AU

Instructions For Use

HDL LDL CONTROL
HDL LDL Cholesterol Control Serum

REF ODC0005 Control 1 3 x 5 mL
Control 2 3 x 5 mL

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED USE

The HDL/LDL-Cholesterol Control Serum is a lyophilised human serum control designed to monitor the analytical performance of the HDL and LDL Cholesterol reagents, OSR6187 and OSR6183 respectively, on Beckman Coulter analysers.

REAGENTS

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 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

Lyophilised human serum containing human HDL-cholesterol and LDL-cholesterol.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

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

STORAGE AND STABILITY

The controls are stable, unopened, up to the stated expiry date when stored at 2…8°C. Once reconstituted the controls are stable for 7 days when stored at 2…8°C. They can be aliquoted and frozen once. The reconstituted and frozen controls are stable for 30 days when stored at -20°C.

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

QUALITY CONTROL

CONTROL PREPARATION

1. Carefully remove the cap and rubber stopper from the bottle, avoiding any loss of lyophilised material.
2. Add 5.0 mL of sterile deionised water at 15…25°C to the lyophilised material using a volumetric pipette calibrated to deliver exactly 5.0 mL.
3. With the rubber stopper back in place, dissolve the contents completely by gently mixing for 30 minutes. Avoid foaming.
4. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.
5. Record the date the control was reconstituted on the bottle label.

ASSAY VALUES

Refer to table of means and ranges.

The HDL/LDL-Cholesterol Control Sera values are traceable to the US CDC (Centre for Disease Control) HDL and LDL-cholesterol reference methods.[1,2]

TESTING PROCEDURE(S)

Refer to relevant product instructions for use.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the enclosed table.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

ADDITIONAL INFORMATION

REVISION HISTORY

Added new languages

Updated Additional Information section

Preceding version revision history

IFU updated to add Vietnamese language.

Updated Warning and Precautions section

Added Revision History

REFERENCES

1. Hainline A, Karon J, Lippel K, eds. Manual of laboratory operations. In: Lipid Research Clinics Program, Lipid and lipoprotein analysis, 2nd ed. Bethesda, MD: U.S. Dept. Health and Human Services, 1982.

2. Bachorik PS, Ross JW, for the National Cholesterol Education Program Working Group on Lipoprotein Measurement. Guidelines on the measurement of low-density -lipoprotein cholesterol: executive summary. Clin Chem 1995;44:1414-20.

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