AU

Instructions For Use

UALB CAL
Urine/CSF Albumin Calibrator

REF B38859 Low 1 x 2 mL Calibrator # 1 White Cap
1 x 2 mL Calibrator # 2 Yellow Cap
1 x 2 mL Calibrator # 3 Orange Cap
1 x 2 mL Calibrator # 4 Red Cap
High 1 x 2 mL Calibrator # 5 Black Cap

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED USE

The Urine/CSF Albumin calibrator is intended to be used to calibrate the Urine/CSF Albumin reagent on the Beckman Coulter AU clinical chemistry systems

REAGENTS

CONTENTS

The Urine/CSF Albumin Calibrator consists of known quantities of human albumin in a buffered solution.

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

WARNING - POTENTIAL BIOHAZARDOUS MATERIAL

The calibrator is manufactured from human material; therefore it should be handled as though capable of transmitting infectious disease. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for the antibodies to HIV and HCV and nonreactive for HBsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material and all patient samples should be handled as though capable of transmitting infectious disease. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled as specified in the Centers for Disease Control's Biosafety Level 2 guidelines[1].

REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

Urine/CSF Albumin Calibrator Levels 1 - 5	
Human Albumin	Various
Sodium Azide (used as a preservative)	< 0.1% (w/w)

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

INDICATIONS OF DETERIORATION

Visible signs of microbial growth, turbidity, precipitate or any change in color in the Urine/CSF Albumin calibrator may indicate degradation and warrant discontinuation of use.

CALIBRATION

CALIBRATOR PREPARATION

The calibrators are ready for use.

No preparation is required.

Recommended Procedure

1. Allow contents of the bottles to come to room temperature.
2. Mix the contents by gently inverting the vials several times to achieve a homogenous mixture.
3. Transfer sufficient volume of the calibrator to sample cups. Handle this calibrator with the same care used for patient samples.
4. Replace the cap immediately and store unused calibrator at 2...8°C. Do not mix caps among the various bottles in the calibrator set.
5. For detailed calibration instructions, refer to the AU Instrument User's Guide.
6. Good Quality Control Practices should be observed to assure proper system performance.

CALIBRATOR STORAGE AND STABILITY

1. The unopened calibrators are stable up to the stated expiration date when stored at 2…8°C.
2. Opened bottles of calibrators are stable for 30 days, provided they are free from contamination, tightly capped immediately after each use, and stored at 2…8°C.

Do not freeze.

CALIBRATOR LIMITATIONS

This calibrator can only be used with the application of Urine/CSF Albumin reagent B38858/B46435.

The results obtained with this calibrator are dependent on several factors, including proper storage of the calibrator, and proper technique and use of Beckman Coulter AU Analyzers and their respective reagents.

The albumin result of a urine sample may be elevated when it immediately follows a serum sample. In order to eliminate this effect, it is recommended to calibrate the Urine/CSF albumin assay separately to serum assays.

TRACEABILITY

The Urine/CSF Albumin calibrator values are traceable to the International Federation of Clinical Chemistry Certified Reference Material CRM470.

Value Assignment

Refer to table of assigned values provided in the kit.

Calibration values have been determined using standardised procedures and Beckman Coulter System Reagents on Beckman Coulter analysers. Please ensure that the lot number on the calibrator vial is the same as the one listed in the table of assigned values in the package insert.

Note: Following calibration, the resulting curve should be visually reviewed, on the Beckman Coulter analyzer, for acceptability using the software options - Routine, Calibration Monitor, Calibration Curve. Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice.

ADDITIONAL INFORMATION

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

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

REVISION HISTORY

Add new languages

Preceding version revision history

IFU updated to add Vietnamese language.

Updated Warning and Precautions section

REFERENCES

1. CDC-NIH manual, Biosafety in Microbiological and Biomedical Laboratories, 5th Edition (CDC 21-1112), U.S. Government Printing Office, Washington, D.C. (2009).

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