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## Instructions For Use

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## Apo A1 and B Cal Apo A1 and B Calibrator

**REF**

- ODR3022 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)
- 1 x 2 mL Calibrator 5 (Black Cap)

For *in vitro* diagnostic use only.

## PRINCIPLE

### INTENDED USE

The Apo A1 & B Calibrator is a liquid human serum based matrix calibrator intended to be used with the Apo A1 and Apo B reagents (OSR6142 & OSR6143 respectively) for the quantitative determination of Apo A1 & Apo B on Beckman Coulter analysers.

## REAGENTS

### CONTENTS

Liquid human serum matrix containing variable amounts of human apolipoprotein A1, human apolipoprotein B and preservative.


### 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.

### REACTIVE INGREDIENTS

 <b>CAUTION</b> <b>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.</b>
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### GHS HAZARD CLASSIFICATION

Not classified as hazardous

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

## **CALIBRATOR PREPARATION**

The calibrators are ready for use. Gently invert each vial several times, prior to each use, to ensure a homogeneous mixture.

## **CALIBRATOR STORAGE AND STABILITY**

The calibrators are stable, unopened, up to the stated expiry date when stored at 2...8°C. Once open, the calibrators are stable for 30 days, provided they are free from contamination, tightly capped immediately after each use, and stored at 2...8°C.

## **CALIBRATOR ASSIGNED VALUES**

Refer to table of assigned values provided in the kit.

The Apo A1 and B Calibrator values have been assigned using WHO International reference materials SP1-01 and SP3-07 respectively by immunoturbidimetry.<sup>1,2,3</sup>

## **TESTING PROCEDURE(S)**

Refer to relevant product instructions for use.

## **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**

| Added new languages

### **Preceding version revision history**

IFU updated to add Vietnamese language.


Updated Warning and Precautions section

Revised GHS section

## REFERENCES

1. Reference Materials for the Standardization of the Apolipoproteins A-I and B, and Lipoprotein(a), Dati F, Tate J, eJIFCC vol 13 no 3: <http://www.ifcc.org/ejifcc/vol13no3/130301003.htm>.
2. Barr JR, Maggio VL, Patterson DG Jr., Cooper GR, Henderson LO, Turner WE, et al. Isotope dilution-mass spectrometric quantification of specific proteins: model application with apolipoprotein A-I. Clin Chem 1996;42:1676-82.
3. Marcovina SM, Albers JJ. Apolipoprotein assays: standardization and quality control. Scand J Clin Lab Invest Suppl 1990;198:58-65.

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