June 16, 2026

Diazyme Laboratories Inc.
Abhijit Datta
VP Operations
12889 Gregg Ct.
Poway, California 92064

Re: K253069
Trade/Device Name: Lipoprotein (a) Molarity Assay
Regulation Number: 21 CFR 866.5600
Regulation Name: Low-density lipoprotein immunological test system
Regulatory Class: Class II
Product Code: DFC
Dated: May 12, 2026
Received: May 13, 2026

Dear Abhijit Datta:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

PAULA V. CAPOSINO
-S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
k253069

Device Name
Lipoprotein (a) Molarity Assay

Indications for Use *(Describe)*
The Lipoprotein (a) Molarity Assay is intended as an in vitro test for quantitative determination of Lipoprotein(a) [Lp(a)] concentrations in human serum and plasma on validated automated analyzers. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular disease risk, when used in conjunction with clinical evaluation and other lipoprotein tests.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Lipoprotein (a) Molarity Assay
K253069 – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

Submitter Name	Diazyme Laboratories Inc.
Address	12889 Gregg Ct Poway, CA 92064 USA
Contact	Abhijit Datta Phone: (858) 455-4762 Email: abhijit.datta@diazyme.com
Date Prepared	June 16, 2026
Proprietary Name	Lipoprotein (a) Molarity Assay
Classification Name	Low-Density Lipoprotein Immunological Test System
Product Codes, Regulation Numbers	DFC, 21 CFR 866.5600
Predicate Device	Diazyme Lipoprotein (a) Assay (k180074)
Establishment Registration	Diazyme Laboratories, Inc. 12889 Gregg Ct Poway, CA 92064 USA Registration Number: 2032900

1. DEVICE DESCRIPTION

The Lipoprotein (a) Molarity Assay is intended as an *in vitro* test for quantitative determination of Lipoprotein(a) [Lp(a)] concentrations in human serum and plasma on validated automated analyzers. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular disease risk, when used in conjunction with clinical evaluation and other lipoprotein tests.

The Lipoprotein Assay is based on a latex particle enhanced immunoturbidimetric assay. Lipoprotein (a) in the sample binds to specific anti-Lipoprotein (a) antibody, which is coated on latex particles, and causes agglutination. The degree of the turbidity caused by agglutination can be measured optically and is proportional to the amount of Lipoprotein (a) in the sample. The instrument calculates the Lipoprotein (a) concentration by interpolation of obtained signal of a calibration curve prepared from calibrators of known concentrations.

The Lipoprotein (a) Molarity Assay quantifies lipoprotein (a) in human serum and plasma and reports the values in nmol/L with calibrator values Standardized to CDC CSP materials with Lp(a) measured by IFCC WG-APO MS reference measurement procedure (RMP), provisionally calibrated to the WHO-IFCC reference material SRM-2B for nmol/L.

1.1 Reagents – working solutions

Reagent R1: Tris buffer solution: pH 7.5; BSA; EDTA; stabilizers; preservative

Reagent R2: Latex particles coated with anti-human Lipoprotein(a) antibodies; Tris buffer solution: pH 8.2; BSA; sucrose; preservative

2. INDICATIONS FOR USE

The Lipoprotein (a) Molarity Assay is intended as an in vitro test for quantitative determination of Lipoprotein(a) [Lp(a)] concentrations in human serum and plasma on validated automated analyzers. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular disease risk, when used in conjunction with clinical evaluation and other lipoprotein tests.

3. TECHNOLOGICAL CHARACTERISTICS

The following table compares the Lipoprotein (a) Molarity Assay with the predicate device, Diazyme Lipoprotein (a) Assay (k180074).

Table 1: Technical Characteristics Comparison Table between Lipoprotein (a) Molarity Assay and Diazyme Lipoprotein (a) Assay

	K253069 (Subject Device)	**k180074 (Predicate)**
Device Trade Name	Lipoprotein (a) Molarity Assay	Diazyme Lipoprotein (a) Assay
Intended Use	The Lipoprotein (a) Molarity Assay is intended as an in vitro test for quantitative determination of Lipoprotein(a) [Lp(a)] concentrations in human serum and plasma on validated automated analyzers. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular disease risk, when used in conjunction with clinical evaluation and other lipoprotein tests.	The Diazyme Lipoprotein (a) Assay 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 on Clinical Chemistry Systems. The measurement of Lipoprotein (a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular diseases in specific populations, when used in conjunction with clinical evaluation. For in vitro diagnostic use only.
Assay Method	Same	Particle enhanced immunoturbidimetric assay
Instrument Platform	Beckman Coulter AU680 Chemistry Analyzer	Beckman Coulter AU400 chemistry analyzer
Sample Type/Matrix	Human serum and Li-heparin, K2-EDTA, K3-EDTA plasma	Human serum, EDTA plasma and lithium heparin plasma
Calibrator	Lipoprotein (a) Molarity Assay Calibrator Set	Diazyme Lipoprotein (a) Assay Calibrator Set
Traceability/ Standardization	Standardized to CDC CSP materials with Lp(a) measured by IFCC WG-APO MS reference measurement procedure (RMP), provisionally	Standardized against an internal reference material.

	calibrated to the WHO-IFCC reference material SRM-2B for nmol/L.	
Calibration Method	Same	6-point, spline
Controls	Lipoprotein (a) Molarity Assay Control Set	Diazyme Lipoprotein (a) Assay Control Set
Measuring Range	4.85 – 240 nmol/L	5.4 – 100 mg/dL
Lower Limits of Measurement	LOB (Limit of Blank): 0.49 nmol/L LOD (Limit of Detection): 1.5 nmol/L LOQ (Limit of Quantification): 4.85 nmol/L	LOB (Limit of Blank): 0.40 mg/dL LOD (Limit of Detection): 1.3 mg/dL LOQ (Limit of Quantification): 3.2 mg/dL
Method Comparison	Method comparison between subject device Lipoprotein(a) Molarity assay and the isoform insensitive Lp(a) ELISA method: Sample size (n) =209 Deming regression slope = 1.012 y intercept = - 0.149 r = 0.992 Sample concentrations were between 7.8 – 223.3 nmol/L	

4. NON-CLINICAL PERFORMANCE EVALUATION

Performance characteristics were evaluated with Lipoprotein (a) Molarity Assay on the Beckman Coulter AU680 Chemistry Analyzer and are briefly summarized below.
All acceptance criteria were met.

4.1 Precision

Precision/Reproducibility:

A precision study to assess repeatability and within-laboratory precision was conducted according to CLSI EP05-A3. Five human serum samples and two controls were run in replicates of two per run, with two runs per day, over 21 days on the AU680 analyzer using three reagent lots. Results meet acceptance criteria and are shown below:

Sample	Mean (nmol/L)	Within-Run		Between-Run		Between-Day		Between-Lot		Total	
	(N=252)	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Control 1	34.24	0.581	1.70%	0.405	1.18%	0.512	1.50%	0.110	0.32%	0.714	2.09%
Control 2	94.21	0.622	0.66%	0.455	0.48%	0.532	0.57%	0.180	0.19%	0.769	0.82%
Sample 1	34.57	0.607	1.76%	0.444	1.28%	0.392	1.13%	0.218	0.63%	0.680	1.97%
Sample 2	74.59	0.623	0.83%	0.422	0.57%	0.557	0.75%	0.102	0.14%	0.766	1.03%
Sample 3	115.55	0.690	0.60%	0.552	0.48%	0.484	0.42%	0.149	0.13%	0.794	0.69%
Sample 4	148.85	1.429	0.96%	0.949	0.64%	0.827	0.56%	0.176	0.12%	1.467	0.99%
Sample 5	198.84	1.804	0.91%	1.271	0.64%	1.056	0.53%	0.432	0.22%	1.906	0.96%

An additional precision study was conducted per CLSI EP05-A3 using samples with known apolipoprotein a (apo(a)) isoform sizes (as determined by SDS agarose gel electrophoresis and Western blot analysis). Three human serum sample pools and two native human serum samples were tested in two replicates, two runs per day for > 21 days on the AU680 analyzer using one lots of reagent. Results support that precision is not dependent on apo(a) isoform size. Results meet acceptance criteria and are shown below:

Sample	Mean (nmol/L)	Within-Run		Between-Run		Between-Day		Total	
	(N=84)	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Lp(a)_Low	45.27	1.115	2.46%	0.837	1.85%	1.752	3.87%	1.985	4.38%
Lp(a)_Med	87.63	1.317	1.50%	1.181	1.35%	2.926	3.34%	3.136	3.58%
Lp(a)_High	123.40	1.446	1.17%	1.250	1.01%	3.307	2.68%	3.519	2.85%
PS22	74.78	1.452	1.94%	1.461	1.95%	2.341	3.13%	2.725	3.64%
PS27	112.18	0.940	0.84%	0.466	0.42%	1.008	0.90%	1.239	1.10%

4.2 Analytical Sensitivity

Limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) studies were conducted based on CLSI EP17-A2.

For determination of LoB, one analyte-free saline (0.9% NaCl) sample was measured with three reagent lots in six runs, with ten replicates per run, over three days on the AU680 analyzer for a total of 60 determinations per lot. The LoB was determined as the 95th percentile of the 60 determinations.

For determination of LoD, five human serum samples with low Lp(a) concentrations were measured with three reagent lots with 4 replicates per sample per run, over 3 days on the AU680 analyzer for a total of 60 determinations per lot. The LoD was determined as the lowest amount of analyte in a sample that can be detected with 95% probability.

For determination of LoQ, five human serum samples with low Lp(a) concentrations were measured with three reagent lots in five replicates per sample per run, over 3 days on the AU680 analyzer for a total of 15 determinations per sample per lot. The LoQ was determined as the lowest concentration of analyte that can be quantified with an intermediate precision of no more than 20% CV. The results of the studies are shown below.

	Lot 1 (nmol/L)	Lot 2 (nmol/L)	Lot 3 (nmol/L)	Labeling claim (nmol/L)
LoB	0.465	0.485	0.475	0.49
LoD	1.17	1.50	0.99	1.50
LoQ	4.85	4.32	4.00	4.85

4.3 Linearity/Assay Reportable Range

Linearity studies

A linearity study was conducted to demonstrate that measurements across the claimed assay reportable range are linear. The study was conducted according to CLSI EP06 2nd Edition. Dilution series were prepared from either a human serum sample or a human K3EDTA plasma sample containing a high concentration of Lp(a) diluted with 0.9% NaCl to create 18 levels for serum (ranging from ~4 to 240 nmol/L) and plasma (ranging from ~4 to 241 nmol/L). The sets of dilutions were run on one AU680 analyzer in one run using three replicates per level per lot of

reagent and three reagent lots. Linear regression was conducted for each dilution series and the deviation from linearity was calculated. The linear regression results meet acceptance criteria and are shown below.

Sample type, Lot	Linear regression equation	R^2
Serum, Lot 1	y = 0.9913x	0.9996
Serum, Lot 2	y = 0.9930x	0.9997
Serum, Lot 3	y = 1.0028x	0.9998
Plasma, Lot 1	y = 0.9955x	0.9994
Plasma, Lot 2	y = 0.9971x	0.9998
Plasma, Lot 3	y = 0.9963x	0.9994

An additional linearity study was conducted according to CLSI EP06 2nd Edition to assess linearity in serum samples with known apo(a) isoform sizes. Dilution series were prepared from either a high Lp(a) concentration human serum (with small apo(a) isoform size of 22 kringle IV (KIV) repeats) and low Lp(a) concentration human serum (with large apo(a) isoform size of 25 KIV repeats) diluted with 0.9% NaCl to create 13 levels for the small apo(a) isoform sample (ranging from ~4 to 157 nmol/L) and large apo(a) isoform size sample (ranging from ~4 to 37 nmol/L).. The dilution series was run on one AU680 analyzer in one run using three replicates per level and one reagent lot. The linear regression results support that linearity is not dependent on apo(a) isoform size.
The linearity studies support the claimed measuring interval of 4.85 – 240 nmol/L. The reportable range of the assay is 4.85 – 240 nmol/L.

4.4 Dilution
A dilution study was conducted to validate the automatic rerun function on the AU680 analyzer. Five native human serum samples were diluted manually and automatically (via the automatic rerun function) using a 1:3 dilution. Each sample was measured in one replicate per lot of reagent using three lots of reagent on the AU680 analyzer. The results support the automatic rerun function on the AU680 analyzer.

4.5 High Dose Hook Effect
A high dose hook effect study was conducted to confirm that no false results will be reported due to a high dose hook effect. One native human serum sample containing high concentrations of Lp(a) were diluted with 0.9% NaCl to create 16 levels. Each level was measured in triplicate on one AU680 analyzer and one reagent lot. The results meet acceptance criteria and support the labeling claim of no false results up to an Lp(a) concentration of 432 nmol/L.

4.6 Endogenous interference
An endogenous interference study was conducted to assess whether endogenous substances interfere with assay results. Two human serum pools with two different Lp(a) concentrations (low level ranged from 45.2 to 53.5 nmol/L; high level ranged from 104.1 to 119.5 nmol/L) were split into two parts with one part spiked with potential interferent (interference pool) and the

other part spiked with solvent (dilution pool). Each part was measured in 3 replicates according to CLSI EP07 3rd Edition and the mean value was used to calculate the difference between matched samples with or without interferent. The observed maximum difference was < 10% at the following levels of interferent. Results meet acceptance criteria and are shown below:

Interference	Concentration
Albumin	7400 mg/dL
Bilirubin	77 mg/dL
Bilirubin Conjugated	70 mg/dL
Hemoglobin	1220 mg/dL
Immunoglobulin G	6700 mg/dL
Intralipid	2500 mg/dL
Rheumatoid Factor	1330 IU/mL
Triglyceride	1000 mg/dL

4.7 Exogenous interference

An exogenous interference study was conducted to assess whether the presence of common drugs substances interferes with assay results. Two human serum pools with two different Lp(a) concentrations (low level ranged from 45.2 to 53.5 nmol/L; high level ranged from 104.1 to 119.5 nmol/L) were split into two parts with one part spiked with potential interferent (interference pool) and the other part spiked with solvent (dilution pool). Each part was measured in 3 replicates according to CLSI EP07 3rd Edition and the mean value was used to calculate the difference between matched samples with or without interferent. The observed maximum difference was < 10% at the following levels of interferent. Results meet acceptance criteria and are shown below:

Interferent	Concentration
Ascorbic Acid	176.1 mg/dL
N-Acetylcysteine	15 mg/dL
Acetylsalicylic acid	3 mg/dL
Ampicillin-Na	7.5 mg/dL
Cefoxitin	660 mg/dL
Doxycycline	1.8 mg/dL
Heparin	3300 IU/L
Levodopa	0.8 mg/dL
Methyldopa	2.3 mg/dL
Metronidazole	12.3 mg/dL

Rifampicin	4.8 mg/dL
Acetaminophen	15.6 mg/dL
Cyclosporine	0.2 mg/dL
Ibuprofen	21.9 mg/dL
Theophylline	6 mg/dL
Phenylbutazone	32.1mg/dL

4.8. Analytical Specificity/Cross-reactivity

A cross-reactivity study was conducted to assess whether substances structurally related to Lp(a) cross-react with the assay. Two native serum samples (low level ranged from 40.28 – 41.85 nmol/L; high level ranged from 107.05 – 112.49 nmol/L) were split into two parts with one part spiked with potential cross-reactant and the other part not spiked with cross reactant. Each part was measured in 5 replicates, and the mean values were used to determine the absolute difference between matched samples with or without potential cross-reactant. Percent cross reactivity was then calculated using the following formula: (100 * absolute difference) / cross-reactant concentration. No cross reactivity was detected for apolipoprotein B at 223 mg/dL or plasminogen at 160 mg/dL at either level of Lp(a). Results meet acceptance criteria.

4.9. Sample Matrix Comparison

The effect on quantitation of lipoprotein (a) values in the presence of anticoagulants with the Lipoprotein (a) Molarity Assay was determined on the Beckman Coulter AU680 Chemistry Analyzer by comparing values obtained from samples collected in serum, Li-Heparin, K2-EDTA and K3- EDTA plasma tubes. The study was performed using 71 donors (71 sets of four-way matched samples) measured on the Beckman Coulter AU680 Chemistry Analyzer. All predefined acceptance criteria were met, supporting the labeling claim that serum, Li-Heparin, K2-EDTA and K3-EDTA plasma are acceptable sample types.

comparison groups	N	Sample range (nmol/L)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient (r)
serum vs. K2EDTA	71	6.29-224.40	1.002 (0.983-1.020)	-0.957 (-2.574-0.659)	0.9970
serum vs. K3EDTA	71	6.07-213.59	0.961 (0.945-0.976)	0.288 (-1.072-1.648)	0.9977
serum vs. Li-Hep	71	6.53-216.53	0.974 (0.955-0.993)	-1.283 (-2.970-0.404)	0.9966

4.10. Method Comparison to Lp(a) ELISA reference method

A method comparison study was conducted with the Diazyme Lp(a) Molarity assay on the AU680 analyzer and an Lp(a) apo(a) size insensitive ELISA assay measuring Lp(a) in nmol/L. Two hundred and nine (209) native human serum samples were tested in singlicate on the candidate device reagent and AU680 analyzer using two operators and three lots of reagents, as well as by the Lp(a) ELISA assay. Deming regression analysis was conducted. The results of the

analysis, including slope with 95% confidence interval (CI), intercept with 95% CI, and correlation coefficient, are shown below. Results meet acceptance criteria.

Value (N=209)	**Operator 1 Lot 1**	**Operator 1 Lot 2**	**Operator 1 Lot 3**	**Operator 2 Lot 1**	**Operator 2 Lot 2**	**Operator 2 Lot 3**	**All Lots**
Slope	1.006	0.989	1.024	1.015	1.009	1.025	1.012
Slope Lower 95% CI	0.990	0.973	1.007	0.997	0.991	1.008	1.005
Slope Upper 95% CI	1.023	1.005	1.041	1.033	1.026	1.043	1.019
Intercept	-0.230	2.429	-0.453	-1.401	0.510	-1.672	-0.149
Intercept Lower 95% CI	-1.745	0.938	-2.049	-3.048	-1.116	-3.310	-0.797
Intercept Upper 95% CI	1.285	3.920	1.144	0.245	2.137	-0.034	0.500
Corr Coeff (R)	0.9930	0.9930	0.9925	0.9919	0.9920	0.9921	0.9923
R Squared	0.9860	0.9860	0.9851	0.9839	0.9841	0.9843	0.9847

4.11. Stability

The stability data supports Diazyme's claims as reported in the package labeling.

5. CLINICAL PERFORMANCE EVALUATION

5.1. Expected Values/Reference Range:

A reference range study was conducted and Lp(a) levels among various sub-populations were measured. The expected ranges were determined using samples from apparently healthy adults in the United States.

The reference ranges are not intended to be used as medical decision thresholds for cardiovascular risk. Each laboratory should investigate the transferability of the expected values to its own patient population and, if necessary, determine its own reference ranges.

Lp(a) by Race

	n	Median	2.5th percentile	97.5th percentile	Unit
All	534	52.7	< 4.85	357.4	nmol/L
White	123	27.4	< 4.85	296.5	nmol/L
African-American/Black	211	89.2	10.0	382.5	nmol/L
Asian	120	38.9	5.3	169.4	nmol/L
Other	80	48.3	< 4.85	210.7	nmol/L

6. CLINICAL LITERATURE

The National Lipid Association (2024) (PMID: 38565461) provides risk classification guidelines for associations between Lp(a) and ASCVD risk: individuals with Lp(a) levels <75 nmol/L are classified as low risk, those with Lp(a) levels ≥125 nmol/L as high risk, and those with Lp(a) levels between 75 and 125 nmol/L as intermediate risk. These thresholds align with the 2018 AHA/ACC/AACVPR multi-society guideline on cholesterol management (PMID: 30423393) and the 2019 ACC/AHA guideline on primary prevention of cardiovascular disease (PMID: 30879339), both of which identify Lp(a) ≥125 nmol/L as a risk-enhancing factor for atherosclerotic cardiovascular disease (ASCVD), particularly at higher values (PMID: 28183512). Associations between Lp(a) and ASCVD risk have also been demonstrated in the Dallas Heart Study (DHS) (PMID: 19307470, PMID: 27831500). In addition, these thresholds are aligned with the Lp(a) Consensus Statement by the European Atherosclerosis Society, which uses UK Biobank data to derive the thresholds. The relationship of Lp(a) concentrations to incident ASCVD was studied in 460,506 participants and is one of the biggest studies. The increasing ASCVD risk with higher Lp(a) values is supported by prospective cohort data from the UK Biobank study (PMID: 33115266). Information was provided to bridge the results from the published studies to the candidate device.

7. CONCLUSIONS

The analytical performance data for Lipoprotein (a) Molarity Assay met the acceptance criteria. The analytical performance data and clinical performance evaluation support the substantial equivalence of Lipoprotein (a) Molarity Assay on the Beckman Coulter AU680 Chemistry Analyzer to the predicate.