respons®910

# ß-Hydroxybutyrate 21 FS*

**Diagnostic reagent for quantitative in vitro determination of β-hydroxybutyrate in serum or plasma on DiaSys respons®910**

## Order Information

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

## 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.

## 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 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

Refer to local legal requirements.

### Reagent Preparation

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

## Specimen

Serum or 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

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) or use rerun function. | |
| LOD (Limit of detection)**<br>LOB (Limit of blank) | 0.05 mmol/L β-hydroxybutyrate<br>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 | 0.226 |
| | 1.50 mmol/L | 2.86 |
| **Acetoacetate** | 5.00 mmol/L | 0.208 |
| | 5.00 mmol/L | 2.91 |
| **Acetylsalicylic acid** | 60 mg/dL | 0.200 |
| | 60 mg/dL | 2.88 |
| **Ascorbic acid** | 50 mg/dL | 0.211 |
| | 50 mg/dL | 2.89 |
| **Bilirubin** (conjugated) | 50 mg/dL | 0.224 |
| | 50 mg/dL | 2.87 |
| **Bilirubin** (unconjugated) | 50 mg/dL | 0.225 |
| | 50 mg/dL | 2.88 |
| **Hemoglobin** | 500 mg/dL | 0.223 |
| | 1000 mg/dL | 2.87 |
| **α-Hydroxybutyrate** | 7.0 mmol/L | 0.270 |
| | 7.0 mmol/L | 1.26 |
| **Lipemia** (triglycerides) | 1000 mg/dL | 0.243 |
| | 1500 mg/dL | 2.21 |
| **NAC** | 1000 mg/L | 0.204 |
| | 1000 mg/L | 2.86 |
| 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] | 0.265 | 0.517 | 2.42 |
| CV [%] | 1.43 | 1.26 | 0.715 |
| **Total precision CLSI (n=80)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mmol/L] | 0.273 | 0.528 | 2.48 |
| CV [%] | 1.87 | 1.71 | 2.31 |

| Method comparison (n = 100 ) | |
|---|---|
| Test x | DiaSys ß-Hydroxybutyrate 21 FS BioMajesty® JCA-BM6010/C |
| Test y | DiaSys ß-Hydroxybutyrate 21 FS respons®910 |
| Slope | 0.999 |
| Intercept | –0.006 mmol/L |
| Coefficient of correlation | 0.9998 |

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

## Conversion Factor

ß-Hydroxybutyrate [mg/dL] x 0.0962 = ß-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

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respons®910

# β-Hydroxybutyrate 21 FS

## 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.

| Identification | |
|---|---|
| This method is usable for analysis: | Yes |
| Twin reaction: | No |
| Name: | HBUT 21 |
| Shortcut: | |
| Reagent barcode reference: | 069 |
| Host reference: | 069 |

| Technic | |
|---|---|
| Type: | Linear kinetic |
| First reagent:[µL] | 160 |
| Blank reagent | Yes |
| Sensitive to light | |
| Second reagent:[µL] | 40 |
| Blank reagent | No |
| Sensitive to light | |
| Main wavelength:[nm] | 340 |
| Secondary wavelength:[nm] | 700 |
| Polychromatic factor: | 1.0000 |
| 1 st reading time [min:sec] | 04:48 |
| Last reading time [min:sec] | 10:00 |
| Reaction way: | Increasing |
| Linear Kinetics<br>Substrate depletion: Absorbance limit | 0.6500 |
| Linearity: Maximum deviation [%] | |
| Fixed Time Kinetics<br>Substrate depletion: Absorbance limit | |
| Endpoint<br>Stability: Largest remaining slope | |
| Prozone Limit [%] | |

| Reagents | |
|---|---|
| Decimals | |
| Units | |

| Sample | |
|---|---|
| Diluent | DIL A (NaCl) |
| Hemolysis: | |
| Agent [µL] | 0 (no hemolysis) |
| Cleaner | |
| Sample [µL] | 0 |
| Technical limits | |
| Concentration technical limits-Lower | 0.0040 |
| Concentration technical limits-Upper | 6.0000 |
| SERUM | |
| Normal volume [µL] | 12.0 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | |
| Below normal dilution (factor) | |
| Above normal volume [µL] | |
| Above normal dilution (factor) | |
| URINE | |
| Normal volume [µL] | 12.0 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | |
| Below normal dilution (factor) | |
| Above normal volume [µL] | |
| Above normal dilution (factor) | |
| PLASMA | |
| Normal volume [µL] | 12.0 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | |
| Below normal dilution (factor) | |
| Above normal volume [µL] | |
| Above normal dilution (factor) | |
| CSF | |
| Normal volume [µL] | 12.0 |
| Normal dilution (factor) | 1 |
| Below normal volume[ µL] | |
| Below normal dilution (factor) | |
| Above normal volume [µL] | |
| Above normal dilution (factor) | |
| Whole blood | |
| Normal volume [µL] | 12.0 |
| Normal dilution (factor) | 1 |
| Below normal volume[ µL] | |
| Below normal dilution (factor) | |
| Above normal volume [µL] | |
| Above normal dilution (factor) | |

| Results | |
|---|---|
| Decimals | 2 |
| Units | mmol/L |
| Correlation factor-Offset | 0.0000 |
| Correlation factor-Slope | 1.0000 |

| Range | |
|---|---|
| Gender | All |
| Age | |
| SERUM | >=0.02 <=0.27 |
| URINE | |
| PLASMA | >=0.02 <=0.27 |
| CSF | |
| Whole blood | |
| Gender | |
| Age | |
| SERUM | |
| URINE | |
| PLASMA | |
| CSF | |
| Whole blood | |

| Contaminants |
|---|
| Please refer to r910 Carryover Pair Table |

| Calibrators details | |
|---|---|
| **Calibrator list** | **Concentration** |
| Cal. 1/Blank | 0 |
| Cal. 2 | * |
| Cal. 3 | |
| Cal. 4 | |
| Cal. 5 | |
| Cal. 6 | |
| | **Max delta abs.** |
| Cal. 1 | 0.100 |
| Cal. 2 | 0.100 |
| Cal. 3 | |
| Cal. 4 | |
| Cal. 5 | |
| Cal. 6 | |
| Drift limit [%] | 0.80 |

| Calculations | |
|---|---|
| Model | X |
| Degree | 1 |

* Enter calibrator value