

## LIPOPROTEIN (a) CONTROL (Lp (a) CONTROL 3) QUALITY CONTROL LEVEL 3

**CAT. NO.** LP 3406

**SIZE:** 3 x 1 ml

**GTIN:** 05055273204445

**LOT NO.** 1715LP

**EXPIRY:** 2026-01-28

### INTENDED USE

For use in the quality control of Lipoprotein(a) assays.

### CHARACTERISTICS

Radox Lipoprotein(a) level 3 control is based on lyophilised human serum containing Lipoprotein(a).

### SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This material has been tested for the HIV (Human Immunodeficiency Virus) Antibody, HBs Ag and HCV antibody and was found to be non-reactive using FDA approved methods. However, as no method can offer complete assurance as to the absence of infectious agents, this material should be handled as though capable of transmitting infectious disease.

Dispose of this material according to local regulations.

### PREPARATION

The Controls must be reconstituted using the following procedure:

1. Open each vial carefully.
2. Reconstitute by pipetting exactly 1 ml of redistilled water into each vial.
3. Replace the rubber stopper and leave to stand for 30 minutes.
4. Dissolve contents completely by swirling or rotating.
5. Prior to use, mix contents by inverting the vials. Ensure that no lyophilised material remains unreconstituted.
6. The control is then ready for use.

### STABILITY AND STORAGE

Unreconstituted controls are stable up to the expiry date shown on the side of each individual bottle when stored at +2°C to +8°C. Once reconstituted, the Radox LP(a) control is stable for 14 days at +2°C to +8°C in the absence of bacterial contamination.

### VALUE ASSIGNMENT

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

MEAN (mg/dl)	RANGE (mg/dl)	MEAN (nmol/l)	RANGE (nmol/l)
47	37.6 – 56.4	100.3	80.2 – 120.3

Each lot of control is assayed immunoturbidimetrically by Radox Laboratories Ltd., with reference to a master lot of Lipoprotein(a) Control.

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