Lyophilized Chemistry Calibrator

DR0070-1	12 x 5 mL	Level 1	Calibrator, dry
	12 x 6 mL	Level 1	Diluent
DR0070-2	12 x 5 mL	Level 2	Calibrator, dry
	12 x 6 mL	Level 2	Diluent

DxC 700 AU

REF DR0070-1 LOT 6101K51

DxC 700 AU

REF DR0070-2 LOT 6102K51

INTENDED USE

Beckman Coulter Chemistry Calibrators are intended for use when calibrating methods run on the Beckman Coulter AU® series of chemistry analyzers.

SUMMARY

Beckman Coulter Chemistry Calibrators are lyophilized, human serum based products formulated for use as a reference material when calibrating Beckman Coulter AU® clinical chemistry system assays.

CONSTITUENTS

Beckman Coulter Chemistry Calibrators are prepared from human serum with human and nonhuman proteins and non-protein constituents added. Bacteriostatic agents have been added.

The Beckman Coulter Chemistry Calibrators have been assayed for the following constituents: Albumin, Bicarbonate (CO_2), Direct Bilirubin, Total Bilirubin, Calcium, Cholesterol, Creatinine, Glucose, Inorganic Phosphorus, Iron, Lactate, Magnesium, Total Protein, Triglyceride, Unbound Iron Binding Capacity (UIBC), Urea Nitrogen (BUN), and Uric Acid. The above constituents have been separated into two separate vials so as to provide maximum stability and 2 levels of set points (in some assays).

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. WARNING-POTENTIAL BIOHAZARDOUS MATERIAL.

   These calibrators are prepared from human source material. Components of the calibrator which are derived from human source material have been tested using FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HbsAg), Hepatitis C (HCV), HIV-1 and HIV-2.

   However, no test method can offer complete assurance that products derived from human source materials are free of infectious agents. These calibrators must be handled in accordance with recommendations from the Centers for Disease Control / National Institutes of Health manual, “Biosafety in Microbiological and Biomedical Laboratories”, 1996.
3. DO NOT pipette calibrator diluents by mouth as this may introduce carbon dioxide into the materials and cause erroneous results.

Manufactured for
Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821
Made in U.S.A.

P/N: 16000104 (Rev. 2) (December 2016)

RECONSTITUTION 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.
6. Ensure each 2 Dimensional bar code is scanned and loaded individually on to the DxC 700 AU.

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 (CO_2), 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.
4. The 2 Dimensional bar codes are intended for use with the DxC 700 AU analyzer only.
5. The DxC 700 AU is not available in all geographies.

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 Beckman Coulter 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 its respective reagents. Any instrument or reagent modification may invalidate these assigned values.

LOT NO.: 6101K51 6102K51 **EXP. DATE:** 2018-01-31

BECKMAN COULTER AU® SERIES ANALYZERS

Test Name	Constituent	Traceability	Units	DR0070-1 Level 1	DR0070-2 Level 2	SI	DR0070-1 Level 1	DR0070-2 Level 2
ALB1U	Albumin	ERM DA470k	g/dL		4.24	g/L		42.4
CO21U	Bicarbonate	NIST SRM 351	mEq/L	19	35	mmol/L	19	35
DBC1U	Bilirubin, Direct (OSR6x11)	NIST SRM 916a	mg/dL	4.4		µmol/L	75.2	
DBC2U	Bilirubin, Direct (OSR6x181)	Beckman Coulter Master Calibrator	mg/dL	2.3		µmol/L	39.3	
TBC1U	Bilirubin, Total (OSR6x12)	Jendrassik-Grof Method	mg/dL	6.5		µmol/L	111	
CAZ1U	Calcium (Ars)	NIST SRM 956c	mg/dL	7.9	11.7	mmol/L	2.0	2.9
CAO1U	Calcium (oCPC)	NIST SRM 956c	mg/dL	7.9	11.6	mmol/L	2.0	2.9
CHO1U	Cholesterol	NIST SRM 1951b	mg/dL		232	mmol/L		6.0
CRE1U	Creatinine	NIST SRM 967a	mg/dL	0.41	5.7	µmol/L	36	504
GLU1U	Glucose	NIST SRM 965b	mg/dL		233	mmol/L		12.9
PHO1U	I. Phosphorus	Beckman Coulter Master Calibrator	mg/dL		5.0	mmol/L		1.61
FE-1U	Iron	Beckman Coulter Master Calibrator	µg/dL	328		µmol/L	59	
LAC1U	Lactate	Gravimetric Std	mg/dL		38	mmol/L		4.2
MG-1U	Magnesium	NIST SRM 956c	mg/dL		3.0	mEq/L		2.5
MG-1U	Magnesium	NIST SRM 956c	mg/dL		3.0	mmol/L		1.2
TP-1U	Total Protein	NIST SRM 927d	g/dL		7.0	g/L		70
TRG1U	Triglycerides	NIST SRM 1951b	mg/dL		268	mmol/L		3.0
UBC1U	UIBC	Beckman Coulter Master Calibrator	µg/dL		320	µmol/L		57
BUN1U	Urea Nitrogen (BUN)	NIST SRM 909b	mg/dL		49	mmol/L		18
UA-1U	Uric Acid	ID-GCMS	mg/dL		7.0	µmol/L		417