BECKMAN COULTER CE

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Instructions For Use

LDL-Chol Cal
LDL Cholesterol Calibrator

REF ODC0012 2 x 1 mL

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED USE

The LDL-Cholesterol Calibrator is a lyophilised human serum calibrator intended to be used with the LDL-Cholesterol reagent OSR6183/OSR6283 for the quantitative determination of LDL-cholesterol on Beckman Coulter analysers.

REAGENTS

CONTENTS

Lyophilised human serum containing human LDL-cholesterol.

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.

GHS HAZARD CLASSIFICATION

LDL-Cholesterol Calibrator

WARNING

H317	May cause an allergic skin reaction.
H411	Toxic to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before use.
P391	Collect spillage.
	reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

CALIBRATION

CALIBRATOR PREPARATION

1. Carefully remove the cap and rubber stopper from the bottle, avoiding any loss of lyophilised material.
2. Add 1.0 mL of sterile deionised water at 15…25ºC to the lyophilised material using a volumetric pipette calibrated to deliver exactly 1.0 mL.
3. With the rubber stopper back in place, dissolve the contents completely by gently mixing for 30 minutes. Avoid foaming.
4. Record the date the calibrator was reconstituted on the bottle label.

CALIBRATOR STORAGE AND STABILITY

The calibrator is stable, unopened, up to the stated expiry date when stored at 2…8ºC. Once reconstituted the calibrator is stable for 7 days when stored at 2…8ºC. It can be aliquoted and frozen once. The reconstituted and frozen calibrator is stable for 30 days when stored at -20ºC.

To ensure stability, Beckman Coulter recommend that vials are tightly capped immediately after use and that care is taken to avoid contamination.

CALIBRATOR ASSIGNED VALUES

Refer to table of assigned values provided in the kit.

The LDL-Cholesterol Calibrator value is traceable to the US CDC (Centre for Disease Control) LDL-cholesterol reference method.[1]

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

Revised GHS section

REFERENCES

1. Bachorik PS, Ross JW. National Cholesterol Education Program recommendations for measurement of low-density lipoprotein cholesterol: executive summary. The National Cholesterol Education Program Working Group on Lipoprotein Measurement. Clin Chem 1995; 41: 1414 - 20.

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