

DIRECT HBA1C ASSAY (ENZYMATIC, ON-BOARD-LYSIS)



Diabetic
Marker

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 provided 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:  

Health Canada Registered

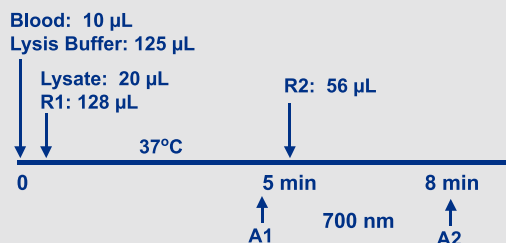
DIRECT HbA1C ASSAY (ENZYMATIC, ON-BOARD LYSIS)

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

| | |
|-----------------------------------|---|
| Method | Enzymatic Assay |
| Sample Type & Volume | <ul style="list-style-type: none"> EDTA Whole blood with onboard blood lysis application Sample Volume: 10 μ L 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 | 0.2% |
| LOD | 0.5% |
| LOQ | 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

- American Diabetes Association. Standards of medical care in diabetes-2015. *Diabetes Care* 2015; 38(suppl 1): S1-S93
- Sacks DB (ed). Global harmonization of hemoglobin A1c. *Clinical Chemistry* 2005; 51(4): 681-683
- 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-Lot | 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% |

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