

HEMOGLOBIN A1C

Turbidimetry

The application parameters comprised here constitute a guide to facilitate the validation of our reagents by the instrument. It is advisable to validate the use when there is any change in software or reagent versions.

Instrument: HITACHI 912

Samples

Capillary or venous blood collected by standard procedures and with heparin or EDTA as anticoagulants.

HbA1C in blood is stable 3 days at 15-25°C, 7 days at 2-8°C and 6 months at -20°C. Freeze once only.

Hemolysate preparation

The calibrators do not require pretreatment.

1. Bring the reagent A to room temperature.
2. Pipette into a test tube:

Blood	10 µL
Reagent (A)	1000 µL

3. Shake thoroughly. Avoid the formation of foam. The hemolysate can be used after the solution has changed color from red to brownish-green (approximately 3 minutes).

The hemolysate is stable 4 hours at 15-25°C, 24 hours at 2-8°C and 6 months at -20°C. Freeze once only.

Reagent preparation

Reagents (A), (B), (C) and (D) are provided ready to use.

HbA1C Standards (S1-S4): Reconstitute with 2.0 mL of distilled water. Stable for 8 hours at 15-25 °C, 2 days at 2-8°C and 3 months at -20°C. Freeze once only.

Hb Reagent 1: Reagent B
HbA1c Reagent 1: Reagent C Reagent 2: Reagent D

Instrument settings

HB

ANALYZE Select Test: HB Test Name: Hemoglobin Assay/Time/Point: End Point / 10 / 15 Analyse cycle time: 10 sec. Diluent/Expiration: Water / 0 Wavelength (Second./Main): 660 / 570 Sample Volume (Normal): 20 / 0 / 0 (Decreased): 10 / 0 / 0 (Increased): 20 / 0 / 0 Reagent (R1) T1: 230 / 0 / ... / 28 (R2) T2: 0 / 0 / ... / 0 (R3) T3: 0 / 0 / ... / 0 (R4) T4: 0 / 0 / ... / 0 Abs. Limit: 32000 – Increase Prozone Limit: -32000 – Lower		CALIBRATION Select Test: HB Calibration Type: Linear Points/Span Point: 2 / 2 Weigh: 0 SD Limit: 0.1 Duplicate Limit: 10 % / 50 Abs Sensitivity Range: -9999 / 9999 S1 Abs. Range: -32000 / 32000																									
RANGE Select Test: HB Report Name: Hemoglobin Name: HB Select Sample Type: Ser/PI Unit: g/dL Data Mode: On board Control Interval: 1000 Instrument Factor (Y=aX+b): a = 1.0 b = 0.0 Expected Ranges Male: ... - ... Female: ... - ... Repeat Range: 1.10 – 40 Technical Range: 1.10 – 40		OTHERS Select Test: HB <table border="1"> <thead> <tr> <th></th> <th>Calib. Code</th> <th>Concentration</th> <th>Position</th> </tr> </thead> <tbody> <tr> <td>(1)</td> <td>...</td> <td>0.0</td> <td>...</td> </tr> <tr> <td>(2)</td> <td>...</td> <td>(*)</td> <td>...</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th></th> <th>Sample volume</th> <th>Diluted</th> <th>Diluent</th> </tr> </thead> <tbody> <tr> <td>(1)</td> <td>20</td> <td>0</td> <td>0</td> </tr> <tr> <td>(2)</td> <td>20</td> <td>0</td> <td>0</td> </tr> </tbody> </table> Blank: Make reagent blank with sodium chloride 154 mmol/L. Calibrator: Standard S4 ... Data entered by the operator (*) Enter S4 Standard value			Calib. Code	Concentration	Position	(1)	...	0.0	...	(2)	...	(*)	...		Sample volume	Diluted	Diluent	(1)	20	0	0	(2)	20	0	0
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HBA1C

<p>ANALYZE</p> <p>Select Test: HBA1C Test Name: Hemoglobin A1C Assay/Time/Point: 2 Point End / 10 / 15 - 31 Analyse cycle time: 10 sec. Diluent/Expiration: Water / 0 Wavelength (Second./Main): 700 / 340 Sample Volume (Normal): 10 / 0 / 0 (Decreased): 5 / 0 / 0 (Increased): 20 / 0 / 0 Reagent (R1) T1: 250 / 0 / ... / 28 (R2) T2: 0 / 0 / ... / 0 (R3) T3: 50 / 0 / ... / 28 (R4) T4: 0 / 0 / ... / 0 Abs. Limit: 32000 - Increase Prozone Limit: -32000 - Lower</p> <p>RANGE</p> <p>Select Test: HBA1C Report Name: Hemoglobin A1C Name: HBA1C Select Sample Type: Ser/PI Unit: g/dL Data Mode: On board Control Interval: 1000 Instrument Factor (Y=aX+b): a = 1.0 b = 0.0 Expected Ranges Male: ... - ... Female: ... - ... Repeat Range: 0.05 - 2.5 Technical Range: 0.05 - 2.5</p>	<p>CALIBRATION</p> <p>Select Test: HBA1C Calibration Type: Logit-Log (4P) Points/Span Point: 5 / 4 Weigh: 0 SD Limit: 250 Duplicate Limit: 10% / 50 Abs Sensitivity Range: -9999 / 9999 S1 Abs. Range: -32000 / 32000</p> <p>OTHERS</p> <p>Select Test: HBA1C</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 20%; text-align: center;"><i>Calib. Code</i></th> <th style="width: 20%; text-align: center;"><i>Concentration</i></th> <th style="width: 15%; text-align: center;"><i>Position</i></th> </tr> </thead> <tbody> <tr><td>(1)</td><td style="text-align: center;">...</td><td style="text-align: center;">0.00</td><td style="text-align: center;">...</td></tr> <tr><td>(2)</td><td style="text-align: center;">...</td><td style="text-align: center;">*</td><td style="text-align: center;">...</td></tr> <tr><td>(3)</td><td style="text-align: center;">...</td><td style="text-align: center;">*</td><td style="text-align: center;">...</td></tr> <tr><td>(4)</td><td style="text-align: center;">...</td><td style="text-align: center;">*</td><td style="text-align: center;">...</td></tr> <tr><td>(5)</td><td style="text-align: center;">...</td><td style="text-align: center;">*</td><td style="text-align: center;">...</td></tr> </tbody> </table> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 20%; text-align: center;"><i>Sample volume</i></th> <th style="width: 20%; text-align: center;"><i>Diluted</i></th> <th style="width: 15%; text-align: center;"><i>Diluent</i></th> </tr> </thead> <tbody> <tr><td>(1)</td><td style="text-align: center;">10</td><td style="text-align: center;">0</td><td style="text-align: center;">0</td></tr> <tr><td>(2)</td><td style="text-align: center;">10</td><td style="text-align: center;">0</td><td style="text-align: center;">0</td></tr> <tr><td>(3)</td><td style="text-align: center;">10</td><td style="text-align: center;">0</td><td style="text-align: center;">0</td></tr> <tr><td>(4)</td><td style="text-align: center;">10</td><td style="text-align: center;">0</td><td style="text-align: center;">0</td></tr> <tr><td>(5)</td><td style="text-align: center;">10</td><td style="text-align: center;">0</td><td style="text-align: center;">0</td></tr> </tbody> </table> <p>Blank: Make reagent blank with sodium chloride 154 mmol/L. (*) Calibrators 2-5: Standards S1-S4 ... Data entered by the operator</p>		<i>Calib. Code</i>	<i>Concentration</i>	<i>Position</i>	(1)	...	0.00	...	(2)	...	*	...	(3)	...	*	...	(4)	...	*	...	(5)	...	*	...		<i>Sample volume</i>	<i>Diluted</i>	<i>Diluent</i>	(1)	10	0	0	(2)	10	0	0	(3)	10	0	0	(4)	10	0	0	(5)	10	0	0
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Version 0704

CALCULATION

$$\% \text{HbA}_{1c} - \text{IFCC} = \frac{\text{HbA}_{1c} (\text{g/dL})}{\text{Hb} (\text{g/dL})} \times 100$$

The HbA_{1c} percentage in the sample is calculated using the following general formula. The values are traceable to IFCC Reference Method:

The traceable values to Reference Method as described by the US National Glycohemoglobin Standardization Program (NGSP) are calculated using the following general formula:

$$\% \text{HbA}_{1c} - \text{NGSP} = 0.915 \times \% \text{HbA}_{1c} - \text{IFCC} + 2.15$$