respons®920

β-Hydroxybutyrate 21 FS*

Diagnostic reagent for quantitative in vitro determination of β-hydroxybutyrate in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 3711 99 10 921
4 twin containers for 120 tests each

Method

Enzymatic determination with β-hydroxybutyrate-dehydrogenase

Principle

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

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

Reagents

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 and contamination is avoided. Do not freeze the reagents and protect from light. DiaSys respons® containers provide protection from light.

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 animal 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 [1].
5. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
6. To avoid contamination and carryover, special care should be taken in combination with Magnesium XL FS reagent (1 4610..).
7. 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.
8. For professional use only.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum or heparin plasma

Stability [2]: 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

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

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).	
LOD (Limit of detection)** LOB (Limit of blank)	0.05 mmol/L β-hydroxybutyrate 0.004 mmol/L β-hydroxybutyrate
Onboard stability	6 weeks
Calibration stability	6 weeks

Interfering substance	**Interferences <10% up to**	**HBUT [mmol/L]**
Acetaminophen	1.50 mmol/L	0.229
	1.50 mmol/L	2.91
Acetoacetate	5.00 mmol/L	0.222
	5.00 mmol/L	2.92
Acetylsalicylic acid	60 mg/dL	0.220
	60 mg/dL	2.97
Ascorbic acid	50 mg/dL	0.222
	50 mg/dL	2.97
Bilirubin (conjugated)	50 mg/dL	0.229
	50 mg/dL	2.88
Bilirubin (unconjugated)	50 mg/dL	0.232
	50 mg/dL	2.88
Hemoglobin	500 mg/dL	0.215
	1000 mg/dL	2.71
α-Hydroxybutyrate	7.0 mmol/L	0.219
	7.0 mmol/L	2.95
Lipemia (triglycerides)	1000 mg/dL	0.246
	1500 mg/dL	2.16
NAC	1000 mg/L	0.218
	1000 mg/L	2.96
No interference by lactate and lactate dehydrogenase. For further information on interfering substances refer to Young DS [3].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	0.286	0.543	2.48
CV [%]	0.717	0.542	0.472
Total precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	0.290	0.550	2.54
CV [%]	1.59	1.62	2.31

* fluid stable

Method comparison (n=100)	
Test x	DiaSys β-Hydroxybutyrate 21 FS (BioMajesty JCA-BM6010/C)
Test y	DiaSys β-Hydroxybutyrate 21 FS (respons®920)
Slope	1.00
Intercept	–0.002 mmol/L
Coefficient of correlation	0.9998

** according to CLSI document EP17-A2, vol. 32, no.8

Conversion factor

β-Hydroxybutyrate [mg/dL] x 0.0962 = β-Hydroxybutyrate [mmol/L]

Reference Range

As follows [4]:

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

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

Literature

1. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.
2. Data on file at DiaSys Diagnostic Systems GmbH.
3. 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.
4. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 155-60.

Manufacturer

IVD CE

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respons®920

β-Hydroxybutyrat 21 FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	HBUT 21				Auto Rerun		☐
Report Name	:	β-Hydroxybutyrate				Online Calibration		☐
Unit	:	mmol/L	Decimal Places	:	3	Cuvette Wash		☐
Wavelength-Primary	:	340	Secondary	:	700	Total Reagents	:	2
Assay Type	:	Rate-A	Curve Type	:	Linear	Reagent R1	:	HBUT 21 R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	HBUT 21 R2
M2 Start	:	20	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	Consumables/Calibrators:		
Control Replicates	:	1	Control Interval	:	0	Blank/Level 0	:	0
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.0000	Calibrator 1	:	*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	0.004	Technical Maximum	:	6.00			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	HBUT 21		
Sample Type	:	Serum		

Sample Volumes

Normal	:	12.00	µL	Dilution Ratio	:	1	X
Increase	:	12.00	µL	Dilution Ratio	:	1	X
Decrease	:	12.00	µL	Dilution Ratio	:	1	X
Standard Volume	:	12.00	µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160	µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	40	µL	R2 Stirrer Speed	:	Medium

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	HBUT 21		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mmol/L)	Upper Limit (mmol/L)
Normal	:	0.02	0.27
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other