

**AU/DxC AU**  
**Instructions For Use**

© 2022 Beckman Coulter, Inc. All rights reserved.

**System Cal**  
**System Calibrator**
**REF** 66300 20 x 5 mL

 For *in vitro* diagnostic use only.

**PRINCIPLE**
**INTENDED PURPOSE**

The System Calibrator is a calibration serum intended to be used with Beckman Coulter System reagents listed in the table below using the automated Beckman Coulter AU/DxC AU analyzers.

Reagent	Cat. No.	Reagent	Cat. No.
ALBUMIN	OSR6x02	GGT	OSR6x20
ALP	OSR6x04	GLUCOSE	OSR6x21
ALT	OSR6x07 with Pyridoxal Phosphate	INORGANIC PHOSPHOROUS	OSR6x22
ALT	OSR6x07 Modified without Pyridoxal Phosphate	IRON	OSR6x86
ALPHA-AMYLASE	OSR6x06	LACTATE	OSR6x93
ALPHA-AMYLASE	OSR6x82	LDH	OSR6x26
AST	OSR6x09 with Pyridoxal Phosphate	LDH	OSR6x28
AST	OSR6x09 Modified without Pyridoxal Phosphate	LIPASE	OSR6x30
CALCIUM oCPC	OSR6x13	MAGNESIUM	OSR6x89
CALCIUM (ARSENAZO)	OSR6x117	TOTAL BILIRUBIN	OSR6x12
CHOLESTEROL	OSR6x16	TOTAL PROTEIN	OSR6x32
CHOLINESTERASE	OSR6x14	TRIGLYCERIDE	OSR6x118
CK-NAC	OSR6x79	UIBC	OSR6x205
CREATININE	OSR6x78	UREA	OSR6x34
CREATININE (ENZYMATIC)	OSR6x204	UREA STAT	OSR6x41
DIRECT BILIRUBIN	OSR6x11	URIC ACID	OSR6x98

# REAGENTS

## WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1/2 on a single donor basis using FDA approved methods and were found to be non-reactive. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents, this product should be handled as a potentially infectious material.

## ACTIVE INGREDIENTS

Human serum with chemical additives and appropriate enzymes of human, animal and plant origin.

## GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS	Safety Data Sheet is available at <a href="http://beckmancoulter.com/techdocs">beckmancoulter.com/techdocs</a>
-----	--

# CALIBRATION

## CALIBRATOR PREPARATION

1. Allow the vial to equilibrate to room temperature before opening to prevent condensation in the vial.
2. Tap the top of the vial before opening to dislodge any lyophilisate caught in the stopper. Always open the vial gently to prevent any loss of lyophilisate.
3. Add to the vial fresh deionised water equilibrated to room temperature, (approx. 20°C). Use a calibrated pipette that can accurately dispense 5.0 mL - weigh if unsure.
4. Invert the vial 3 times and then leave to stand for 10 minutes. Dissolve the contents completely by gently mixing on a roller for 30 minutes. Do not shake the vial as this will cause foaming.
5. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.
6. Record the date the vial was reconstituted on the bottle label. Store at 2...8°C.

## Notes

1. For determination of Alkaline Phosphatase, it is recommended that the reconstituted serum be allowed stand for at least 2 hours at 2...8°C before use.
2. Lipase reagent is to be calibrated as normal in AB mode. See product insert.

## Important for Enzymes (Except Lipase)

To provide a robust and easy approach to generate the analyser specific MB factor, it is recommended that 5 separate calibration events should be used. A fresh vial of calibrator should be used for each of these runs. When calculating the mean factor from the separate runs the data should be examined for obvious outliers which should be repeated and replaced.

## CALIBRATOR STORAGE AND STABILITY

Closed vial shelf life per stability study: 36 months.

The calibrator is stable, unopened, up to the stated expiry date when stored at 2...8°C.

Once reconstituted the calibrator is stable according to the reconstitution stability table below, provided it is free from contamination, tightly capped immediately after each use and stored appropriately.

Reconstituted Stability	- 20°C *	2...8°C
Alkaline Phosphatase, ALT, AST, Amylase, Cholinesterase, CK-NAC, GGT, HBDH, LDH	Not recommended	8 hours
Albumin, Creatinine, Cholesterol, Glucose, Lactate, Lipase, Total Protein, Triglyceride, UIBC, Urea, Uric Acid, Bilirubin**, Inorganic Phosphorous	1 month	30 hours
Calcium, Iron, Magnesium	1 month	1 week

\*When frozen once.

### Exceptions

\*\* Bilirubin: The Stability of Bilirubin in the calibrator after freezing is 5 Days.

Since Bilirubin is light sensitive and total protection is not given by the brown bottle, storage of calibrator vials in the dark is recommended when calibrating Bilirubin.

## CALIBRATOR ASSIGNED VALUES

Calibration values have been determined using standardised procedures and Beckman Coulter System Reagents on Beckman Coulter AU/DxC AU analyzers.

### TRACEABILITY

The assigned value for each component is traceable to reference materials/methods or where reference materials/methods of a higher metrological order are not available Beckman Coulter have chosen an in- house master calibrator material as the primary reference standard.

Refer to table of assigned values provided in the kit or to each individual reagent IFU for further information.

## TESTING PROCEDURE(S)

Refer to appropriate product literature.

## ADDITIONAL INFORMATION

Ensure the lot number on the vial is the same as the one listed in the table on the value assign sheet.

Ensure the selected value is appropriate for the units on the analyzer parameter settings.

### Notice to User

This device is for healthcare professional use only.

Any serious incident that has occurred in relation to this device should be reported to Beckman Coulter and the competent authority of the Member State in which the user and/or patient is established.

The Summary of Safety and Performance is available from the EUDAMED database: [ec.europa.eu/tools/eudamed](http://ec.europa.eu/tools/eudamed)

Refer to the Beckman Coulter Chemistry Systems Reagent Guide (BLGUIDE) for specific chemistry information for the AU/DxC AU clinical chemistry systems and guidance on symbols used on all AU/DxC AU product labelling.

## REVISION HISTORY

Updated based on IVDR 2017/746 requirements.



Beckman Coulter Ireland Inc., Lismeehan, O'Callaghan's Mills, Co. Clare, Ireland +(353) (0) 65 683 1100  
[www.beckmancoulter.com](http://www.beckmancoulter.com)