

# **β-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

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| <b>Intended Use</b> | 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<br>R2: 1 x 8.5 mL<br>Std.: 1 x 3 mL |
| TDM/B-Hydroxybutyrate Tri-level Controls             | 2460605        | Levels 1, 2 & 3:<br>2 x 5 mL/each                 |
| TDM/B-Hydroxybutyrate Bi-level Controls              | 2465605        | Levels 1 & 2<br>3 x 5mL/each                      |
| TDM/B-Hydroxybutyrate Linearity Standards            | 2450604        | Levels 1-6;<br>6 x 4mL                            |

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

| US                                                                                                                                                                                              | Canada                                                                                                                                                                                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| U.S. Toll Free: (800) 828-6316, prompt #1<br>Fax: (585) 453-3660<br>Email: <a href="mailto:US-CustomerService@orthoclinicaldiagnostics.com">US-CustomerService@orthoclinicaldiagnostics.com</a> | Phone (English): (800) 616 9000<br>Phone (French): (800) 211-4911<br>Fax: (905) 940 9267<br>Email: <a href="mailto:CA-CustomerService@orthoclinicaldiagnostics.com">CA-CustomerService@orthoclinicaldiagnostics.com</a> |

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

| US                                                                                                                                                                                              | Canada                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| U.S. Toll Free: U.S. Toll Free: (800) 421-3311<br>Email: <a href="mailto:OrthoCareTechnicalSolutions@orthoclinicaldiagnostics.com">OrthoCareTechnicalSolutions@orthoclinicaldiagnostics.com</a> | Phone: (800) 421-3311<br>Email: <a href="mailto:hotlinerollovers@orthoclinicaldiagnostics.com">hotlinerollovers@orthoclinicaldiagnostics.com</a> |

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**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 |

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**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 $\beta$ -Hydroxybutyrate LiquiColor<sup>®</sup> Assay

### Configure Assay

Full Assay Name:  $\beta$ -Hydroxybutyrate Version Date: 3/28/2017  
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

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### 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: On Dilution Factor: 2.0  
Reduction Factor: 1.0

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### 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: 0.00 to 8.00

Slope: 1.0 Intercept: 0.0  
Cuvette Tip Exp Time: 35 Temp Sens : No

### Edit Additional Parameters

Initial Abs. Limits: -0.200 to 3.500  
Second Abs. Limits: -0.200 to 3.500

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### 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     |

## Ortho Clinical Diagnostics VITROS 5600 and 4600 System Parameters, continued

### $\beta$ -Hydroxybutyrate LiquiColor<sup>®</sup> Assay

#### Edit Calibration Parameters

| Bottle # | Dil Factor | Cal Rep Resp Range | Calibrator Lot: <u>Cal Kit lot</u> |
|----------|------------|--------------------|------------------------------------|
| 1        | <u>1.0</u> | <u>0.20000</u>     | Cal value: 0.00                    |
| 2        | <u>1.0</u> | <u>0.20000</u>     | Cal Value: 1.00                    |

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#### Edit Additional Calibration Parameters

|                               |                              |                                      |
|-------------------------------|------------------------------|--------------------------------------|
| Monotonicity: <u>Increase</u> |                              |                                      |
| Max Resp High: <u>3.00</u>    | Min. Resp. High: <u>3.00</u> | Cal Fit Goodness Limit: <u>0.990</u> |
| Max Resp. Low: <u>-3.00</u>   | Min Resp. Low: <u>-3.00</u>  | Calibration Interval: <u>45 Days</u> |

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#### Edit Triple Read Parameters

|                  | Reportable Conc. | Triple Read Limit |
|------------------|------------------|-------------------|
| Reportable Min.: | <u>0.00</u>      | <u>0.32</u>       |
| Critical Conc.:  | <u>4.00</u>      | <u>8.0</u> %      |
| Reportable Max.: | <u>8.00</u>      | <u>8.0</u> %      |

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