

Indication for Use

510(k) Number (if known): k082488

Device Name: Diazyme Lp(a) Assay

Indication For Use:

The Diazyme Lp(a) is intended as a latex particle enhanced immunoturbidimetric assay for the in vitro quantitative determination of lipoprotein(a) [Lp(a)] concentration in human serum or plasma (EDTA) on Clinical Chemistry Systems. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular diseases in specific populations, when used in conjunction with clinical evaluation.

Diazyme Lp(a) Control is intended for use in monitoring the quality control of results obtained with the Diazyme Lp(a) reagents by turbidimetry.

Diazyme Lp(a) standard is intended for use in establishing the calibration curve for the Diazyme Lp(a) reagents by turbidimetry.

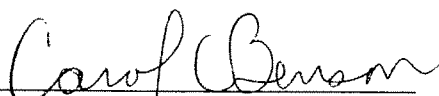
Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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