July 21, 2023

Abbott Ireland Diagnostics Division
Cherie Lipowsky
Regulatory Affairs Project Manager
Lisnarnuck, Longford
Co. Longford, Ireland

Re: K223317
Trade/Device Name: Alkaline Phosphatase2
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline Phosphatase Or Isoenzymes Test System
Regulatory Class: Class II
Product Code: CJE
Dated: June 15, 2023
Received: June 16, 2023

Dear Cherie Lipowsky:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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.
Acting Deputy Director
Division of Chemistry 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223317

Device Name
Alkaline Phosphatase2

Indications for Use *(Describe)*
The Alkaline Phosphatase2 assay is used for the quantitation of alkaline phosphatase in human serum or plasma on the ARCHITECT c System.
Measurements of alkaline phosphatase or its isoenzymes are to be used as an aid in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

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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Section 5: 510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Amendments (SMDA) of 1990 and 21 CFR §807.92.

I. 510(k) Number

K223317

II. Applicant Name

Abbott Ireland Diagnostics Division
Lisnamuck, Longford
Co. Longford,
Ireland

Primary contact person for all communications:

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Date Summary Prepared: July 20, 2023

III. Device Name

Trade Name: Alkaline Phosphatase2

Device Classification: Class II
Classification Name: Alkaline phosphatase or isoenzymes test system
Governing Regulation Number: 21 CFR §862.1050
Product Code: CJE

IV. Predicate Device

Alkaline Phosphatase (k023807)

V. Description of Device

A. Principles of the Procedure

Alkaline Phosphatase in a sample catalyzes the hydrolysis of colorless para-nitrophenyl phosphate (*p*-NPP) to give para-nitrophenol (yellow phenoxide form at alkaline pH) and inorganic phosphate. The rate of absorbance increase at 404 nm is directly proportional to the alkaline phosphatase activity in the sample. Optimized concentrations of zinc and magnesium ions are present to activate the alkaline phosphatase in the sample.

Methodology: Para-nitrophenyl phosphate (*p*-NPP)

B. Reagents

The configurations of the Alkaline Phosphatase2 reagent kits are described below.

	List Number	
	04S8720	**04S8730**
Tests per cartridge set	200	600
Number of cartridge sets per kit	8	8
Tests per kit	1600	4800
Reagent 1 (R1)	53.9 mL	53.9 mL
Reagent 2 (R2)	12.9 mL	33.6 mL

R1: Active ingredient: 2-amino-2-methylpropanol (AMP) (179.550 g/L).
Preservative: sodium azide.

R2: Active ingredient: 4-nitrophenyl phosphate (30.430 g/L).
Preservative: sodium azide.

VI. Intended Use of the Device

The Alkaline Phosphatase2 assay is used for the quantitation of alkaline phosphatase in human serum or plasma on the ARCHITECT c System.

Measurements of alkaline phosphatase or its isoenzymes are to be used as an aid in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

VII. Comparison of Technological Characteristics

The Alkaline Phosphatase2 assay (subject device) is an automated clinical chemistry assay for the quantitation of alkaline phosphatase in human serum or plasma on the ARCHITECT c System.

The similarities and differences between the subject device and the predicate device are presented in the following table.

Similarities and Differences Between		
Device & Predicate Device		
	Device: **Alkaline Phosphatase2**	**Predicate Device:** **Alkaline Phosphatase (LN 7D55) (k023807)**
General Device Similarities		
Platform	ARCHITECT c System	Same
Intended Use and Indications for Use	The Alkaline Phosphatase2 assay is used for the quantitation of alkaline phosphatase in human serum or plasma on the ARCHITECT c System. Measurements of alkaline phosphatase or its isoenzymes are to be used as an aid in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.	The Alkaline Phosphatase assay is intended to measure alkaline phosphatase in serum or plasma. Measurement of alkaline phosphatase is used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.
Methodology	Para-nitrophenyl phosphate (*p*-NPP)	Same
Specimen Type	Human serum or plasma	Same

Similarities and Differences Between		
Device & Predicate Device		
	Device: **Alkaline Phosphatase2**	**Predicate Device:** **Alkaline Phosphatase (LN 7D55) (k023807)**
Assay Principle / Principle of Procedure	Alkaline Phosphatase in a sample catalyzes the hydrolysis of colorless para-nitrophenyl phosphate (*p*-NPP) to give para-nitrophenol (yellow phenoxide form at alkaline pH) and inorganic phosphate. The rate of absorbance increase at 404 nm is directly proportional to the alkaline phosphatase activity in the sample. Optimized concentrations of zinc and magnesium ions are present to activate the alkaline phosphatase in the sample.	Alkaline phosphatase in the sample catalyzes the hydrolysis of colorless *p*-nitrophenyl phosphate (*p*-NPP) to give *p*-nitrophenol and inorganic phosphate. At the pH of the assay (alkaline), the *p*-nitrophenol is in the yellow phenoxide form. The rate of absorbance increase at 404 nm is directly proportional to the alkaline phosphatase activity in the sample. Optimized concentrations of zinc and magnesium ions are present to activate the alkaline phosphatase in the sample.
Use of Controls	Yes	Same
Tube Types	Serum: - Serum tubes - Serum separator tubes Plasma: - Lithium heparin tubes - Lithium heparin separator tubes - Sodium heparin tubes	Serum: - Glass or plastic tubes with or without gel barrier Plasma: - Glass or plastic tubes - Lithium heparin (with or without gel barrier) - Sodium heparin
General Device Differences		
Standardization	IFCC* traceable material	Molar extinction of *p*-nitrophenol (non-IFCC method)
Calibration method	Calibration and Calibration Factor method	Factor method
Assay Range	Analytical Measuring Interval: 4–4522 U/L Reportable Interval: 3–4522 U/L	Analytical Measuring Interval: 5–4555 U/L

* IFCC = International Federation of Clinical Chemistry and Laboratory Medicine

Similarities and Differences Between		
Device & Predicate Device		
	Device: **Alkaline Phosphatase2**	**Predicate Device:** **Alkaline Phosphatase (LN 7D55) (k023807)**
Lower Limits of Measurement	Limit of Blank: 1 U/L Limit of Detection: 3 U/L Limit of Quantitation: 4 U/L	Limit of Detection: 5.0 U/L Limit of Quantitation: 5.0 U/L

VIII. Summary of Nonclinical Performance

A. Reportable Interval

Based on the limit of detection (LoD), limit of quantitation (LoQ), precision, and linearity, the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.*

	U/L
Analytical Measuring Interval (AMI)[a]	4–4522
Reportable Interval[b]	3–4522

[a] AMI: The AMI is determined by the range of values in U/L that demonstrated acceptable performance for linearity, imprecision, and bias.
[b] The reportable interval extends from the LoD to the upper limit of the AMI.

* Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking. 1st ed*. CLSI Document EP34. Wayne, PA: CLSI; 2018.

B. Within-Laboratory Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 3 lots of the Alkaline Phosphatase2 reagents, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Two controls and 4 human serum panels were tested in a minimum of 2 replicates, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot are paired with 1 instrument. The performance from a representative combination is shown in the following table.

Calibration method

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	**n**	**Mean (U/L)**	**SD (Range[b])**	**%CV (Range[b])**	**SD (Range[b])**	**%CV (Range[b])**
Control Level 1	80	116	0.8 (0.8 – 1.0)	0.7 (0.7 – 0.8)	3.0 (2.7–3.0)	2.6 (2.3–2.6)
Control Level 2	80	428	1.4 (1.2 – 1.7)	0.3 (0.3 – 0.4)	7.8 (7.5–8.4)	1.8 (1.7–2.0)
Panel A	80	9	0.6 (0.6 – 1.1)	6.3 (6.3 – 11.7)	0.6 (0.6–1.1)	6.7 (6.7–11.8)
Panel B	80	42	0.7 (0.7 – 0.9)	1.6 (1.6 – 2.3)	1.0 (1.0–1.2)	2.3 (2.3–2.9)
Panel C	80	2045	6.8 (6.3 – 13.3)	0.3 (0.3 – 0.6)	43.6 (40.5–43.6)	2.1 (1.9–2.1)
Panel D	80	4306	14.6 (14.6 – 28.0)	0.3 (0.3 – 0.6)	77.7 (77.7–98.7)	1.8 (1.8–2.2)

[a] Includes within-run, between-run, and between-day variability.
[b] Minimum and maximum SD or %CV across the 3 reagent lot/calibrator lot/instrument combinations.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

Calibration Factor method

Sample	n	Mean (U/L)	Within-Run (Repeatability) SD (Range[b])	Within-Run (Repeatability) %CV (Range[b])	Within-Laboratory[a] SD (Range[b])	Within-Laboratory[a] %CV (Range[b])
Control Level 1	80	114	0.9 (0.8 – 0.9)	0.8 (0.7 – 0.8)	3.0 (2.7–3.1)	2.6 (2.3–2.6)
Control Level 2	80	423	1.3 (1.2 – 1.7)	0.3 (0.3 – 0.4)	7.9 (7.5–8.3)	1.9 (1.7–1.9)
Panel A	80	9	0.7 (0.7 – 1.0)	7.2 (7.2 – 11.3)	0.7 (0.7–1.1)	7.2 (7.2–11.5)
Panel B	80	41	0.7 (0.7 – 0.9)	1.7 (1.6 – 2.2)	0.9 (0.9–1.2)	2.1 (2.1–2.9)
Panel C	80	2017	6.7 (6.4 – 13.4)	0.3 (0.3 – 0.6)	44.9 (39.5–44.9)	2.2 (1.8–2.2)
Panel D	80	4248	14.4 (14.4 – 28.5)	0.3 (0.3 – 0.6)	81.0 (81.0–94.5)	1.9 (1.9–2.1)

[a] Includes within-run, between-run, and between-day variability.
[b] Minimum and maximum SD or %CV across the 3 reagent lot/calibrator lot/instrument combinations.

System Reproducibility

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 1 lot of the Alkaline Phosphatase2 reagents, 1 lot of the Consolidated Chemistry Calibrator, 1 lot each of 2 commercially available control sets, and 3 instruments. Each instrument was operated by a different technician, and each technician prepared an individual sample set. Five levels of controls were tested in a minimum of 3 replicates at 2 separate times per day on 5 different days.

Calibration method

			Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	**n**	**Mean (U/L)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	90	113	1.1	1.0	2.6	2.3	2.6	2.3
Control Level 2	90	460	2.6	0.6	5.6	1.2	6.6	1.4
Control Level A	90	71	0.8	1.2	0.9	1.3	1.1	1.5
Control Level B	90	177	1.7	0.9	4.4	2.5	4.4	2.5
Control Level C	90	359	2.1	0.6	6.3	1.8	7.0	2.0

[a] Includes within-run, between-run, and between-day variability.
[b] Includes within-run, between-run, between-day, and between-instrument variability.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

Calibration Factor method

Sample	n	Mean (U/L)	Repeatability		Within-Laboratory[a]		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV
Control Level 1	90	108	1.0	0.9	2.4	2.3	2.7	2.5
Control Level 2	90	443	2.6	0.6	5.4	1.2	8.0	1.8
Control Level A	90	68	0.8	1.2	0.9	1.3	1.5	2.2
Control Level B	90	171	1.6	0.9	4.4	2.6	5.2	3.0
Control Level C	90	345	2.1	0.6	6.1	1.8	8.9	2.6

[a] Includes within-run, between-run, and between-day variability.
[b] Includes within-run, between-run, between-day, and between-instrument variability.

C. Accuracy

A study was performed to estimate the bias of the Alkaline Phosphatase2 assay relative to materials standardized to the IFCC reference method.

Calibration method

Testing was conducted with each of the 2 materials standardized to the IFCC reference method using 3 lots of the Alkaline Phosphatase2 reagents, 1 lot of the Consolidated Chemistry Calibrator, and 2 instruments. The bias was within ± 3.7%.

Calibration Factor method

Testing was conducted with each of the 2 materials standardized to the IFCC reference method using 3 lots of the Alkaline Phosphatase2 reagents and 2 instruments. The bias was within ± 3.2%.

D. Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.* Testing was conducted using 3 lots of the Alkaline Phosphatase2 reagents on each of 2 instruments over a minimum of 3 days. The limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

Calibration method

	U/L
LoB[a]	1
LoD[b]	3
LoQ[c]	4

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met and was determined from n ≥ 60 replicates of low-analyte level samples.

Calibration Factor method

	U/L
LoB[a]	1
LoD[b]	3
LoQ[c]	4

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met and was determined from n ≥ 60 replicates of low-analyte level samples.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

E. Linearity

A study was performed based on guidance from CLSI EP06, 2nd ed.* This assay is linear across the analytical measuring interval of 4 to 4522 U/L for both the calibration and calibration factor methods.

F. Potentially Interfering Endogenous and Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.* Each substance was tested at 2 levels of the analyte (approximately 70 U/L and 200 U/L).

Potentially Interfering Endogenous Substances

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)	
Potentially Interfering Substance	**Interferent Level**
Bilirubin - conjugated	15 mg/dL
Bilirubin - unconjugated	20 mg/dL
Hemoglobin	250 mg/dL
Total protein	15 g/dL
Triglycerides	1500 mg/dL

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedure.* 2nd ed. CLSI Document EP06. Wayne, PA: CLSI; 2020.

* Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

Interference beyond ± 10% (based on 95% Confidence Intervals [CI]) was observed at the concentration shown below for the following substance.

Interference beyond ± 10% (based on 95% CI)			
Potentially Interfering Substance	**Interferent Level**	**Analyte Level**	**% Interference (95% CI)**
Bilirubin - conjugated	40 mg/dL	70 U/L	28% (27%, 29%)
Bilirubin - conjugated	40 mg/dL	200 U/L	11% (10%, 11%)
Bilirubin - unconjugated	40 mg/dL	70 U/L	21% (20%, 22%)
Bilirubin - unconjugated	60 mg/dL	200 U/L	10% (10%, 11%)
Hemoglobin	1000 mg/dL	70 U/L	-33% (-34%, -31%)
Hemoglobin	1000 mg/dL	200 U/L	-13% (-14%, -13%)

Potentially Interfering Exogenous Substances

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)	
Potentially Interfering Substance	**Interferent Level**
Acetaminophen	160 mg/L
Acetylcysteine	150 mg/L
Acetylsalicylic acid	30 mg/L
Ampicillin-Na	80 mg/L
Ascorbic acid	60 mg/L
Biotin	4250 ng/mL
Ca-dobesilate	60 mg/L
Cefotaxime	60 mg/dL
Cefoxitin	6600 mg/L
Cyclosporine	2 mg/L
Desacetylcefotaxime	6 mg/dL
Doxycycline	20 mg/L
Ibuprofen	220 mg/L
Levodopa	8 mg/L
Magnesium sulfate	50 mg/dL
Methyldopa	25 mg/L
Metronidazole	130 mg/L
Phenylbutazone	330 mg/L
Rifampicin	50 mg/L
Sodium heparin	4 U/mL
Theophylline (1,3-dimethylxanthine)	60 mg/L

G. Method Comparison

A study was performed based on guidance from CLSI EP09-A3[*] using the Passing-Bablok regression method.

Calibration method

Alkaline Phosphatase2 vs Alkaline Phosphatase on the ARCHITECT c8000 System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range[a]
Serum	145	U/L (µkat/L)	1.00	-1 (-0.02)	1.07[b]	8 - 4534 (0.12 – 75.59)

[a] Alkaline Phosphatase (7D55) comparator range.

[b] Slope relative to non-IFCC traceable Alkaline Phosphatase.

Calibration Factor method

Alkaline Phosphatase2 vs Alkaline Phosphatase on the ARCHITECT c8000 System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range[a]
Serum	143	U/L	1.00	-2	1.08[b]	8 - 4042

[a] Alkaline Phosphatase (7D55) comparator range.

[b] Slope relative to non-IFCC traceable Alkaline Phosphatase.

[*] Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. CLSI Document EP09-A3. Wayne, PA: CLSI; 2013.

H. Tube Type

A study was performed to evaluate the suitability of specific blood collection tube types for use with the Alkaline Phosphatase2 assay. Samples were collected from a minimum of 40 donors and evaluated across tube types. The following blood collection tube types were determined to be acceptable for use with the Alkaline Phosphatase2 assay:

Serum

- Serum tubes
- Serum separator tubes

Plasma

- Lithium heparin tubes
- Lithium heparin separator tubes
- Sodium heparin tubes

IX. Summary of Clinical Performance

This section does not apply.

X. Conclusion Drawn from Nonclinical Laboratory Studies

The similarities and differences between the subject device and predicate device are presented in Section 5-VII. The results presented in this 510(k) demonstrate that the subject device Alkaline Phosphatase2 is as safe and effective as the predicate. Any differences between the subject device and the predicate device shown in the tables do not raise different questions of safety and effectiveness.

There is no known potential adverse effect to the operator when using this *in vitro* device according to the Alkaline Phosphatase2 reagent package insert instructions.