

Intended Use

Mission's High Sensitivity (HS) Nitrite Control solutions are intended for use as a control for methods run on 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 HS Nitrite Control is a product prepared from chemicals that have been specially formulated for the Mission HS Nitrite assay.

Principle Of Procedure

The Mission HS Nitrite control solutions are utilized by the analyst to provide suitability data to assess the calibration of the Mission CA200 HS Nitrite 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 nitrite 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 HS Nitrite 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 open vial to ambient air and/or technical errors associated with instrumentation or reagents.

Expected Values

The HS Nitrite controls data was 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-101302, Control 1	110525	11/30/2026	5.1	0.4%	5.1	5.2
MD-101302, Control 2	110725	11/30/2026	14.9	0.3%	14.8	15.0
MD-101302, Control 1	061226	6/30/2027	5.1	2.9%	4.8	5.4
MD-101302, Control 2	061426	6/30/2027	14.9	0.4%	14.8	15.0

	Beckman Coulter AU680		Repeatability (n = 20)		Range (2 SD)	
	Lot #	Expiry	Mean (mg/dL)	% CV	low	high
MD-101302, Control 1	110525	11/30/2026	5.1	0.3%	5.1	5.2
MD-101302, Control 2	110725	11/30/2026	15.1	0.3%	15.0	15.2
MD-101302, Control 1	061226	6/30/2027	5.2	0.5%	5.1	5.2
MD-101302, Control 2	061426	6/30/2027	15.1	0.5%	14.9	15.2

* Also known as Zybio EXC200 Analyzer