

Instructions For Use

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Serum Protein Multi-Calibrator 2**REF**

ODR3023 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 Serum Protein Multi-Calibrator 2 is intended to be used with the Beckman Coulter immuno-turbidimetric reagents listed in the table below for the quantitative determination of α -1 acidglycoprotein, α -1 antitrypsin, β -2 microglobulin, ceruloplasmin and haptoglobin on Beckman Coulter analysers. The material is prepared from human serum with the constituent values adjusted where necessary by the addition of analytical grade chemicals and appropriate serum proteins.

Reagent	Cat. No.
α -1 acidglycoprotein	OSR6162
α -1 antitrypsin	OSR6163
β -2 microglobulin	OSR6151
Ceruloplasmin	OSR6164
Haptoglobin	OSR6165

REAGENTS**CONTENTS**

Variable amounts of the following human proteins in a liquid serum matrix, pH 7.0.

α -1 acidglycoprotein

α -1 antitrypsin

β -2 microglobulin

Ceruloplasmin

Haptoglobin

Also contains 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

 **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

CALIBRATION

CALIBRATOR PREPARATION

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

It is recommended to record the date the calibrator was opened on the bottle label.

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 Serum Protein Multi-Calibrator 2 values have been assigned¹ using the following reference materials^{2,3} by immuno-turbidimetry:

Reagent	Cat. No.	Standard
α-1 acidglycoprotein	OSR6162	IFCC standard CRM 470.
α-1 antitrypsin	OSR6163	IFCC standard CRM 470.
β-2 microglobulin	OSR6151	WHO 1st International Standard 1985
Ceruloplasmin	OSR6164	IFCC standard CRM 470.
Haptoglobin	OSR6165	IFCC standard CRM 470.

TESTING PROCEDURE(S)

Refer to relevant product literature.

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. Blirup-Jensen S, Johnson AM, Larsen M. Protein standardization IV: value transfer procedure for the assignment of serum protein values from a reference preparation to a target material. Clin Chem Lab Med 2001;39:1110-1122.
2. Baudner S, Bienvenu J, Blirup-Jensen S, Carlström A, Johnson AM, Milford Ward A, et al. The certification of a matrix reference material for immunochemical measurement of 14 human serum proteins. CRM 470. EUR 15243 EN, 1993.
3. Vincent C, Esteve J, Cooper EH, Deconninck I, Forbes M, Poulik MD, et al. A collaborative study of a preparation of normal human serum for use as a reference in the assay of beta 2 microglobulin. J Biol Stand 1985;13:185-97.

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