

Lyophilized Chemistry Calibrator

DR0070-1	12X5mL	Level 1	Calibrator, dry
	12X6mL	Level 1	Diluent
DR0070-2	12X5mL	Level 2	Calibrator, dry
	12X6mL	Level 2	Diluent

RECONSTITUTE INSTRUCTIONS

1. Remove the vials of calibrator and diluent from storage and let stand at room temperature (15-25°C) for 5 minutes.
2. Remove the cap and stopper from the vials of the lyophilized serum and reconstituting diluent.
3. Using a volumetric pipette or a calibrated air-displacement pipettor, add exactly 5.0 mL of reconstituting diluent to DR0070 lyophilized serum vial. Do Not pour directly from the reconstituting diluent vial.
4. Replace the cap and stopper to the vial of the lyophilized serum immediately after adding the diluent.
5. Allow the material to stand for 5 to 10 minutes. Gently swirl the contents until completely dissolved.

STORAGE AND STABILITY

1. Unreconstituted lyophilized calibrators and diluents are stable until the expiration date stated on the label when stored at 2-8°C.
2. Reconstituted calibrator materials are stable for 7 days from the date of reconstitution when stored at 2-8°C, except for Total and Direct Bilirubin which are stable for 4 days and Bicarbonate for 3 days. The materials should be capped and stored upright at 2-8°C when not in use.
3. If there is any evidence of microbial contamination in the reconstituted calibrator, discontinue use and discard.

RECOMMENDED PROCEDURES

1. Gently swirl for 30 seconds prior to each use.
2. Transfer sufficient volume of the calibrator to sample cups. Handle

this calibrator with the same care used for patient samples.

3. Replace the cap immediately and store unused calibrator at 2-8°C.
4. Refer to the appropriate Instrument User's Guide for System Calibration Information.
5. Good Quality Control Practices should be observed to assure proper System performance.

USE LIMITATIONS

1. This calibrator has not been tested for use with any other Chemistry System method other than those listed on the Assay Value section.
2. For best results when measuring Bicarbonate (CO₂), avoid prolonged exposure of the samples to air; run calibrator samples without delay.
3. The results obtained using these calibrators are dependent upon several factors, including proper storage of the calibrator, proper technique and good laboratory practices.

VALUE ASSIGNMENT

The assigned values for the constituents are traceable to the materials listed in the table below.

1. The assigned value for each constituent has been established in accordance to ClearChem Diagnostics Inc. testing protocols and the values ONLY APPLY to this particular lot of materials.
2. All values were obtained using Beckman Coulter AU® chemistry analyzers in conjunction with ClearChem Diagnostics Inc. reagents. Any instrument or reagent modification may invalidate these assigned values.

LOT NO: 6101K61 6102K61 EXP. DATE: 2019-08-31

Chemistry	Cat. No.	Method	Units	Level 1	Level 2
Albumin	ALB1000	B.C.B	g/dL		4.2
Bilirubin, Direct	BRD1050	Daizo	mg/dL	2.35	
Bilirubin, Total	BRB1060	Sulphanilit	mg/dL	6.2	
Blood Urea Nitrogen	BUN1070	Urease/GLDH	mg/dL		50
Calcium	CAL1080	Arsenazoll	mg/dL	8.2	12.1
CO ²	CAR1090	PEPC	mEq/L	20	
Cholesterol, Total	CHL1100	Enzymatic Rapid Liquid	mg/dL		230
Creatinine	CRE1120	Jaffe	mg/dL	0.44	5.80
Glucose	GLU1140	Hexokinase	mg/dL		240
I. Phosphorus	PHO1300	Phosphomolybdate	mg/dL		4.8
Iron	IRN1150	Ferene	µg/dL	328	
Magnesium	MAG1180	Colormetric-Xylidyl Blue ¹	mg/dL		3.2
Total Protein	TPR1310	Biuret	g/dL		7.0
Triglycerides	TRG1400	INT-Colormetric	mg/dL		292
Uric Acid	URA1500	Enzymatic-Color	mg/dL		7.9