

Catalog No. 2440-058

For in vitro diagnostic use

Intended Use

The Stanbio β -Hydroxybutyrate Reagent is for the quantitative determination of β -Hydroxybutyrate in serum or plasma on the SIRRUS[®] Chemistry System.

β -Hydroxybutyrate Reagent

Cat. No. 2440-058 1 x 50mL (R1), 1 x 8.5mL (R2)
Approximately 170 Tests/Kit

Reagent Preparation

The reagents are supplied ready to use.

Reagent Storage and Stability

Stability	Storage	Claim To Expiration
Unopened:	2 - 8°C, do not freeze	21 days
Opened:	On-board SIRRUS [®]	

Materials Needed but not Provided

SIRRUS[®] Chemistry Analyzer
TDM/B-Hydroxybutyrate Tri-level Controls, Cat. No. 2460-605

Acceptable Specimens

Serum or plasma collected with EDTA, heparin, or sodium fluoride can be used in the assay.

Specimen Stability and Storage Requirements

Serum or plasma β -hydroxybutyrate levels are stable at least one week if kept refrigerated (2-8 °C). Specimens should not be repeatedly frozen and thawed.

Acceptable Chemical Additives

EDTA, heparin or sodium fluoride.

Interfering Substances

Serum, or plasma collected by use of any heparin should be free of hemolysis. See the package insert for a list of non-interfering substances.

Programming Instructions

The analyzer is programmed for this assay by inputting the parameters located on the back of this application sheet.

Assay Procedure

1. Add the R1 reagent to an R1 open channel reagent bottle then add the R2 reagent to its attached R2 reagent bottle.
2. Remove the reagent caps and place the reagents in its assigned position in the reagent tray.
3. Calibration is required after loading a new lot number of reagent. Use standard provided in kit.
4. Program and assay samples and controls as directed in the SIRRUS[®] Operator's Manual.

Calibration

Calibrate the analyzer after loading a new lot of reagent, after maintenance and when quality control results fall outside established limits. Calibration factors are valid for **21 days**.

Quality Control

Assay at least two (2) levels of control at least once per day. Controls should also be assayed after calibration, instrument maintenance and after loading a new lot of reagent.

Do not report patient results from any run where control recoveries fall outside the laboratory's established limits. Repeat the run if control results are unacceptable. If problems persist, examine the analyzer to determine the cause or repeat the run using fresh controls and if needed fresh reagent. For technical service, contact Stanbio Laboratory Technical Service Department at 800.531.5535.

Calculations

All calculations are performed by the analyzer.

Limitations

Use only serum, or plasma collected with EDTA, heparin or sodium fluoride for this assay.

Usable Range

Linear from 0 to 4.5 mmol/L. If the auto re-run feature is OFF then select a 10X dilution and select a re-run. The result is automatically calculated by the dilution factor.

Expected Values^{1,2}

Group	Reference Range
Normal Range	0.02-0.27 mmol/L
Abnormal (possible ketoacidosis)	>2.0 mmol/L

Use these ranges only as guides. Each laboratory should establish its own reference ranges.

For additional information please refer to the SIRRUS[®] Operator's Manual and the Stanbio β -hydroxybutyrate package insert.

Item No. **
Item Name BHOB

Page: 1	
Data Information	
Units	mmol/L
Decimals	2
Analysis	
Type	END
Main W.Length1	505
Main W.Length2	700
Method	B-Hydroxybutyrate
Corr.	
Slope	Inter
Y= [1.000] X + [0.000]	
Calibration	
Type	Linear 1
Standard	* Stability: 21 days
Normal Range	
	Male Female
	Low High Low High
Serum	0.02** 0.27** 0.02** 0.27**
Urine	
Plasma	0.02** 0.27** 0.02** 0.27**
CSF	
Dialysis	
Other	

Page: 2	
Aspiration	
Kind:	Double
Sample	3 µL
Reagent1 Vol	200 µL Stability: 21 days
Reagent2	50 µL
Third Mix.	OFF
O R1-Blank	Water - Blank
Factor MAX	1
MIN	10
CV%	3
Monitor	
O Level Point	1
Span	3.000
Data Process	
Read	Start End Absorbance Limit
Main	35 45 Low 0.000
Sub	--- --- High 1.600
Factor	
Blank Correction:	1
Endpoint Limit:	1.000
Linear Check (%):	0
Dilution	
Diluent	100:DiI2
Prozone Check	
	Start End Limit % L/H
First	
Second	

Page 3:				
Auto Rerun SW				
On/Off: ON				
Auto Rerun (Result)				
On/Off:		OFF	ON	
Serum	Lower	Higher		
		4.50		
Urine				
Plasma		4.50		
CSF				
Dialysis				
Other				
Bottle Size (mL)				
24 Items		36 Items		
Reagent1	0	Reagent1	32.5	
Reagent2 R1	0	Reagent2 R1	21^	
Reagent2 R2	0	Reagent2 R2	15^	
Auto Rerun Condition (Absorbance)				
Absorbance Range				
Lower:	ON			
Higher:	ON			
Prozone Range:	OFF			
Panic Range				
	Male		Female	
	Above	Below	Above	Below
Serum	2.00**	0.00**	2.00**	0.00**
Urine				
Plasma				
CSF				
Dialysis				
Other				

* Enter calibrator value

** User defined

^ User defined based on # of tests per bottle

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