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CE

Total Human Lipoprotein a (Lp(a)) ELISA Assay

REF

Catalog No.E4-245

IVD

For Research Use Only

Intended Use:

To quantitative total human Lipoprotein A (Lpa)

Principle of Procedure:

Solid phase capture sandwich ELISA assay using a microwell format.

Shelf Life:

The expiration date for the package and each component is stated on the label(s). Store all components at 2°- 8°
degrees C with the exception of the standard, which should be stored at -20°C.

Patient and Standard Dilutions:

(a.) Dilute each serum or plasma specimen to be tested **1:400** with the Lp(a) specimen diluent provided. Prepare a series of at least four, two fold serial dilutions of the pre-diluted 1:400 standard provided, e.g. Neat (N), 1:2, 1:4, 1:8. Use the Lp(a) specimen diluent alone as a blank or zero control.

(b.) Use the declared value on the vial of Lp(a) pre-diluted standard to prepare the standard curve.

Materials Supplied:

Goat Anti-Human Lp(a) coated microwell strips 12 x 8 with plastic frame

HRP conjugated goat anti-Apo B-100 - 12mL

Lp(a) standard (pre-diluted 1:400) - 1ml

TMB/peroxide substrate color developer - 12mL

Lp(a) specimen diluent - 60mL

Sulfuric acid termination reagent (0.5N) - 12mL

15 X Wash buffer concentrate - 60mL

Limitations of the Procedure:

No single assay should be used as the only basis for arriving at a diagnostic conclusion.

Dynamic Range:

0.975 mg/dL-62.4 mg/dL

Reproducibility:

C.V. 4%-8% depending upon the region of the standard curve.

Assay Procedure:

Allow each reagent to reach room temperature before use

1.Add 100uL of ***diluted*** specimen or standard to each microwell

2. Incubate at room temperature for 60 minutes

3. Decant and wash each microwell four times with wash buffer (dilute buffer 1:15 with reagent grade water). After the last decanted wash grip firmly at each end of the microwell frame so the strips don't come out and pound up side down on a clean dry paper towel to assure that all wash buffer residue is removed.

4. Add 100uL of anti-human Apo B-100 conjugate to each well

5. Incubate at room temperature for 60 minutes

6. Decant and wash as in "step 3"

7. Add 100uL of TMB/peroxide substrate and incubate at room temperature for 30 minutes

8. Terminate the reaction with 100uL of 0.5N sulfuric acid

9. Zero the microwell reader at 450nm using the specimen diluent zero control well

10. Determine the optical density (O.D.@450nm) of the remaining wells

11. Construct a standard curve using the O.D.@450nm obtained for each of the corresponding standards. This should result in a sigmoid curve.

12. Interpolate the unknowns from the standard curve

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PIE4-245
Revision1
Revision date: 12/2006