

## DIRECT ENZYMATIC HbA1c

### SINGLE CHANNEL ASSAY IFCC CERTIFIED

510(k) Cleared   
Health Canada Registered

#### **RELIABLE AND ACCURATE REGARDLESS OF THE PATIENTS HEMOGLOBIN VARIANT TYPE**

- Diazyme's enzymatic HbA1c virtually eliminates interference from hemoglobin variants
- The assay's unique enzymatic methodology directly measures glycosylated hemoglobin and is resistant to interference from post transcript modifications

#### **PRECISE AND ACCURATE TEST RESULTS**

- The assay correlates with Tosoh HPLC and Roche Tina-Quant methods
- Inter and Intra CV's  $\leq 1.8\%$  across the entire linear range of 4% - 12%

#### **SINGLE CHANNEL ASSAY OPTIMIZED FOR CONVENIENCE WITH HIGH THROUGHPUT INSTRUMENTATION**

- A single instrument channel needed without a separate channel test for total hemoglobin
- Eliminates latex particle build up, thereby reducing instrument maintenance requirements
- Reagent transfer can be eliminated for most chemistry systems
- Instrument specific packaging for analyzers include:
  - Roche Hitachi 917 Series
  - Olympus AU (400/600/640/680)
  - Beckman Synchron (CX, LX and DX)

#### **COST EFFECTIVE**

- Diazyme's direct enzymatic HbA1c assay has performance advantages over conventional immunoassay and chromatography methods, making it cost effective
- Minimum maintenance reporting and improved workflow
- Low reagent cost per test for virtually all laboratories





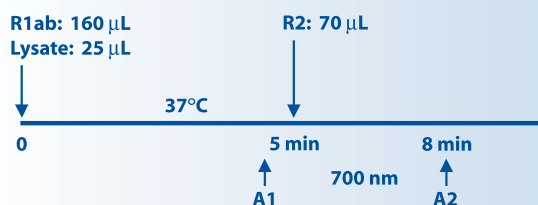
## Direct Enzymatic HbA1c

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## SINGLE CHANNEL ASSAY

<b>Method</b>	Single channel enzymatic
<b>Correlation to HPLC Method</b>	<ul style="list-style-type: none"> <li>• N = 44</li> <li>• R<sup>2</sup> = 0.9874</li> <li>• Slope = 1.0212</li> <li>• y Intercept = 0.0135</li> </ul>
<b>Linearity</b>	4.0% - 12.0%
<b>On-Board Stability</b>	Four weeks
<b>Calibration Interval</b>	One week
<b>Calibration</b>	Two point
<b>Sample Type</b>	<ul style="list-style-type: none"> <li>• Whole Blood</li> <li>- EDTA</li> </ul>
<b>Results Format</b>	Can be expressed in IFCC preferred nomenclature

### Assay Method



This diagram is for a 2-reagent system

Parameter questions for Direct Enzymatic HbA1c assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email [support@diazyme.com](mailto:support@diazyme.com)

### EFFICIENT AND CONVENIENT

- Single channel assay eliminates the need for a dedicated channel for total hemoglobin measurement
- Fully enzymatic, no latex particle residue to cloud cuvettes
- Liquid stable with a variety of instrument specific packaging options for Roche Hitachi, Beckman Synchron and Olympus Chemistry Analyzers

### RELIABLE AND ACCURATE

- No interference from major hemoglobin variants including HbS, HbC, HbE
- No interference from carbamylated Hb, acetylated Hb or labile HbA1c
- IFCC certified, excellent correlation to HPLC and Immunochemical methods

### PRECISE

- CV's ≤ 1.8% - from 4% to 12% HbA1c

### Precision per NCCLS-EP-5

	Level 1: (% HbA1c)	Level 2: (% HbA1c)
<b>Mean</b>	5.7%	10.3%
<b>Within-Run SD</b>	0.06	0.07
<b>Within-Run CV%</b>	1.0%	0.7%
<b>Total SD</b>	0.10	0.18
<b>Total CV%</b>	1.8%	1.8%

### DIAZYME LABORATORIES

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