DIAZYME

DIABETIC MARKER

DIRECT HbA1c ASSAY (ENZYMATIC, ON-BOARD LYSIS)

Dual Vial Liquid Stable

This unique single channel assay is ideal for labs requiring a high throughput HbA1c method with no off-line pretreatment steps. Diazyme's HbA1c Assay (Enzymatic, On-Board Lysis) offers enhanced precision and 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 turnaround time, precision and provides the added convenience of instrument specific packaging options.

DIAZYME DIRECT HbA1c ASSAY (ENZYMATIC, ON-BOARD LYSIS) ADVANTAGES

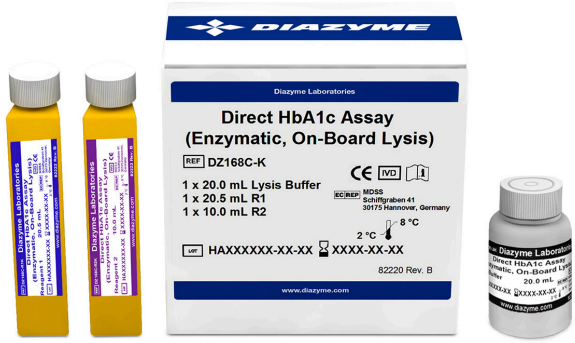
- NGSP certified and traceable to the Diabetes Control and Complication Trial Reference (DCCT) Method
- Single channel assay eliminates the need for a dedicated channel for total hemoglobin measurement
- On-board lysis allows for a faster, more efficient process
- Fully enzymatic, no latex particle residue to cloud cuvettes
- Virtually eliminates interference from hemoglobin variants
- 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

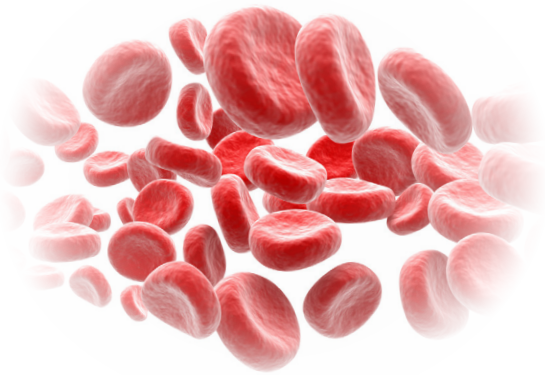
REGULATORY STATUS

510(k) Cleared; EU: CE IVD; Health Canada Registered

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Modular P
- **Beckman**
  - AU Series





DIRECT HBA1C ASSAY (ENZYMATIC, ON-BOARD LYSIS)

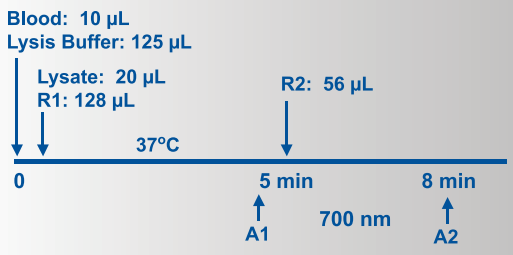
Dual Vial Liquid Stable

DIAZYME

ASSAY SPECIFICATIONS

Method	Enzymatic Assay
Sample Type & Volume	• EDTA Whole blood with on-board blood lysis application Sample Volume: 10 µL of whole blood
Method Correlation	Linear Regression N = 374 y-intercept = -0.090 Slope = 1.023 R^2 = 0.9937 Sample Range = 4.2 - 12.0
Linear Range	4 - 12% HbA1c
LOB ***LOD*** ***LOQ***	0.2% 0.5% 0.8%
Calibration Levels	2-Point Calibration
Reagent On-Board Stability	Opened: 4 weeks when stored at 2-8°C (Analyzer Dependent)

*Direct HbA1c Assay (Enzymatic, On-Board Lysis) Procedure**



***Analyzer Dependent**

For a list of validated parameters please contact Diazyme technical support at 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 dec-ades: 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

The precision of the Diazyme Direct HbA1c Assay was evaluated according to CLSI EP5-A2 guideline. In the study, 5 whole blood samples were tested in duplicates per run, 2 runs per day over 20 working days with three lots of reagents. The results of the within-run, between-run, between-day, between-lot, and total CV% for three lots of the reagents combined are listed in the following table (N =240).

Sample		S1	S2	S3	S4	S5
Mean (%)		4.64	5.36	7.51	9.61	11.89
Within-Run	SD	0.04	0.05	0.05	0.06	0.09
	%CV	0.8%	0.9%	0.6%	0.6%	0.7%
Between-Run	SD	0.07	0.05	0.05	0.05	0.08
	%CV	1.5%	0.9%	0.7%	0.5%	0.6%
Between-Day	SD	0.00	0.00	0.00	0.03	0.04
	%CV	0.0%	0.0%	0.0%	0.3%	0.4%
Between-Lot	SD	0.08	0.07	0.07	0.08	0.12
	%CV	1.6%	1.2%	0.9%	0.9%	1.0%
Total	SD	0.08	0.07	0.07	0.08	0.12
	%CV	1.7%	1.2%	0.9%	0.9%	1.0%

Multi-site precision study was performed at Diazyme Laboratories and two external sites on Modular P analyzers. In this study, the same set of 5 whole blood samples were tested in duplicates per run, 2 runs per day for 5 working days with one lot of reagent at three different testing sites, by three different operators on three different Modular P analyzers. The results of the within-run, between-run, between-day, between-site, and total CV% for the three sites combined are listed in the following tables (N =60):

Sample		S1	S2	S3	S4	S5
Mean (%)		4.67	5.37	7.52	9.67	11.92
Within-Run	SD	0.05	0.04	0.05	0.07	0.09
	%CV	1.0%	0.8%	0.7%	0.8%	0.8%
Between-Run	SD	0.04	0.05	0.06	0.11	0.09
	%CV	0.8%	1.0%	0.8%	1.1%	0.8%
Between-Day	SD	0.02	0.00	0.00	0.00	0.06
	%CV	0.5%	0.0%	0.0%	0.0%	0.5%
Between-Site	SD	0.07	0.06	0.07	0.12	0.14
	%CV	1.4%	1.2%	0.9%	1.3%	1.2%
Total	SD	0.07	0.07	0.08	0.13	0.14
	%CV	1.4%	1.2%	1.0%	1.4%	1.2%

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

DIAZYME EUROPE GMBH
Zum Windkanal 21, 01109 Dresden, Deutschland
Tel. +49 (0) 351 886 3300 Fax +49 (0) 351 886 3366
sales@diazyme.de

SHANGHAI DIAZYME CO., LTD.
Room 201,1011 Halei Road, Zhangjiang Hi-tech Park
Shanghai, 201203, People's Republic of China
Tel: 086-21-51320668 Fax: 086-21-51320663
www.lanyuanbio.com service@lanyuanbio.com