



AU US

Instructions For Use

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APO A1 and B Cal Apolipoprotein A1 and B Calibrator

- REF** ODR3022 Zero 1 x 2 mL Calibrator #1 White Cap
- Low 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.

For Rx use only

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The Apolipoprotein A1 and B Calibrator is designed to provide suitable calibration levels for Beckman Coulter AU analyzers employing the immuno-turbidimetric assays for Apolipoprotein A1 and B determinations.

REAGENTS

CONTENTS

Constituents

The Apo A1 and B Calibrator is a liquid human serum based product assayed for various levels of Apolipoprotein A1 and Apolipoprotein B. Constituent values are adjusted where necessary by the addition of analytical grade serum proteins.

WARNING AND PRECAUTIONS

1. Do not ingest. Harmful if swallowed.
2. WARNING: POTENTIAL BIOHAZARDOUS MATERIAL.

The calibrator reagent is manufactured from the lipoprotein fraction of human serum. Each human serum donor used in the preparation of this material was tested by an FDA approved method for the presence of the antibody to HIV-1/2 and HCV as well as for hepatitis B surface antigen and was not repeatedly reactive. Because no test method can offer complete assurance that HIV-1/2, HCV, hepatitis B virus or other infectious agents are absent from biological materials, all reagents should be handled at the Biosafety Level 2 as recommended for any infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual, Biosafety in Microbiological and Biomedical Laboratories, 1993.

REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

Human Apolipoprotein A1 approx. 0.0 - 2.5 g/L

Human Apolipoprotein B approx. 0.0 - 2.0 g/L

Also contains preservatives.

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



Safety Data Sheet is available at techdocs.beckmancoulter.com

CALIBRATION

CALIBRATOR PREPARATION

The calibrators are ready to use as supplied. No preparation is required.

CALIBRATOR STORAGE AND STABILITY

1. The unopened calibrators are stable until the expiration date printed on the label when stored at 2 to 8°C.
2. Opened bottles are stable until the expiration date printed on the label providing that the stopper and cap are replaced immediately after each use and the reagent is stored at 2 to 8°C.

Indications of Deterioration

Visible signs of microbial growth, gross turbidity, or precipitate in the calibrator may indicate degradation and warrant discontinuation of use.

CALIBRATOR ASSIGNED VALUES

Refer to table of assigned values provided in the kit.

The assay values for each constituent have been determined in accordance with Beckman Coulter test protocol, on Beckman Coulter AU analyzers, and the values apply only to this lot of calibrator. All values for each Beckman Coulter AU Analyzer have been assigned using their respective reagents. Any instrument or reagent modification may invalidate these assay values.

The assay values for the constituents are traceable to the World Health Organization (WHO) standards (SP1-01 for Apolipoprotein A1 and SP3-07 for Apolipoprotein B) according to IFCC protocols.

CALIBRATOR LIMITATIONS

This calibrator can only be used with the application of Apo A1 and Apo B reagents, OSR6x42 and OSR6x43 respectively. This calibrator has not been tested with any other chemistry system. 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.

TESTING PROCEDURE(S)

Recommended Procedure

1. Gently invert the vial several times to achieve a homogenous mixture.
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 to 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.

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.

Technical Assistance

For technical assistance contact the Beckman Coulter Technical Support Center at (800) 223-0130.

Ordering Information

To place an order for Apolipoprotein A1 and B calibrator contact the Beckman Coulter Customer Service Department at (800) 223-0125.

Catalog No.	Description	Packaging	
ODR3022	Apo A1 and B Calibrator	1 x 2 mL Calibrator # 1 White Cap	Zero
		1 x 2 mL Calibrator # 2 Yellow Cap	Low
		1 x 2 mL Calibrator # 3 Orange Cap	
		1 x 2 mL Calibrator # 4 Red Cap	
		1 x 2 mL Calibrator # 5 Black Cap	High

REVISION HISTORY

Revised GHS section

Preceding version revision history

Updated Warning and Precautions section

Updated Additional Information section

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