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Instructions For Use

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RF LATEX CAL RF LATEX CALIBRATOR



- ODC0028 1 x 1 mL Calibrator 2 (White Cap)
- 1 x 1 mL Calibrator 3 (Blue Cap)
- 1 x 1 mL Calibrator 4 (Green Cap)
- 1 x 1 mL Calibrator 5 (Red Cap)
- 1 x 1 mL Calibrator 6 (Orange Cap)

For *in vitro* diagnostic use only.

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The RF Latex Calibrator is a liquid human serum based matrix calibrator intended to be used with the RF Latex reagent OSR61105 for the quantitative determination of Rheumatoid Factor on Beckman Coulter analysers.

REAGENTS

CONTENTS

Liquid human serum matrix containing variable amounts of human RF 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.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

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 3 months, 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 RF Calibrator values have been assigned using the WHO International reference material, NIBSC 64/2¹, 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

IFU updated to add Vietnamese language.

Updated Warning and Precautions section

Preceding version revision history

Updated Warning and Precautions section

Updated Additional Information section

REFERENCES

1. Anderson SG, Bentzon MW, Houba V, Krag P. International reference preparation of rheumatoid arthritis serum. Bull Wild Hlth Org 1970;42:311-318.

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

 Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.