

510(K) SUMMARY

SUBMITTED BY: Judith J. Smith
DiaSorin, Inc.
9175 Guilford Rd. Suite 100
Columbia, MD 21046

NAME OF DEVICES:
Trade Name: SPQ Test System Antibody Reagent Set for Lp(a)

Common Names/Descriptions: Immunoprecipitin assay for quantitative determination of Lp(a) levels

Classification Names: Lipoprotein a (Lp(a)) test

PREDICATE DEVICES: Strategic Diagnostics Macra Lp(a)

DEVICE DESCRIPTION:

INTENDED USE: The SPQ™ Antibody Reagent Set for Lp(a) is designed for the quantitative determination of human lipoprotein(a) in mg/dL in human serum by immunoprecipitin analysis using a turbidimetric clinical analyzer. The measurement of Lp(a) is indicated for use in conjunction with clinical evaluation, patient risk assessment and other lipoprotein tests to evaluate disorders of lipid metabolism and to assess coronary heart disease (CHD) in male Caucasian populations.

KIT DESCRIPTION: The SPQ™ Test System for Lp(a) provides the quantitative determination of human lipoprotein(a) by automated immunoprecipitin analysis. Standards, controls, and samples are pipetted undiluted into sample cups. Microvolumes of these samples and a polymeric enhancer are pipetted into individual cuvettes. Following an initial incubation and measurement of sample blank, undiluted antiserum is added to the cuvettes. The sample and antiserum are mixed in the reaction cuvettes. Reaction temperature is controlled at 37°C. Insoluble antigen-antibody complexes form immediately, producing turbidity in the mixture and increasing the amount of light scattered by the solution. The amount of antigen-antibody complex formed, and thus the amount of light scatter, is proportional to the amount of lipoprotein(a) in the initial sample. The solution absorbance is measured after a 10 minute incubation period.

A calibration curve is generated by analyzing a series of calibrators with known concentrations of lipoprotein(a) and using the instrument's data reduction capability or manually plotting the change in absorbance versus lipoprotein(a) concentration. Concentrations of lipoprotein(a) within the controls and samples are interpolated from the calibration curve.

The test is designed for use on instruments capable of immunoprecipitin analysis, as the Cobas FARA II. The instruments measure the amount of light scattering in the reaction cuvettes due to the formation of insoluble antigen-antibody complexes. The systems are capable of storing a calibration curve. This assay is not designed for manual use.

PERFORMANCE DATA: All performance data were collected using the Cobas FARA II.

Clinical Correlation: A clinical study was conducted with the SPQ Test System to assess whether the assay could detect a difference in Lp(a) levels between a normal population with known cardiac risk factors and a population with known atherosclerotic heart disease. The median Lp(a) level for the normal male population was 11.6 mg/dL, while the median level for the diseased male population was 26.3 mg/dL. The populations were statistically significantly different.

The assay was compared to the Northwest Lipid Research Laboratory reference method and to the Strategic Diagnostics Macra assay. The correlation coefficient to the NWLRL assay was 0.962 (equivalent to the correlation of the Macra assay to the NWLRL method) and the correlation to the Macra assay was 0.961.

Recovery: A study was performed to evaluate the quantitative recovery of different Lp(a) polymorphs which spanned the molecular weight range from 419 to 796 kD. A model of dilution parallelism was used to test whether the different polymorphs were recovered equivalently. Statistical analysis of the data obtained from this study showed that no departure from parallelism was observed.

Reproducibility: Reproducibility studies were performed at 3 sites using one lot of SPQ reagents. Assay reproducibility was determined by testing 6 samples that spanned the range of the assay as well as the 2 control samples. Samples were tested in duplicate once a day for 7 days over a 2 week period. The results are summarized below.

REPRODUCIBILITY RESULTS FOR SPQ LP(A) ASSAY - COMBINED SITES

Sample	Mean mg/dL	Within Run %CV	Total %CV
Level 1 Control	22.3	4.0	5.4
Level 2 Control	52.0	2.7	4.9
RP 1	9.9	9.4	13.9
RP 2	21.9	3.6	7.7
RP 3	45.2	3.1	6.1
RP 4	58.4	5.3	8.6
RP 5	71.9	2.6	4.9
RP 6	85.5	2.0	3.6
N	42		

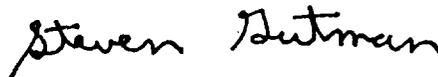
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER: K982708

DEVICE NAME: Antibody Reagent Set for Lp(a) SPQ™ Test System

INDICATIONS FOR USE: The SPQ™ Antibody Reagent Set for Lp(a) is designed for the quantitative determination of human lipoprotein(a) in mg/dL in human serum by immunoprecipitin analysis using a turbidimetric clinical analyzer. The measurement of Lp(a) is indicated for use in conjunction with clinical evaluation, patient risk assessment and other lipoprotein tests to evaluate disorders of lipid metabolism and to assess coronary heart disease (CHD) in male Caucasian populations.

K982708 Juan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982708

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use