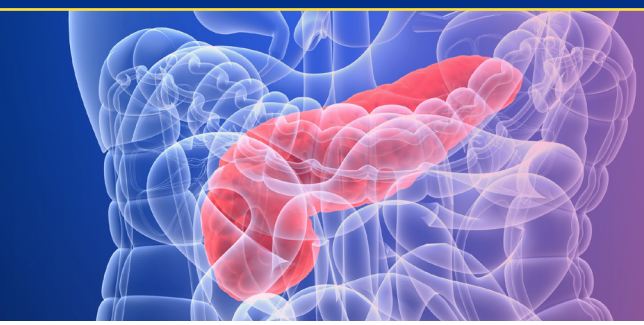
DIRECT ENZYMATIC HBA1C ASSAY

Diabetic Marker



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 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 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; EU: CE IVD;

Health Canada Registered

DIAZYME

Innovations in Clinical Diagnostics

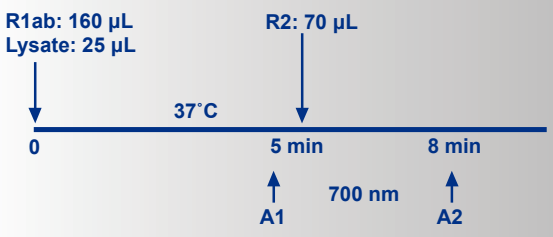
DIRECT ENZYMATIC HBA1C ASSAY

Single Channel
Liquid Stable

ASSAY SPECIFICATIONS

Method	Single Channel Enzymatic
Sample Type & Volume	• EDTA Whole Blood Sample Volume 25 µL
Method Correlation	N = 44 Y = 0.0135 Slope = 1.0212 R^2 = 0.9874 HPLC Method
Linearity	4 - 12%
LOD	1.94 %HbA1c
Calibration Levels	2-Point Calibration
Reagent On-Board Stability	Opened: 4 weeks when stored at 2-8°C

Direct Enzymatic HbA1c Assay Procedure*



***Analyzer Dependent**

Parameter questions for Direct Enzymatic HbA1c Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

1. *American Diabetes Association. Standards of medical care in diabetes — 2015. Diabetes Care 2015; 38(suppl 1): S1-S93*
2. *Sacks DB (ed). Global harmonization of hemoglobin A1c. Clinical Chemistry 2005; 51(4): 681-683*
3. *Steffes M, et al. Hemoglobin A1c measurements over nearly two decades: sustaining comparable values throughout the diabetes control and complications trial and the epidemiology of diabetes interventions and complications study. Clinical Chemistry 2005; 51(4):753-758*

ASSAY PRECISION

Precision per NCCLS–EP-5

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

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 diabetes1 is listed in the following table:

Category	HbA1c Range (NGSP/DCCT)
Normal	<5.7%
Prediabetes (increased risk for diabetes)	5.7% - 6.4%
Diabetes	≥6.5%

The HbA1c value can be found at as low as 4.0% in healthy population.2,3 The American Diabetes Association recommends that a reasonable diabetes treatment goal for many nonpregnant adults is <7.0% HbA1c.1 However, each laboratory should establish its own reference range and HbA1c goal in their contry of business taking into account sex, age, ethnicity and individual patient situation.

DIAZYME LABORATORIES, INC.
12889 Gregg Court, Poway, CA 92064 USA
PO Box 85608, San Diego, CA 92186 USA
Tel: +1-858-455-4768 +1-888-DIAZYME
www.diazyme.com sales@diazyme.com

DIAZYME EUROPE GMBH
Zum Windkanal 21, 01109 Dresden, Germany
Tel: +49-351-886-3300 Fax: +49-351-886-3366
sales@diazyme.de

DIAZYME SHANGHAI CO., LTD.
Room 201,1011 Halei Road, Zhangjiang Hi-tech Park
Shanghai, 201203, People's Republic of China
Tel: +86-21-51320668 Fax: +86-21-51320663
www.lanyuanbio.com service@lanyuanbio.com