		<b>Approved</b>	
		<b>Document Control</b>	
Document #:	RAP-00010	Revision:	1
Owners:	Johnny Hulek	Effective Date:	May 7, 2024
Title:	RAP.V2440 BHB Application-OCD-Vitros-EN 11.16.21		

## β-Hydroxybutyrate (BHB) Application QuidelOrtho Vitros® XT 7600 Integrated System, 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. For package inserts, visit [www.quidelortho.com](http://www.quidelortho.com) > **Resources > Technical Documents > MicroTip Partnership Assays (MPAs)**

**Ordering Information** Please place your order with QuidelOrtho. Ordering information available at [www.quidelortho.com](http://www.quidelortho.com).

Item	Reference Number	Configuration
B-Hydroxybutyr-240t/kit <i>(Includes standard calcs)</i>	2440058	R1: 1 x 50 mL R2: 1 x 8.5 mL Std.: 1 x 3 mL
B-Hydroxybutyr 3 Level Control	2460605	Levels 1, 2 & 3: 2 x 5 mL/each
B-Hydroxybutyr 2 Level Control	2465605	Levels 1 & 2 3 x 5mL/each
B-Hydroxybutyr Linearity	2450604	Levels 1-6; 6 x 4mL

**Technical Support Information** Contact QuidelOrtho for technical support. Contact information available at [www.quidelortho.com](http://www.quidelortho.com).

	<b>Approved</b>		
	<b>Document Control</b>		
Document #:	RAP-00010	Revision:	1
Owners:	Johnny Hulek	Effective Date:	May 7, 2024
<b>Title:</b>	<b>RAP.V2440 BHB Application-OCD-Vitros-EN 11.16.21</b>		

**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 56 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 QuidelOrtho)

Reference Number	Description	Quantity
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

	<b>Approved</b>		
	<b>Document Control</b>		
Document #:	RAP-00010	Revision:	1
Owners:	Johnny Hulek	Effective Date:	May 7, 2024
<b>Title:</b>	<b>RAP.V2440 BHB Application-OCD-Vitros-EN 11.16.21</b>		

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
680 2256	UDDL1 Packs (Empty)	1 BOX/6PKS
680 2257	UDDL2 Packs (Empty)	1 BOX/6PKS

**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.

	<b>Approved</b>		
	<b>Document Control</b>		
Document #:	RAP-00010	Revision:	1
Owners:	Johnny Hulek	Effective Date:	May 7, 2024
Title:	RAP.V2440 BHB Application-OCD-Vitros-EN 11.16.21		

**β-Hydroxybutyrate LiquiColor® Assay  
 QuidelOrtho Vitros® XT 7600 Integrated System, Vitros® 5600 Integrated System and Vitros® 4600 Chemistry System Parameters**

Full Assay Name: β-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: 56 Days  
1.0

Reagent Lot Num. Kit Lot

above)

Shelf Exp. Date: Kit Exp Date

**Edit Dilution Parameters**

Diluent: Saline or DI Water Standard Dilution Factor:

Reflex Dilution: Off Dilution Factor: 3.0

(Refer to Out Of Range Codes Section

Reduction Factor: 1.0

**Edit Result Parameters**

Units: mmol/L

Significant Digits: 3 Precision Digits: 2

User Adjusted Parameters

Slope: 1.0 Intercept: 0.0

Cuve Tip Exp Time: 35 Temp Sens : No

Reference Interval: 0.02 to 0.27

Supplementary: 0.00 to 90000000


Reportable Range: 0.02 to 6.00

**Edit Additional Parameters**

Initial Abs. Limits: -0.200 to 3.500

Second Abs. Limits: -0.200 to 3.500

**β-Hydroxybutyrate LiquiColor® Assay**

		<b>Approved</b>	
		<b>Document Control</b>	
Document #:	RAP-00010	Revision:	1
Owners:	Johnny Hulek	Effective Date:	May 7, 2024
Title:	RAP.V2440 BHB Application-OCD-Vitros-EN 11.16.21		

**QuidelOrtho Vitros® XT 7600 Integrated System, Vitros® 5600 Integrated System and Vitros® 4600 Chemistry System Parameters,**

**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: <u>Cal Kit lot</u>
1 (saline)	<u>1.0</u>	<u>0.20000</u>	Cal value: 0.00 (reagent grade water or saline)
2 (standard)	<u>1.0</u>	<u>0.20000</u>	Cal Value: 1.00 (provided 1.00 mmol/L)

**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.:	<u>0.02</u>	<u>0.33</u>
Critical Conc.:	<u>3.01</u>	<u>11.0</u> %
Reportable Max.:	<u>6.00</u>	<u>11.0</u> %


*Performance characteristics for the Vitros® 5600 Integrated System are applicable to the Vitros® XT 7600 Integrated System.*

© 2019 EKF Diagnostics. All rights reserved. All trademarks are the property of EKF Diagnostics and its subsidiaries unless otherwise specified. Vitros is a registered trademark of QuidelOrtho Clinical Diagnostics.

**Electronic Signature**

Gisele Gomes;Draft;May 2, 2024, 3:38 PM CDT

Gisele Gomes;Document Control Review;May 2, 2024, 3:39 PM CDT

			<b>Approved</b>	
			<b>Document Control</b>	
<b>Document #:</b>	RAP-00010	<b>Revision:</b>	1	
<b>Owners:</b>	Johnny Hulek	<b>Effective Date:</b>	May 7, 2024	
<b>Title:</b>	<b>RAP.V2440 BHB Application-OCD-Vitros-EN 11.16.21</b>			

---

Johnny Hulek;Initial Approval;May 2, 2024, 3:43 PM CDT  
 Lesley Johnson;Review;May 7, 2024, 1:59 PM CDT  
 Lesley Johnson;Final Approval;May 7, 2024, 2:00 PM CDT  
 Gisele Gomes;Awaiting Release;May 7, 2024, 2:28 PM CDT

---