

Intended Use

Mission Betahydroxybutyrate (BHB) Control solutions are intended for use as a control for methods run on Mission Diagnostics Affirm C200* and Beckman AU680 Analyzers in accordance with the instrument manufacturer's directions.

Summary and Explanation

The use of specific controls is an established procedure for optimal performance of analyzer systems. The Mission 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 Affirm C200 BHB assay in accordance with the instrument manufacturer's directions. Refer to the assay procedures and to the instrument manual for details.

Formulation

The product consists of ready-to-use solutions of betahydroxybutyrate 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 were analyzed over a period of 30 days on two analyzers to generate representative data to support their use in the lab. The data on the Mission Diagnostics Affirm C200 and Beckman AU680 Analyzers are as follows:

Mission Diagnostics Affirm C200

Control ID	Lot #	Expiry	Repeatability (n = 20)		Reproducibility (n = 29)		Range (2 SD)	
			Mean (mg/dL)	% CV	Mean (mg/dL)	% CV	low	high
MD-101308.01	LF282402	6/28/2027	8.3	0.9	8.2	1.9	7.9	8.5
MD-101308.02	LF282403	6/28/2027	24.8	0.7	24.8	1.9	23.9	25.8

Beckman Coulter AU680

Control ID	Lot #	Expiry	Repeatability (n = 20)		Reproducibility (n = 20)		Range (2 SD)	
			Mean (mg/dL)	% CV	Mean (mg/dL)	% CV	low	high
MD-101308.01	LF282402	6/28/2027	8.2	1.0	7.9	2.7	7.4	8.3
MD-101308.02	LF282403	6/28/2027	25.8	1.0	24.2	2.5	23.0	25.4

* Also known as Zybio EXC200 Analyzer