BioMajesty

β-Hydroxybutyrate 21 FS*

Diagnostic reagent for quantitative in vitro determination of β-hydroxybutyrate in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. **1 3711 99 10 964**
R1: 6 x 90 tests
R2: 6 x 90 tests

Method

Enzymatic determination with β-hydroxybutyrate-dehydrogenase

Principle

β-Hydroxybutyrate + NAD $\xrightarrow{\text{β-Hydroxybutyrate-dehydrogenase}}$ Acetoacetate + NADH + H^+

The absorbance at 340 nm is proportional to the β-hydroxybutyrate concentration in the sample.

Reagent

Components and Concentrations

R1:	Buffer	pH 8.5	< 150 mmol/L
	β-Hydroxybutyrate-dehydrogenase		≥ 1 kU/L
R2:	Buffer	pH 4.3	< 70 mmol/L
	NAD		< 25 mmol/L
Standard:			1 mmol/L

Storage Instructions and Reagent Stability

The reagents and the standard are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents.

Warnings and Precautions

1. Reagent 1: Warning. H319 Causes serious eye irritation. P264 Wash hands and face thoroughly after handling. P 280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+ P313 If eye irritation persists: Get medical advice/attention.
2. Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagent 1 contains biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [5].
5. Refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents and the standard are ready to use. The reagent bottles are placed directly into the reagent tray.

Specimen

Serum and heparin plasma

Stability [6]:

1 month	at	20 – 25°C
1 month	at	2 – 8°C
1 month	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys β-Hydroxybutyrate Standard FS is recommended for calibration. β-Hydroxybutyrate Standard FS values have been made traceable to the weighing of purest β-hydroxybutyrate. Use DiaSys TruLab N and P for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat.-No.	Kit size
β-Hydroxybutyrate Standard FS	1 3700 99 10 030	3 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Data evaluated on BioMajesty JCA-BM6010/C

Measuring range	
Measuring range from 0.05 – 6.0 mmol/L β-hydroxybutyrate. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.05 mmol/L
On-board stability	12 weeks
Calibration stability	12 weeks

Interfering substance	**Interferences < 10% up to**	**HBUT [mmol/L]**
Acetaminophen	1.50 mmol/L	0.276
	1.50 mmol/L	4.25
Acetoacetate	5.00 mmol/L	0.267
	5.00 mmol/L	4.24
Acetylsalicylic acid	60 mg/dL	0.274
	60 mg/dL	4.27
Ascorbic acid	50 mg/dL	0.202
	50 mg/dL	2.20
Conjugated bilirubin	50 mg/dL	0.234
	50 mg/dL	2.76
Unconjugated bilirubin	50 mg/dL	0.213
	50 mg/dL	2.64
Hemoglobin	500 mg/dL	0.258
	500 mg/dL	3.04
α-Hydroxybutyrate	7.0 mmol/L	0.270
	7.0 mmol/L	1.26
Lipemia (triglycerides)	1000 mg/dL	0.256
	2000 mg/dL	2.82
NAC	1000 mg/L	0.112
	1000 mg/L	2.76
No interference by lactate and lactate dehydrogenase. For further information on interfering substances refer to Young DS [7].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	0.262	0.412	3.09
CV [%]	0.56	0.36	0.32
Total precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	0.271	0.554	3.19
CV [%]	2.15	1.39	1.93

Method comparison (n=102)	
Test x	Competitor HBUT Hitachi 917
Test y	DiaSys HBUT 21 FS BioMajesty JCA-BM6010/C
Slope	1.01
Intercept	-0.014 mmol/L
Coefficient of correlation	0.999

** according to NCCLS document EP17-A2, Vol. 32, No. 8

Conversion factor

β-Hydroxybutyrate [mg/dL] x 0.096 = β-Hydroxybutyrate [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.

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 155-60.
2. 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. Edward C. Chao. SGLT-2 Inhibitors: A New Mechanism for Glycemic Control. Clin Diabetes 2014; 32(1): 4-11.
4. Ogawa W, Sakaguchi K. Euglycemic diabetic ketoacidosis induced by SGLT2 inhibitors: possible mechanism and contributing factors. J Diabetes Investig. 2016; 7(2):135-8.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.
6. Data on file at DiaSys Diagnostic Systems GmbH.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

BioMajesty

ß-Hydroxybutyrate 21 FS

Chemistry code 10 371

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	6.0
Sample vol (U)	6,0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	HBUT21
Digits	2
M-wave L.	340
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	6.0	6.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	23
S-DET.P.r	24
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999