*quantex* $HbA_{1c}$

**Kit Configuration**

| | |
|---|---|
| P/N 3000-2314 | 1 x 50 mL HbA1c (Diluent) |
| | 1 x 28 mL Hb R1 |
| | 1 x 14 mL HbA1c R1 |
| | 1 x 14 mL HbA1c R2 |

**Reagent Preparation**

| | | |
|---|---|---|
| P/N 3000-2314 | HbA1c (Diluent): | Ready to use |
| | Hb R1: | Ready to use. Invert to mix well before first use. Avoid foam formation. |
| | HbA1c R1: | Ready to use. Invert to mix well before first use. Avoid foam formation. |
| | mL HbA1c R2: | Ready to use. Invert to mix well before first use. Avoid foam formation. |

Place the bottles into reagent tray.

**In Use Stability**

For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.

**Specimen**

Whole blood or capillary blood samples.

**Calibration**

Use quantex HbA1c standard multipoint Cat. No 3000-2315.
Calibration of the quantex Hb hemoglobin reagent is performed with quantex HbA1C standard level 1 only.
Calibration of the quantex HbA1C reagents R1 and R2 is performed with quantex HbA1C standards levels 1 to 6.
The concentrations are indicated in the insert sheet. A reagent blank should be run daily before sample analysis. Recalibrate every 20 days or when a new lot of reagent is used.

**Quality Control**

Use quantex HbA1c Control I/II Cat. No.3000-2316.

**Calculation of Analytical Results**

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 600/650 Operator's Manual.

**Reference Interval**

Depending on the assay used, HbA1C is approximately 4-6% in non diabetics, 6-8% in controlled diabetics, and can be as much as 20% in uncontrolled diabetics. 124 apparently normal healthy donors undergoing physical examination were tested for HbA1C using the quantex HbA1C reagents. The range of results of HbA1C was of 4.5-6.2% and a mean of 5.4% resulted.
In any case, it is recommended that each laboratory established its own expected range.

**References / Literatur / Bibliografía / Bibliographie / Bibliografia /**

See package insert enclosed in the kit

## Performance Characteristics

**Limitation/Interfering Substances**

No significant interference from triglycerides up to concentrations of 1600 mg/dL (18 mmol/L) , bilirubin up to concentrations of 30 mg/dL (513 μmol/L) and rheumatoid factor up to 2000 IU/mL. For a comprehensive review of interfering substances, refer to the publication by Young *et al.*[1]

**Linearity**

Total Hb : 7 to 23 g/dL
% HbA1C : 1.8% to 17.2% (for total Hb of 14 g/dL)
Samples with values above 17.2% of HbA1C should not be diluted and results should be reported as > 17.2% HbA1C.



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*quantex* $HbA_{1c}$

# Instrument Settings

| ***Photometric Test Parameters*** | | ***HbA1c*** | ***Hb Total*** |
|---|---|---|---|
| Test No. | | ** | ** |
| Test Name, Test Code | | HbA1c,HbA1c | THb |
| Sample Type | | Others | Others |
| Reporting Unit, Decimal Points | | g/dL, 2 | g/dL, 2 |
| Reation Cycle | | Standard | Standard |
| Twin Analysis | | OFF | OFF |
| Methodology Type, Measuring Point | | End Point, 19/26 | End Point, 17 |
| Photometric Methodology | | 1 Wavelength | 1 Wavelength |
| Primary/Secondary Wavelenght | | 700 | 600 |
| ***Sampling Conditions*** | | | |
| *Sampling 1* | Sample Vol. | 4 | 15 |
| | Sample/Diluent Vol. | 0/0 | 0/0 |
| *Sampling 2* | Sample Vol. | 2 | 5 |
| | Sample/Diluent Vol. | 0/0 | 0/0 |
| *Sampling 3* | Sample Vol. | 8 | 30 |
| | Sample/Diluent Vol. | 0/0 | 0/0 |
| *Sampling 4* | | *** | *** |
| Diluent Code | | Saline | Saline |
| Diluent Warning Limit | | *** | *** |
| First Run | | Sampling 1 | Sampling 1 |
| Below/Above Normal Range | | *** | *** |
| Panic L | | *** | *** |
| Panic H | | Sampling 2 | Sampling 2 |
| Noise | | *** | *** |
| Prozone | | N/A | N/A |
| High!, ABS! | | Sampling 2 | Sampling 2 |
| Sample Volume Reduction | | ** | ** |
| ***Reagent Volumes*** | | | |
| R1 | Code | 01981 | 01971 |
| | Rgt/Dil. Vol. Stirring | 95/5, ON | 195/5, ON |
| | Low Vol. Warning Limit | *** | *** |
| | Stability (days) | ** | ** |
| R2 | Code | 01982 | N/A |
| | Rgt/Dil. Vol. Stirring | 95/5, ON | N/A |
| | Low Vol. Warning Limit | *** | N/A |
| | Stability (days) | ** | N/A |

| ***Ranges and Evaluation Criteria*** | ***HbA1c*** | ***Hb Total*** |
|---|---|---|
| Normal Range-Male | ** | ** |
| Normal Range-Female | ** | ** |
| Normal Range-Other | ** | ** |
| Valid Range | 0 - 2.4 | 0-23 |
| Hemolysis/Icterus/Lipemia Limit | *** | *** |
| Reaction Slope | Positive | Positive |
| Absorbance Limit | Above, 3200 | Above, 3200 |
| Prozone Limit | N/A | N/A |
| Non Linear Limit | N/A | N/A |
| Slope/Intercept Correction | 1/0 | 1/0 |
| Qualitative Report | OFF | OFF |
| ***Calibration Conditions*** | | |
| Calibration | 6 Points, point to point, 2 Reps | 1 Point, Linear, 3 Reps |
| Stability (days) | 20 | *** |
| Calibrator, Concentration | HbA1c Std, *. | Hb Std, *. |
| R-Blank Limit (mAbs) | 1800 | 100 |
| Cal. Reps Range (%) | *** | *** |
| Min Cal. Response (mAbs) | *** | *** |
| Cal. Factor Change (%) | *** | *** |
| M-Point Curve Fit (%) | N/A | N/A |
| Reagent Blank | ON | ON |
| Auto R-Blank by Bottle | ON | ON |

| **Calculated Test Parameters** | |
|---|---|
| Test n° | ** |
| Test Name, Test Code | %HbA1c, %HbA1c |
| Sample Type | N/A |
| Reporting Unit, Decimal Points | %, 2 |
| Equation | ([ HbA1c] / [Hb]) * 100 |
| Normal Range Male | ** |
| Normal Range Female | ** |
| Normal Range Others | ** |
| Valid Range | 1.8 - 17.2 |

* Lot dependent
** operator definable
*** optional
N/A not applicable to this test



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