β-Hydroxybutyrate 21 FS

Leading technology in fluid-stable reagents from DiaSys

- Over 25 years of experience in development and production of clinical chemistry tests
- Premium service in technics, applications and after sales
- Quality products made in Germany
- High performance, ready-to-use reagents with minimized interferences, long shelf life and onboard stability as well as traceability to international references
- Perfectly matched fluid-stable reagents, calibrators and controls
- High grade raw materials from traceable origin
- Processes and resources certified according to ISO 13485, fulfilling highest quality standards
- Sustainable processes and products preserve the environment

DiaSys offers reagent kits for manual and automated use plus appropriate calibrators and controls. Detailed information about the β-Hydroxybutyrate 21 FS test is available on our website **www.diasys-diagnostics.com/products/reagents** and in our product catalog.

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820130 I September 2018

CHOOSING QUALITY.

β-Hydroxybutyrate 21 FS

Best Choice for Reliable Ketosis Management

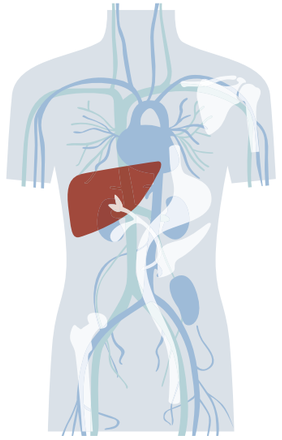
Ready to Use. Precise. Reliable.
DiaSys. Liquid-Stable Solutions.

DiaSys
Diagnostic Systems

CHOOSING QUALITY.

Clinical Relevance

Ketones are side products of fatty acid metabolism in the liver, serving as energy suppliers for various tissues, especially in case of insulin deficiency, insulin resistance or low glucose concentrations. Metabolic acidosis due to increased ketone levels is related to diabetes mellitus, congenital metabolic diseases, alcoholism and fasting. If the amount of ketones exceeds a certain level, acid-base balance is disturbed, leading to fatal outcome, if untreated. ß-hydroxybutyrate is the most stable and predominant ketone body accounting for 78% of total ketones, in contrast to aceto-acetate and acetone (22%). Moreover, this parameter increases more rapidly during development of acidosis than other ketones, qualifying ß-hydroxybutyrate as preferable indicator for early detection of metabolic acidosis.



Importance of ß-Hydroxybutyrate Testing

Diabetic ketoacidosis (DKA) is an acute, life-threatening complication in diabetes mellitus which should be detected and treated immediately. It occurs mainly in patients with type 1 diabetes but also in type 2 diabetes patients. Especially children with new onset of type 1 diabetes often present with DKA. DKA is characterized by hyperglycemia, ketoacidosis and ketonuria. Therefore, determination of ß-hydroxybutyrate level in blood is an important tool in early detection of DKA.

Since 2015, SGLT2 inhibitors (oral antidiabetic drugs) are suspected to cause euglycemic DKA (euDKA) which lacks hyperglycemia and thus may be easily overlooked. In this special case determination of ß-hydroxybutyrate is even more valuable to reveal euDKA.

Advantages of Testing ß-Hydroxybutyrate in Serum or Plasma

Urine test strips based on the nitroprusside method are commonly used for detection of ketoacidosis. However, urine strips only measure acetoacetate and acetone and therefore are associated with several limitations. The benefits of ß-hydroxybutyrate serum determination are:

- Superior biomarker for ketoacidosis since ß-hydroxybutyrate levels increase more rapidly than levels of acetoacetate and acetone
- Minimized risk for false negative results due to underestimation
- Quantitative results ensure earlier identification and treatment of metabolic imbalance
- Less susceptible to drug interference
- Recommended by the American Diabetes Association for reliable diagnosis and monitoring of diabetic ketoacidosis

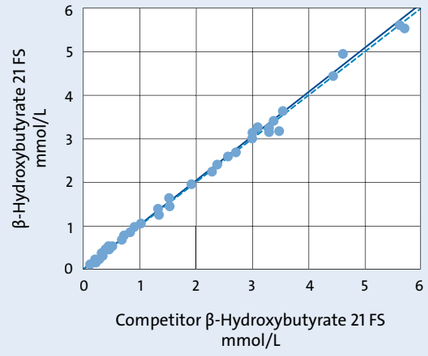
Test characteristics

- Liquid-stable, ready-to-use reagent
- Suitable for serum and plasma samples
- Measuring range 0.05 – 6.0 mmol/L
- Excellent precision
- Superior calibration and onboard stability of up to 12 weeks
- Applicable to common clinical chemistry analyzers

Precision

Intra-assay precision N = 20	Mean [mmol/L]	SD	CV [%]	Total precision CLSI N = 80	Mean [mmol/L]	SD	CV [%]
Sample 1	0.262	0.001	0.56	Sample 1	0.271	0.006	2.15
Sample 2	0.412	0.002	0.37	Sample 2	0.554	0.008	1.39
Sample 3	3.09	0.010	0.32	Sample 3	3.19	0.062	1.93

Method comparison



Y = 1.011 x - 0.014; r = 0.999; N = 102

Interference

Interferent	No interference up to
Bilirubin (unconj.)	50 mg/dL
Ditaurobilirubin	50 mg/dL
Hemoglobin	500 mg/dL
Lipid	1000 mg/dL
Acetaminophen	1.5 mmol/L
Acetoacetate	5.0 mmol/L
Acetylsalicyl acid	60 mg/dL
α-Hydroxybutyrate	7 mmol/L
Ascorbic acid	50 mg/dL
NAC	1000 mg/L