ß-Hydroxybutyrate (BHB) Application
Ortho Clinical Diagnostics VITROS® 5600 Integrated System and VITROS® 4600 Chemistry System

Catalog No. 2440058

Intended for the Quantitative Determination of Beta-Hydroxybutyrate in Human Serum or Plasma

For In Vitro Diagnostic Use Only

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen storage, quality control and additional performance data.

Ordering Information

Please place your order with Ortho Clinical Diagnostics:

Item	Catalog Number	Configuration
Beta-Hydroxybutyrate LiquiColor® Reagents & Standard	2440058	R1: 1 x 50 mL R2: 1 x 8.5 mL Std.: 1 x 3 mL
TDM/B-Hydroxybutyrate Tri-level Controls	2460605	Levels 1 , 2 & 3: 2 x 5 mL/each
TDM/B-Hydroxybutyrate Bi-level Controls	2465605	Levels 1 & 2 3 x 5mL/each
TDM/B-Hydroxybutyrate Linearity Standards	2450604	Levels 1-6; 6 x 4mL

To place an order with Ortho Clinical Diagnostics – North America:

US	Canada
U.S. Toll Free: (800) 828-6316, prompt #1 Fax: (585) 453-3660 Email: US-CustomerService@orthoclinicaldiagnostics.com	Phone (English): (800) 616 9000 Phone (French): (800) 211-4911 Fax: (905) 940 9267 Email: CA-CustomerService@orthoclinicaldiagnostics.com

To contact technical support with Ortho Clinical Diagnostics – North America:

US	Canada
U.S. Toll Free: U.S. Toll Free: (800) 421-3311 Email: OrthoCareTechnicalSolutions@orthoclinicaldiagnostics.com	Phone: (800) 421-3311 Email: OrthoCareTechnicalSolutions@orthoclinicaldiagnostics.com

Reagent Pack Storage

Reagents are stable until the labeled expiration date at 2-8°C when stored in the original container.

Reagents stored in UDxx reagent packs onboard the analyzer are stable for 45 days.

Reagents, controls and standards are supplied liquid ready-to-use.

It is recommended that the reagents be split into 3 UDxx reagent packs containing a sufficient volume for a 30 day period of testing, based on anticipated utilization. The recommended fill volumes for each of the 3 UDxx reagent packs are as followed:

R1 (mL) in UDxx/A	R2 (mL) in UDxx/B	Tests/pack
14.7	2.8	80

3 UDxx reagent packs would be able to perform approximately 240 tests

Note: Once the individual UDxx pack number is selected for use during the protocol programming, it is the only UDxx pack number to use for this protocol.

Special Reagent Packs for User Defined Assays

(Please order from Ortho Clinical Diagnostics)

680 2246	UD01 Packs (Empty)	1 BOX/6PKS
680 2247	UD02 Packs (Empty)	1 BOX/6PKS
680 2248	UD03 Packs (Empty)	1 BOX/6PKS
680 2249	UD04 Packs (Empty)	1 BOX/6PKS
680 2250	UD05 Packs (Empty)	1 BOX/6PKS
680 2251	UD06 Packs (Empty)	1 BOX/6PKS
680 2252	UD07 Packs (Empty)	1 BOX/6PKS
680 2253	UD08 Packs (Empty)	1 BOX/6PKS
680 2254	UD09 Packs (Empty)	1 BOX/6PKS
680 2255	UD10 Packs (Empty)	1 BOX/6PKS
684 4449	UD11 Packs (Empty)	1 BOX/6PKS
684 4448	UD12 Packs (Empty)	1 BOX/6PKS
684 4445	UD13 Packs (Empty)	1 BOX/6PKS
684 4442	UD14 Packs (Empty)	1 BOX/6PKS
684 4447	UD15 Packs (Empty)	1 BOX/6PKS
684 4444	UD16 Packs (Empty)	1 BOX/6PKS
684 4441	UD17 Packs (Empty)	1 BOX/6PKS
684 4446	UD18 Packs (Empty)	1 BOX/6PKS
684 4443	UD19 Packs (Empty)	1 BOX/6PKS
684 4440	UD20 Packs (Empty)	1 BOX/6PKS

Note: We recommend a single UD Pack number be assigned for each assay

Out of Range Codes

A high analyte sample can produce an absorbance within the VITROS System photometer range but above the assay measuring range resulting in an OR code.

A very high analyte sample can produce an absorbance outside the VITROS System photometer range resulting in a CB code.

For either the OR or CB codes, dilute the sample 3X with reagent grade water or saline, and retest. This may be accomplished by off-line manual dilution or an operator requested onboard dilution using either VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) or VITROS Chemistry Products FS Diluent Pack 3 (Specialty Diluent/Water). Multiply the final result by 3 if off-line manual dilution is used and the manual dilution factor was not entered while programming the sample.

Calibration Interval

It is recommended that recalibration occur after reagent pack change, after calibrator lot change, after performance of monthly instrument maintenance and as required following quality control procedure. The calibration interval is 45 days.

Ortho Clinical Diagnostics VITROS5600 and 4600 System Parameters
EKF Diagnostics ß-Hydroxybutyrate LiquiColor® Assay

Configure Assay

Full Assay Name: ß-Hydroxybutyrate

Short Assay Name: BHB

Fluid Type: Serum

Assay Model Type: End Point

Template: *EPT R1-s-R2

Cal Model Type: Linear

Calibrator Bottles: 2 Reagent Reps per Cal : 3

Reagent Lot Information

On-Board Stability: 45 Days

Reagent Lot Num. *Kit Lot*

Shelf Exp. Date: *Kit Exp Date*

Edit Dilution Parameters

Diluent: Saline or DI Water Standard Dilution Factor: 1.0

Reflex Dilution: Off Dilution Factor: 3.0

(Refer to Out Of Range Codes Section above)

Reduction Factor: 1.0

Edit Result Parameters

Units: mmol/L

Reference Interval: 0.02 to 0.27

Significant Digits: 3 Precision Digits: 2

Supplementary: 0.00 to 90000000

User Adjusted Parameters

Reportable Range: 0.02 to 6.00

Slope: 1.0 Intercept: 0.0

Edit Additional Parameters

Cuve Tip Exp Time: 35 Temp Sens : No

Initial Abs. Limits: -0.200 to 3.500

Second Abs. Limits: -0.200 to 3.500

Ortho Clinical Diagnostics VITROS 5600 and 4600 System Parameters, continued

ß-Hydroxybutyrate LiquiColor® Assay

Edit Protocol Parameters

	Step	Volume	Pack ID	Seconds	Wavelength
1.	Reagent	143.3 uL	UDxx /A		
2.	Incubation			0.00	
3.	Sample	4.0 uL			
4.	Incubation			280.25	
5.	Read				510nm
6.	Incubation			14.25	
7.	Reagent	24.0 uL	UD xx/B		
8.	Incubation			313.50	
9.	Read				510 nm

Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: *Cal Kit lot*
1	1.0	0.20000	Cal value: 0.00 (reagent grade water or saline)
2	1.0	0.20000	Cal Value: 1.00 (provided 1.00 mmol/L standard)

Edit Additional Calibration Parameters

Monotonicity: Increase

Max Resp High: 3.00 Min. Resp. High: 3.00 Cal Fit Goodness Limit: 0.990

Max Resp. Low: -3.00 Min Resp. Low: -3.00 Calibration Interval: 45 Days

Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit
Reportable Min.:	0.02	0.33
Critical Conc.:	3.01	11.0 %
Reportable Max.:	6.00	11.0 %