibrator and 2 Level Calibrator Formats
- Calibrators are traceable to IFCC reference methods
- Lyophilized 2 level Controls Provided (Optional)
- Linearity: 17% NGSP.
- Measuring wavelength 630 nm.(600-670)
- 10 Minutes Two Step-End Point Method.
(5 Minutes + 5 Minutes)
- High calibration stability of 30 Days.
- Adaptable to multi analyzer platforms
- Applications validated on multiple analyzers
- Total imprecision <4%.
- No interference from the most common other HB Variants
- Excellent correlation with other methods like HPLC, CLIA and Immunofluorescence



KIVO HBA1C Assay

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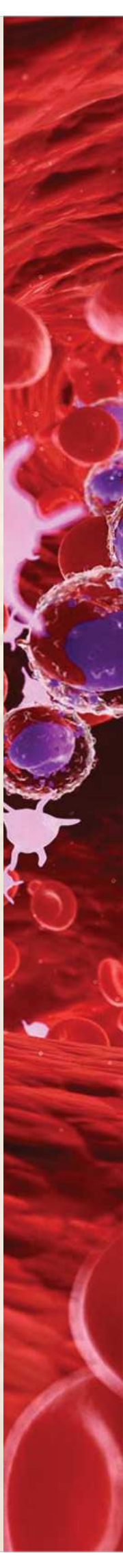
(LETIA)

Diagnostic Significance:

HbA1c is a significant diagnostic marker for Diabetes. HbA1c Latex Enhanced Turbidimetric Immuno Assay (LETIA) is the direct quantitative determination of HbA1c% in human whole blood expressed in NGSP.

The glycation is a non-enzymatic reaction whereby a sugar moiety is linked to the amino groups of proteins. Though numerous human proteins are glycated the glycated hemoglobin is the most widely used analyte in clinical settings for the monitoring of glycemic control mechanisms and treatment of diabetic patients.

Once bound to the red blood cell, the HbA1c circulates for the life span. The research group Diabetes Control and Complications Trial (DCCT) showed a direct relationship between the percentage of HbA1c and the average blood glucose levels over the previous 2-3 months. The DCCT study has also shown that long-term control of diabetes can prevent complications such as cardiovascular disease, retinopathy and neuropathy. A lowering of HbA1c values below 7% has been shown to reduce microvascular and neuropathic complications of type 1 and diabetes type 2. Therefore diabetic patients with HbA1c levels below 7% meet the therapeutic objectives having a good glycemic control



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Although there are several methods for measuring HbA1c Latex Reagents have high repeatability and specificity and are suitable for high throughput simultaneous processing and in addition they are adopted and amenable to all Semi Auto and Fully Auto Analyzers

Results in
NGSP
%

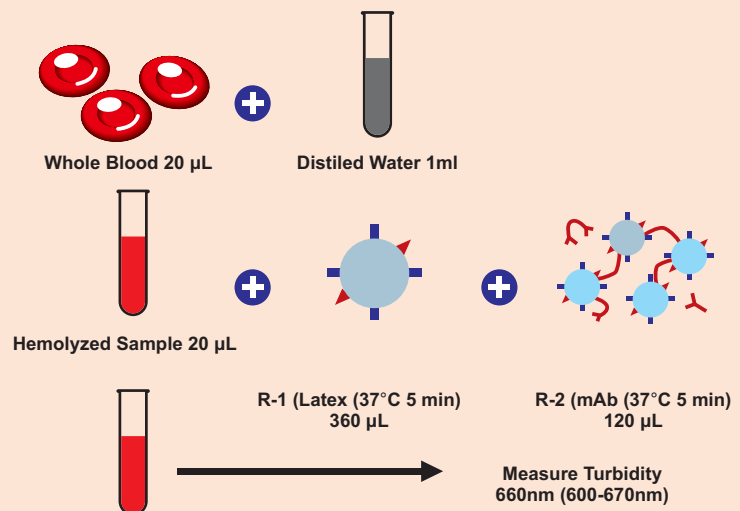
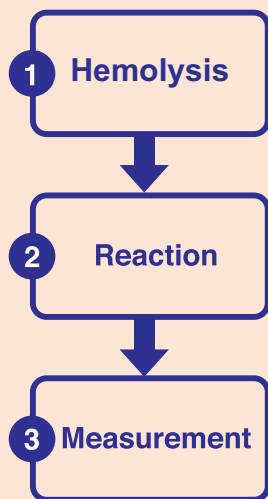
Correlate
with **HPLC**

No
centrifugation
of blood cells
needed

Uses HBA1C
specific
Monoclonal
Antibody

Resistant
to freezing

Principle:





KIVO HBA1C Assay

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(LETIA)

Analytical Performance Data

Reproducibility

	Measure (HBA1C; NGSP %)	
	Sample-Low	Sample-High
1	5.73	13.16
2	5.70	13.31
3	5.70	13.24
4	5.73	13.28
5	5.70	13.30
6	5.71	13.32
7	5.71	13.28
8	5.73	13.27
9	5.72	13.30
10	5.75	13.28
Average	5.72	13.27
S.D.	0.02	0.05
C.V.(%)	0.29	0.35
Max.	5.75	13.32
Min.	5.70	13.16
RANGE	0.05	0.16

Chemistry Analyzer HITACHI 7180

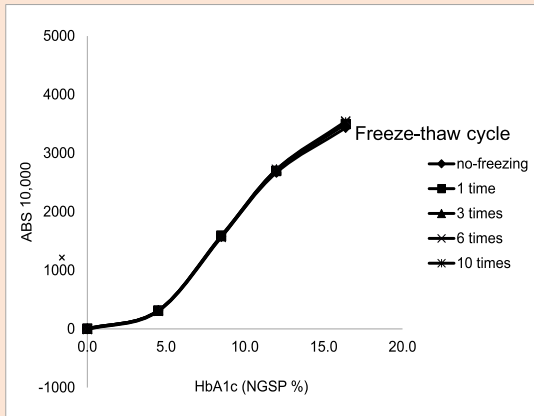
Measurement of CRM

Lot Uncertainty Study		
Level	HbA1c (NGSP)% and expanded uncertainty %	Measure HbA1c (NGSP %)
Level 1	5.10 ±0.13	5.09
Level 2	5.77 ±0.14	5.76
Level 3	7.39 ±0.19	7.35
Level 4	9.60 ±0.23	9.47
Level 5	11.98 ±0.28	11.89

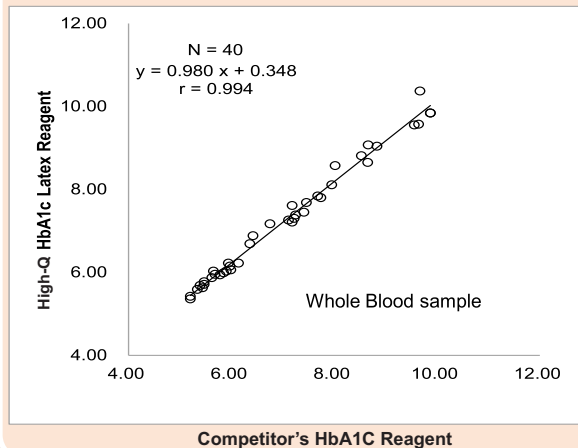
Measurement range

HbA1c (NGSP %) ; 3% □ 17%

Freeze-thaw resistance



Correlation with standard method



Interference Studies

Interference substances up to the following concentrations do not affect the test results.

Interference substance	Concentration
Bilirubin F	20.0 mg/dL
Bilirubin C	21 mg/dL
Chyle	1600 FTU
Hemolytic hemoglobin	520 mg/dL
Reumatoid factor	1200 IU/mL
Ascorbic acid	75 mg/dL

