

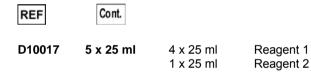
Liquid Reagents - ready to use

β -HYDROXYBUTYRATE

Enzymatic, NBT

2 Reagents

Diagnostic reagent for quantitative in vitro determination of β -Hydroxybutyrate in human serum or plasma on photometric systems



Additionally offered:

D10090SV	1 x 3 ml	β-Hydroxybutyrate S	Standard
D98485	5 x 3 ml	Calibrator	Diacal Auto
D98481	12 x 5 ml	Control normal	Diacon N
D98482	12 x 5 ml	Control abnormal	Diacon P

TEST PARAMETERS

Method:	Enzymatic, NBT
	Increasing Reaction, Endpoint
Wavelength:	546 nm
Temperature:	37°C
Sample:	Serum, plasma
Linearity:	up to 6.9 mmol/L
Sensitivity:	The lower limit of detection is 0.01 mmol/L

REAGENT COMPOSITION

COMPONENTS	CONCEN	TRATION
Reagent 1:		
Buffer, pH 8.4	115	mmol/L
β-Hydroxybutyrate dehydrogenase	≥ 3	kU/L
Diaphorase	2.1	kU/L
Reagent 2: NAD [⁺] Oxalic acid Nitroblue tetrazolium (NBT)		mmol/L mmol/L mmol/L

REAGENT PREPARATION

Substrate Start:

Reagents are ready for use.

NOTE: After a long cool storage, a slightly violet coloured sediment in Reagent 2 can accrue which does not influence the measurement. However, it should be redissolved into solution by shaking the bottle gently before further measurement.

Sample Start:

Not possible.

REAGENT STABILITY AND STORAGE

Conditions:	protect from light close immediately after use do not freeze the reagents!
Storage:	at 2 – 8 °C
Stability:	up to the expiration date

SAMPLE STABILITY AND STORAGE

serum, plasma: [3]	at 20 – 25°C	1 month	
	at 2 – 8°C	1 month	
	at -20 °C	1 month	
Discard contaminated specimens			

Discard contaminated specimens.

STANDARD

(has to be ordered separately)

Concentration	1,00 mmol/L
Storage:	2 – 8°C
Stability:	up to the expiration date
CLOSE IMMEDIATEI	LY AFTER USE!

INTERFERING SUBSTANCES

no interference up to:

ascorbic acid30 mg/dlbilirubin60 mg/dlhaemoglobin500 mg/dltriglycerides2400 mg/dlThe addition of oxalic acid to the reagent eliminatesinterferences with lactate and lactate dehydrogenase.

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate start

Pipette into test tubes	Blank	Cal.	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample or Std./Cal.	-	25 µl	25 µl
Distilled water	25 µl	-	-
Mix. Incubate 3 – 5 min. at 37°C. Read absorbance A1 against reagent blank, then add:			
Reagent 2	250 µl	250 µl	250 µl
Mix. Incubate exactly 5 min. at 37°C and read absorbance A2 against reagent blank.			
$\Delta A = (A2 - A2)$			

CALCULATION

With standard or calibrator

 β -Hydroxybutyrate = $\Delta A \text{ Sample} = \Delta A \text{ Std./Cal.} \times \text{Conc. Std/Cal [mmol/L]}$

UNIT CONVERSION

 $mg/dl \times 0.096 = mmol/L$

REFERENCE RANGE [1]

	[mmol/L]	[mg/dL]
Fasting	0.02 – 0.27	0.21 – 2.81

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

TEST PRINCIPLE

 $\label{eq:bound} \beta \mbox{-Hydroxybutyrate} + \mbox{NAD}^{+} < \box{-} \box{-$

NADH + NTB (oxidised) < Diaphorase > NAD⁺ + NTB (reduced)

The absorbance of the blue dye at 546 nm is proportional to the β -hydroxybutyrate concentration in the sample.

PERFORMANCE CHARACTERISTICS

LINEARITY

The test has been developed to determine β -

Hydroxybutyrate concentrations within a measuring range from 0.01 mmol/L to 6.9 mmol/L.

If values exceed this range, samples should be diluted 1+1 with NaCl solution (9 g/L) and the results multiplied by 2.

PRECISION (at 37°C)

Intra-assay	Mean	SD	CV
n = 20	[mmol/L]	mmol/L]	[%]
Sample 1	0.30	0.004	1.31
Sample 2	0.75	0.008	1.02
Sample 3	1.13	0.006	0.53
r			
Inter-assay	Mean	SD	CV
n = 20	mmol/L]	mmol/L]]	[%]
Sample 1	0.26	0.01	3.78
Sample 2	1.02	0.02	2.33
Sample 3	2.14	0.05	2.47

METHOD COMPARISON

A comparison of Dialab β -Hydroxybutyrate (y) with a commercially available test (x) using 120 samples gave following results: y = 1.00 x + 0.003 mmol/L; r= 0.999.

QUALITY CONTROL

All control sera with β -hydroxybutyrate values determined by this method can be used. We recommend:

REF	Cont.		
D98481	12 x 5 ml	DIACON N	Assayed Control Serum Normal
D98482	12 x 5 ml	DIACON P	Assayed Control Serum Abnormal

CALIBRATION

The assay requires the use of a β -hydroxybutyrate standard or calibrator. We recommend:

REF	Cont.	
1000051	1 v 3 ml	0_ U \/

D10090SV	1 x 3 mi	β-Hydroxybutyrate Standard	
D98485	5 x 3 ml	DIACAL AUTO	Assayed Multi Calibration Serum

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

- 1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- 2. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

- Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p 155-60
- Sacks DB. Carbohydrates. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B. Saunders Company; 1999. p. 785-787.
- 3. Data on file at Dialab GmbH



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