

 <p>CUSTOMISED SOLUTIONS FOR YOUR LABORATORY</p>	<p>I.S.E. S.r.l. Sistemi Intelligenti Elettronici Via Delle Driadi, 45 – 00133 Roma - Italy</p>	<p>Code MM-CNTHDL2 Rev. 0 del 07/09/09 pag. 1 / 1</p>
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REF R0400000300	HDL/ LDL CONTROL 1x3 ml	
Serum	Quantity	Physical state
Normal	1 vial of 3 ml	Lyophilized
IVD For in vitro diagnostic use only		

INTENDED USE

This product is intended for in vitro diagnostic use in the quality control of diagnostic assays. The Assayed Human multi-sera is for the control of accuracy:

SAFETY PRECAUTIONS AND WARNINGS

For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents. Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly. Health and Safety Data Sheets are available on request, safety precautions and warnings

STORAGE AND STABILITY

STABILITY AFTER RECONSTRUCTION

at 15-25°C HDL 2 days , LDL 2 hours .
at 2-8°C HDL 5 days , LDL 24 hours .
at -25 / -15°C (when frozen once) 1 month

UNOPENED: Store refrigerated (2 to 8°C). Stable to expiration date printed on individual vials.

LIMITATIONS:

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components. Different lot numbers of this control should not be interchanged as the values assigned to the controls vary from lot to lot. The control should not be used as a calibration material.

PREPARATION FOR USE

The Assayed Human Multi-sera is supplied lyophilised.

- Carefully reconstitute each vial of lyophilised serum with exactly **3 ml** of deionised water at +20°C to 25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
- Refer to the control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse mix contents thoroughly.

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric Pipette , materials required but not provided.

Constituent	Unit	Target	Range	
HDL	mg/dl	50.4	40.3	60.5
	mmol/l	1.30	1.04	1.56
	g/L	0.504	0.403	0.605
LDL	mg/dl	88.0	70.4	106
	mmol/l	2.28	1.82	2.73
	g/L	0.880	0.704	1.06

LOT. N°	24693
EXPIRY	2019/09

