# ß-Hydroxybutyrate (BHB) Application
# Ortho Clinical Diagnostics 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.orthoclinicaldiagnostics.com > Technical Documents > MicroTip Partnership Assays (MPA).**

**Ordering Information**

Please place your order with Ortho Clinical Diagnostics. Ordering information available on www.orthoclinicaldiagnostics.com.

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

**Technical Support Information**

Contact Ortho Clinical Diagnostics for technical support. Contact information available on www.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 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 Ortho Clinical Diagnostics)

| 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 |
| 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 |

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|---|---|
| **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.<br><br>A very high analyte sample can produce an absorbance outside the VITROS® System photometer range resulting in a CB code.<br><br>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. |

## ß-Hydroxybutyrate LiquiColor® Assay
## Ortho Clinical Diagnostics VITROS® XT 7600 Integrated System, VITROS® 5600 Integrated System and VITROS® 4600 Chemistry System Parameters

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

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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: Off

Dilution Factor: 3.0

(Refer to Out Of Range Codes Section above)

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: 0.02 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

## ß-Hydroxybutyrate LiquiColor® Assay
## Ortho Clinical Diagnostics 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 |

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### 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) |

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### 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

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### 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 % |

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