HAEMOGLOBIN A1C (HBA1C) KIT

Latex-Enhanced Immunoturbidimetric Method

SAWIN BIOMEDICALS PVT LTD.

Product Code: 10030 / 11030	**Reaction Type:** End Point (Increasing)
Pack Size: 20 ml / 40 ml	**Matrix Target:** Human Whole Blood (EDTA)
Storage Temp: 2–8°C (Do Not Freeze)	**Wavelength:** 630 nm (Zero: Reagent Blank)

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This diagnostic reagent system is configured for the direct quantitative in vitro immunoturbidimetric determination of Glycated Haemoglobin (% HbA1c) in human whole blood specimens.

Clinical Significance: Haemoglobin A1c forms from the non-enzymatic attachment of glucose to the haemoglobin beta chain, reflecting average blood glucose levels over a red blood cell's lifespan (approximately 120 days). Diabetic individuals exhibit HbA1c levels 2–3 times higher than non-diabetics, acting as a direct window into long-term glycemic management and therapeutic control efficiency.

METHOD PRINCIPLE

This formulation utilizes latex-enhanced immunoturbidimetry. Total haemoglobin and HbA1c in the hemolysed sample bind at the same rate to the suspended latex particles. Upon addition of R2 (containing mouse anti-human monoclonal antibody and goat anti-mouse IgG polyclonal antibody), specific agglutination complexes develop proportional to the bound HbA1c molecules:

> Latex Particles + Sample HbA1c → Unspecified Coating $\&xrightarrow{[R2\ ext{ Antibodies}]}$ → Immuno-Agglutination Complex (Turbidity)

The resulting structural agglutination is measured photometrically as an absorbance shift at 630 nm. Because total Hb and HbA1c bind to the latex particles at an identical rate, the specific percentage of HbA1c relative to total haemoglobin is directly obtained from a calibrated multi-point tracking curve.

STEP 1: CALIBRATION & HEMOLYSATE PROCESSING MATRIX

Calibrator Reconstitution: Reconstitute the lyophilized 4-level calibrators with exactly 1.0 ml of sterile water. Allow to stand for 30 minutes, swirling occasionally without forming foam. *Important: Do not subject reconstituted calibrators to Step-1 lysing; use them directly.*

Sample Hemolysate Step-1: Mix 500 µl of **R3-Lysing Reagent** with 10 µl of well-mixed whole blood for the Test tube. Wait 5 minutes or until complete lysis is structurally evident. Stable for up to 10 days at 2–8°C.

Reagent / Component Line	Blank (B)	Calibrator (C)	Test (T)
R1 - HbA1c Latex Suspension	750 µl	750 µl	750 µl
Direct Reconstituted Calibrator	—	20 µl	—
Prepared Whole Blood Hemolysate (Step-1)	—	—	20 µl
Distilled Water Baseline	20 µl	—	—
Mix thoroughly and incubate for exactly 5 minutes at 37°C. Then add:			
R2 - HbA1c Buffer Reagent	250 µl	250 µl	250 µl

Operational Directive: Mix well, incubate for exactly 5 minutes at 37°C, and read the absolute absorbance of the Calibrator tracks and Test vectors against the Reagent Blank at 630 nm.

STEP 2: CALCULATIONS & DATA TRACKING

HbA1c Concentration (%) = $[A(Test) / A(Calibrator)] \times Calibrator\ Concentration$

TECHNICAL PARAMETERS & CLINICAL SUPPORT MATRIX

Universal Safeguards	Professional in vitro use only. On-board analyzer reagent stability is restricted to 10 days at 2–10°C. Protect from intense direct light lines. Utilize separate pipette tips to safeguard against multi-point contamination. Contains less than 0.1% sodium azide.
Expected Range	< 6.0% : Non-diabetic Baseline | 6.0% – 7.0% : Good Glycaemic Control 7.0% – 8.0% : Fair Control | > 8.0% : Falsely Elevated / Poor Control
Analytical Linearity	The analytical linearity range spans from 2.0% up to 18.0%. Reagents are stamped up to an 18.0% maximum diagnostic threshold block.

Manufactured by: M/s. SAWIN BIOMEDICALS PVT. LTD.
Plot No: M82/2, Medical Devices Park, Sultanpur, Ameenpur Mandal, Sangareddy Dist-502 319, Hyderabad, Telangana, INDIA.
Phone: +91 8455-240822 / +91 7816 075705 | E-mail: info@sawinbio.com | Web: www.sawinbio.com
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