

### Intended Use

Mission's β-Hydroxybutyrate (BHB) Control solutions are intended for use as a control for BHB assays run on the Mission CA200\* and Beckman AU680 analyzers in accordance with the instrument manufacturer's directions.

For Research Use Only. Site validation required for Lab Developed Test (LDT), 510K approval pending.

### Summary and Explanation

The use of specific controls is an established procedure for optimal performance of analyzer systems. Mission's BHB Control is a product prepared from chemicals that have been specially formulated for the Mission BHB assay.

### Principle Of Procedure

The Mission BHB control solutions are utilized by the analyst to provide suitability data to assess the calibration of the Mission CA200 BHB assay in accordance with the instrument manufacturer's directions. Refer to the assay procedures and to the instrument manual for details.

### Composition

The product consists of ready-to-use solutions of β-hydroxybutyrate at two concentrations.

### Instructions For Use

Each bottle contains 10 mL of formulated control that can be used daily to assess the suitability of the reagent and instrument. In combination with regular calibration these controls can be used to generate data to support the validity of patient data to regulatory authorities.

### Storage And Stability

Mission's BHB control solutions are stable until the expiration date when stored at 2-8°C. Store control solutions tightly capped and protected from light when not in use. Prolonged exposure of an opened control vials to ambient air and lab light should be avoided.

### Limitations

Erroneous results may occur from prolonged exposure of opened vial to ambient air and/or technical errors associated with instrumentation or reagents.

### Expected Values

The BHB controls data were generated from twenty replicate measurements on two analyzers to support their use in the lab. The data on the Mission CA200 and Beckman AU680 analyzers are as follows:

|                      | Mission CA200         |           | Repeatability (n = 20) |      | Range (2 SD) |      |
|----------------------|-----------------------|-----------|------------------------|------|--------------|------|
|                      | Lot #                 | Expiry    | Mean (mg/dL)           | % CV | low          | high |
| MD-101308, Control 1 | LD142602              | 4/14/2029 | 8.6                    | 1.1% | 8.4          | 8.8  |
| MD-101308, Control 2 | LD142603              | 4/14/2029 | 23.7                   | 1.0% | 23.2         | 24.1 |
| MD-101308, Control 1 | LF112602              | 6/11/2029 | 8.1                    | 5.4% | 7.2          | 9.0  |
| MD-101308, Control 2 | LF112603              | 6/11/2029 | 23.3                   | 1.3% | 22.7         | 23.9 |
|                      |                       |           |                        |      |              |      |
|                      | Beckman Coulter AU680 |           | Repeatability (n = 20) |      | Range (2 SD) |      |
|                      | Lot #                 | Expiry    | Mean (mg/dL)           | % CV | low          | high |
| MD-101308, Control 1 | LD142602              | 4/14/2029 | 8.2                    | 0.6% | 8.1          | 8.3  |
| MD-101308, Control 2 | LD142603              | 4/14/2029 | 23.6                   | 0.4% | 23.4         | 23.8 |
| MD-101308, Control 1 | LF112602              | 6/11/2029 | 8.0                    | 0.5% | 8.0          | 8.1  |
| MD-101308, Control 2 | LF112603              | 6/11/2029 | 23.8                   | 0.4% | 23.6         | 24.0 |

\* Also known as Zybio EXC200 Analyzer