Diazyme’s Direct Enzymatic HbA1c assay is a cost effective single channel assay that is ideal for labs requiring a high throughput HbA1c method. The Diazyme Direct Enzymatic HbA1c assay is resistant to interference from variant hemoglobins and post transcript modifications which can impact the accuracy of other HbA1c assays. High throughput is obtained using a patented single channel method which eliminates the need for a dedicated channel for total hemoglobin thereby improving assay precision and turnaround time. This test provides the added convenience of instrument specific packaging options and multiple parameter applications for laboratory simplification and implementation.

**DIAZYME DIRECT ENZYMATIC HbA1c ASSAY ADVANTAGES**

- Single channel assay eliminates the need for a dedicated channel for total hemoglobin measurement
- IFCC certified with excellent correlation to Tosoh HPLC and Roche Tina-Quant methods
- Fully enzymatic, no latex particle residue to cloud cuvettes
- Virtually eliminates interference from hemoglobin variants HbS, HbC, HbE
- Directly measures glycated hemoglobin and is resistant to interference from post transcript modifications
- Liquid stable reagent requires no reagent preparation, saving time and reducing sample handling

**REGULATORY STATUS**

510(k) Cleared  
Health Canada Registered

**AVAILABLE INSTRUMENT SPECIFIC PACKAGING**

- Beckman  
  - Synchron  
  - AU Series
- Roche  
  - Hitachi
- Siemens  
  - Dimension
ASSAY SPECIFICATIONS

<table>
<thead>
<tr>
<th>Method</th>
<th>Single Channel Enzymatic</th>
</tr>
</thead>
</table>
| Sample Type & Volume    | Sample Type: EDTA Whole Blood  
Sample Volume: 25 μL |
| Method Correlation      | N = 44  
Y = 0.0135  
Slope = 1.0212  
R² = 0.9874  
HPLC Method |
| Linear Range            | 4 - 12% |
| LOD                     | 1.94 %HbA1c |
| Calibration Levels      | 2-Point Calibration |
| Reagent On-Board Stability | Opened:  
4 weeks when stored at 2-8°C |

**ASSAY PRECISION**

**Precision per NCCLS–EP-5**

<table>
<thead>
<tr>
<th>Level 1: (% HbA1c)</th>
<th>Level 2: (% HbA1c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>5.7%</td>
</tr>
<tr>
<td>Within-Run SD</td>
<td>0.06</td>
</tr>
<tr>
<td>Within-Run CV%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Total SD</td>
<td>0.10</td>
</tr>
<tr>
<td>Total CV%</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

**ASSAY INTERFERENCE**

This assay is not affected by the following interfering substances at the indicated concentrations:

- Ascorbic Acid: 12 mg/dL
- Triglyceride: 4000 mg/dL
- Bilirubin: 15 mg/dL
- Bilirubin Conjugated: 13 mg/dL
- Uric Acid: 30 mg/mL
- Glucose: 4000 mg/dL
- Urea: 80 mg/mL

Stable glycated hemoglobin serves as a substrate for enzymatic reaction used in the Diazyme Direct Enzymatic HbA1c Assay. Acetylated, carbamylated and labile HbA1c does not adversely affect the enzymatic reaction used in this assay. Variant hemoglobin S, C and E do not significantly interfere with Diazyme Direct Enzymatic HbA1c Assay.

**ASSAY REFERENCE RANGE**

The American Diabetes Association (ADA) criteria for testing HbA1c to diagnose diabetes is listed in the following table:

<table>
<thead>
<tr>
<th>Category</th>
<th>HbA1c Range (NGSP/DCCT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;5.7%</td>
</tr>
<tr>
<td>Prediabetes (increased risk for diabetes)</td>
<td>5.7% - 6.4%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>&gt;6.5%</td>
</tr>
</tbody>
</table>

The HbA1c value can be found at as low as 4.0% in healthy population. The American Diabetes Association recommends that a reasonable diabetes treatment goal for many nonpregnant adults is <7.0% HbA1c. However, each laboratory should establish its own reference range and HbA1c goal in their country of business taking into account sex, age, ethnicity and individual patient situation.

**DIAZYME LABORATORIES**

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