BETA-HYDROXYBUTYRATE ASSAY

The body uses glucose as the primary fuel for meeting its energy needs. However, when the body's energy requirements are greater than its supply of glucose or the body is not able to properly use glucose as in diabetes the body burns fat as an alternative energy source. The burning of fat (fatty acids) leads to the production of ketones (Ketone bodies).[1] In health individuals, there is a constant production of ketone bodies by the liver which in turn are utilized in the tissues and broken down into carbon dioxide and water. The production and use of ketones leads to a low constant level < 0.5 mmol/L in the blood and their excretion in urine is very low and undetectable by routine urine tests. When the rate of synthesis of ketone bodies exceeds the rate of utilization, their concentration in blood increases; this is known as ketonemia. This is followed by ketonuria – excretion of ketone bodies in urine. The overall picture of ketonemia and ketonuria is commonly referred as ketosis. In ketosis the liver breaks down fatty acids into the three ketone bodies β-Hydroxybutyrate, Acetoacetate and acetone.[2]

DIAZYME BETA-HYDROXYBUTYRATE ASSAY ADVANTAGES

- Quantitative results
- Enzymatic method for accurate determination of beta-hydroxybutyrate
- Lower detection limit (0.006 mmol/L) than other commercially available assays
- Liquid stable reagent, calibrator, and controls requiring no additional preparation
- Applications available for chemistry analyzers

REGULATORY STATUS

510(k) Exempt

EU: CE IVD

DIAZYME

Innovations in Clinical Diagnostics

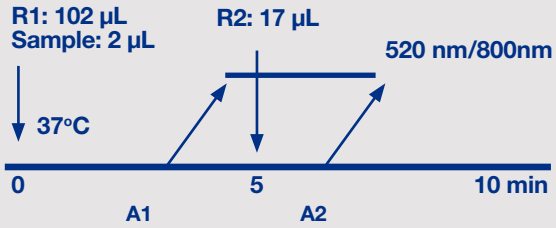
BETA-HYDROXYBUTYRATE ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Enzymatic Colorimetric
Sample Type & Volume	• Serum or plasma Sample Volume 2 µL
Method Comparison	N = 46 y-Intercept = -0.0233 Slope = 0.948 R^2 = 0.9984
Linearity	Up to 4.5 mmol/L
LOD	0.006 mmol/L
Calibration Levels	1-Point Calibration
Reagent On-Board Stability	4 weeks when kept stored at 2-8°C

BHB Assay Procedure*



***Analyzer Dependent**

Parameter questions for BHB assay should be addressed to Diazyme Technical Support. Please call 858-455-4768 or email support@diazyme.com

1. Tietz Textbook of Clinical Chemistry. Edited by CA Burtis, ER Ashwood. Philadelphia, WB Saunders Co. 1999
2. Taboulet P, Deconinck N, Thurel A, Haas L, Manamani J, Porcher R, Schmit C, Fontaine JP, Gautier JF. Correlation between urine ketones (acetoacetate) and capillary blood ketones (3-beta-hydroxybutyrate) in hyperglycaemic patients. Diabetes Metab. 2007 Apr;33(2):135-9. doi: 10.1016/j.diabet.2006.11.006. Epub 2007 Feb 21. PMID: 17320448.

ASSAY PRECISION

Precision studies were conducted using four serum samples and two levels of BHB controls. Samples were tested in duplicate per run, 2 runs per day for 12 days using two lots of the reagents. The results of the within-run, between-run, between-day, between-lot, and total CV% for two lots of the reagent combined are listed in the following table (N=96):

	Mean (mmol/L)	Within-Run SD CV%	Between-Run SD CV%	Between-Day SD CV%	Between-Lot SD CV%	Total SD CV%
Serum 1	0.136	0.0010 0.7%	0.0005 0.4%	0.0022 1.6%	0.0024 1.8%	0.0024 1.8%
Serum 2	0.296	0.0027 0.9%	0.0014 0.5%	0.0085 2.9%	0.0091 3.1%	0.0091 3.1%
Serum 3	1.402	0.0171 1.2%	0.0097 0.7%	0.0751 5.4%	0.0076 5.5%	0.0776 5.5%
Serum 4	3.266	0.0295 0.9%	0.0000 0.0%	0.0714 2.2%	0.0773 2.4%	0.0773 2.4%
Control 1	0.191	0.0014 0.7%	0.0007 0.4%	0.0032 1.7%	0.0036 1.9%	0.0036 1.9%
Control 2	2.789	0.0254 0.9%	0.0000 0.0%	0.0533 1.9%	0.0591 2.1%	0.0591 2.1%

ASSAY INTERFERENCE

The following substances do not interfere with this assay at the levels tested (less than 10% bias):

Ascorbic Acid:	*3 mg/dL*
Hemoglobin:	*12 mg/dL*
Bilirubin:	*10 mg/dL*
Conjugate Bilirubin	*10 mg/dL*
Triglyceride:	*417mg/dL*
Cholesterol:	*314 mg/dL*
Uric Acid:	*16 mg/dL*
Lactic Dehydrogenase:	*30 U/mL*
Sodium Lactate:	*96 mg/dL*
Glucose:	*2000 mg/dL*
Acetoacetic Acid:	*5 mM*
Creatinine:	*5 mg/dL*

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