

Instructions For Use

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**CRP Latex (N) Cal
CRP Latex Calibrator Normal Set****REF**

ODC0026 1 x 2 mL Calibrator level 2 (Cream Cap)
1 x 2 mL Calibrator level 3 (Blue Cap)
1 x 2 mL Calibrator level 4 (Red Cap)
1 x 2 mL Calibrator level 5 (Brown Cap)
1 x 2 mL Calibrator level 6 (Green Cap)

For in vitro diagnostic use only.

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE**INTENDED USE**

The CRP Calibrator (Latex) is a liquid human serum based matrix calibrator intended to be used with the Normal application of the CRP (Latex) reagent OSR6x99 for the quantitative determination of CRP on Beckman Coulter AU analysers.

REAGENTS**CONTENTS**

Liquid human serum matrix containing variable amounts of human CRP 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

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 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. 6 levels are required for calibration. Levels 2 to 6 are provided in the calibrator kit. For the Level 1 (zero) calibrator 0.9% saline should be used.

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 90 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 CRP Calibrator (Latex) values have been assigned¹ using the IFCC (International Federation of Clinical Chemistry) standard CRM470² by immunoturbidimetry.

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

Updated Intended Use section to replace OSR6199 with OSR6x99

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.

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