

Instructions For Use

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Serum Protein Multi-Calibrator 1

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|------------|---|
| REF | ODR3021 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) |
| | 1 x 2 mL Calibrator 6 (Green Cap) |

For in vitro diagnostic use only.

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE
INTENDED USE

The Serum Protein Multi-Calibrator is intended to be used with the immuno-turbidimetric reagents listed in the table below for the quantitative determination of immunoglobulin G, immunoglobulin A, immunoglobulin M, complement 3, complement 4, transferrin, C-reactive protein, anti-Streptolysin O and ferritin 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.	Reagent	Cat. No.
IgG	OSR61172	Transferrin	OSR6152
IgA	OSR61171	CRP	OSR6147
IgM	OSR61173	ASO	OSR6194
C3	OSR6159	Ferritin	OSR61203
C4	OSR6160		

REAGENTS
CONTENTS

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

Immunoglobulin G
Immunoglobulin A
Immunoglobulin M
Complement 3
Complement 4

Transferrin
C-reactive protein
Anti-Streptolysin O
Ferritin

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



Safety Data Sheet is available at techdocs.beckmancoulter.com

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 Serum Protein Multi-Calibrator values have been assigned¹ using the following reference materials^{2,3,4} by immuno-turbidimetry:

Reagent	Cat. No.	Standard
IgG	OSR61172	IFCC standard CRM 470.
IgA	OSR61771	IFCC standard CRM 470.
IgM	OSR61173	IFCC standard CRM 470.
C3	OSR6159	IFCC standard CRM 470 for C3c.
C4	OSR6160	IFCC standard CRM 470.
Transferrin	OSR6152	IFCC standard CRM 470.
CRP	OSR6147	IFCC standard CRM 470.
ASO	OSR6194	WHO NIBSC 1st International standard for Anti-Streptolysin O, AST.
Ferritin	OSR61203	3rd international standard for ferritin, recombinant NIBSC 94/572

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

IFU updated to add Vietnamese language.

Updated Warning and Precautions section

Revised GHS section

Preceding version revision history

Updated Warning and Precautions section

Updated Additional Information 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. Spaun J, Bentzon MW, Olesen Larsen S, Hewitt LF. International standard for anti-streptolysin-O. Bull Wld Hlth Org 1961;24:271-79.
4. Thorpe SJ, Walker D, Arosio P, Heath A, Cook JD, Worwood M. International collaborative study to evaluate a recombinant L ferritin preparation as an international standard. Clin Chem 1997;43:1582-87.

EC REP Beckman Coulter Ireland Inc., Lismeehan, O'Callaghan's Mills Co. Clare, Ireland (001) 703-527-3887

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