Alkaline Phosphatase2

FOR USE WITH

ARCHITECT

en

AlkP2

04S87

G93285R01

B4S870

Created September 2021.

REF 04S8720

REF 04S8730

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

NAME

Alkaline Phosphatase2 (also referred to as AlkP2)

INTENDED USE

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

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.

SUMMARY AND EXPLANATION OF THE TEST

Human alkaline phosphatase consists of a group of at least five tissue-specific isoenzymes which catalyze the hydrolysis of phosphate mono-esters at alkaline pH.[1] In bone, alkaline phosphatase participates in the deposition of hydroxyapatite in osteoid.[2] A variety of disease processes can result in the release of increased quantities of alkaline phosphatase into the blood.[1]

The alkaline phosphatase activity present in the sera of healthy adults originates mainly in the liver and bones.[1] Additional sources include the bile ducts, intestine, kidney, placenta, and leukocytes and may be differentiated by electrophoresis.[1]

Elevation in serum alkaline phosphatase is used as an aid to detect various hepatobiliary and bone diseases. In order to distinguish between liver or bone as the source, clinical findings and additional diagnostic tools, such as liver function tests (LFTs) including gamma-glutamyl transferase (GGT), aspartate aminotransferase (AST) and alanine aminotransferase (ALT), are used.[3] A biliary obstruction may present with alkaline phosphatase levels 10 to 12 times the upper reference limit (URL) and usually returns to baseline on removal of the obstruction.[1]

Alkaline phosphatase levels are usually elevated in hyperthyroidism and hyperparathyroidism.[4] Alkaline phosphatase is also a useful marker for management of patients with Paget's disease[5], osteomalacia[6] and osteoporosis[7], while alkaline phosphatase expressed by intestinal epithelial cells and secreted into serum serves as a marker of intestinal diseases.[8]

Day to day variation of total alkaline phosphatase is 5% to 10%. Postprandially alkaline phosphatase levels may increase, therefore it is preferred to measure alkaline phosphatase in a fasting state.[1, 3]

PRINCIPLES OF THE PROCEDURE

The Alkaline Phosphatase2 assay is an automated clinical chemistry assay.

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)

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

Alkaline Phosphatase2 Reagent Kit 04S87

NOTE: Some kit sizes may not be available. Please contact your local distributor.

Volumes (mL) listed in the following table indicate the volume per cartridge.

REF	04S8720	04S8730
Tests per cartridge set	200	600
Number of cartridge sets per kit	8	8
Tests per kit	1600	4800
R1	53.9 mL	53.9 mL
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.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[9-12]

The following warnings and precautions apply to: R1

WARNING	Contains 2-amino-2-methylpropanol and sodium azide.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / protective clothing / eye protection.

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Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice / attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

The following warnings and precautions apply to: R2	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not pool reagents within a kit or between kits.
- Do not use components from one lot with components from another lot.
- Do not reuse containers, caps or plugs due to the risk of contamination and the potential to compromise reagent performance.
- When either the R1 or R2 reagent cartridge becomes empty, replace both cartridges.
- Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 6 hours before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	10 days	
Opened	2 to 8°C	Until expiration date	Store in upright position.

Reagents may be stored on or off the ARCHITECT c System. If reagents are removed from the system, store at 2 to 8°C (with replacement caps) in their original boxes.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Alkaline Phosphatase2 assay file must be installed on the ARCHITECT c System prior to performing the assay.

Installation of all the required SmartWash updates on the ARCHITECT c Systems Assay Disk Version 17.00 (or higher) must be completed prior to performing the assay. See below for impacted assays:

				VERSION	
Assay Name	**Short Name**	**REF**	**Assay Number**	**Conventional Units / Alternate Units**	**SI Units / Alternate Units**
Albumin BCG	AlbG	7D53	1015	12	10
Magnesium	MAG	3P68	1070	6	4
Magnesium Urine	MAGU	3P68	1099	8	4

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

Alternate Result Units

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
U/L	0.01667	µkat/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types and collection tube types have not been verified with this assay.

Specimen Types	Collection Tubes
Serum	Serum
	Serum separator
Plasma	Lithium heparin
	Lithium heparin separator
	Sodium heparin

- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens.

The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
  - heat-inactivated specimens
  - pooled specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	Room temperature (20 to 25˚C)	7 days[13]
	2 to 8˚C	7 days[13]
	-20˚C	7 days[14]

Avoid multiple freeze/thaw cycles.[14]

It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.

For additional information on sample handling and processing, refer to CLSI GP44-A4.[15] The storage information provided here is based on references.

Each laboratory may establish a range around -20˚C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

04S87 Alkaline Phosphatase2 Reagent Kit

Materials Required but not Provided

- Alkaline Phosphatase2 assay file found on www.corelaboratory.abbott
- 04V1501 Consolidated Chemistry Calibrator, if using the Calibration method
- Controls containing alkaline phosphatase
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the ARCHITECT System Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the ARCHITECT System Operations Manual, Section 5 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 5.5 µL.

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the ARCHITECT System Operations Manual, Section 5.
- Refer to the Consolidated Chemistry Calibrator package insert REF 04V1501 and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Sample dilutions have not been evaluated for the Alkaline Phosphatase2 assay. Samples with an alkaline phosphatase value exceeding 4522 U/L (75.38 µkat/L) are flagged with the code "> 4522 U/L" ("> 75.38 µkat/L").

For details on configuring automated dilutions, refer to the ARCHITECT System Operations Manual, Section 2.

Calibration

For instructions on performing a calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Calibration can be performed using one of 2 methods:

- Calibration method, using the Consolidated Chemistry Calibrator REF 04V1501. For the Calibration method, use assay file AlkP2.
- Calibration Factor method, using a fixed calibration factor value to calculate results. For the Calibration Factor method, use assay file AlkP2F.

Calibration is stable for approximately 10 days (240 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- At least 2 levels of controls (low and high) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to "Basic QC Practices" by James O. Westgard, Ph.D. for guidance on laboratory quality control practices.[16]

RESULTS

Calculation

Calibration method

The Alkaline Phosphatase2 (AlkP2) assay utilizes the Linear data reduction method to generate a calibration and results.

Calibration Factor method

The Alkaline Phosphatase2 (AlkP2F) assay utilizes the Factor data reduction method to generate a calibration and results. The calibration factor for the Alkaline Phosphatase2 assay is 1931.

The Alkaline Phosphatase2 assay is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) reference method.[17]

For additional information on results calculations, refer to the ARCHITECT System Operations Manual, Appendix C.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

Reportable Interval

Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.[18]

	U/L	µkat/L
Analytical Measuring Interval (AMI)[a]	9 – 4522	0.15 – 75.38
Reportable Interval[b]	7 – 4522	0.12 – 75.38

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in U/L (µkat/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.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the reportable interval of 7 U/L (0.12 µkat/L). To flag values using the lower limit of the analytical measuring interval of 9 U/L (0.15 µkat/L), the operator must edit the Low Linearity value.

For detailed information on editing the result settings of the assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- Substances that demonstrated interference with the Alkaline Phosphatase2 assay are listed in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- SmartWashes for assays impacted by Alkaline Phosphatase2 must be configured to avoid interference due to reagent carryover. See the INSTRUMENT PROCEDURE section of this package insert for the required assay file updates.
- Specimens from patients undergoing alkaline phosphatase replacement therapy (asfotase alfa) may exhibit positive interference with alkaline phosphatase assays.[19, 20]

EXPECTED VALUES

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Reference Range[21]

Age	Range (U/L)	Range[a] (µkat/L)
0 to 14 days	90 – 273	1.50 – 4.55
15 days to < 1 year	134 – 518	2.23 – 8.64
1 year to < 3 years	156 – 369	2.60 – 6.15
3 to 5 years	144 – 327	2.40 – 5.45
6 to 10 years	153 – 367	2.55 – 6.12
11 to 15 years, Male	113 – 438	1.88 – 7.30
11 to 15 years, Female	64 – 359	1.07 – 5.98
16 to 21 years, Male	56 – 167	0.93 – 2.78
16 to 29 years, Female	44 – 107	0.73 – 1.78
22 to 79 years, Male	50 – 116	0.83 – 1.93
30 to 79 years, Female	46 – 122	0.77 – 2.03

[a] Alternate result units were calculated by Abbott.

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

Unless otherwise specified, the study results provided in this package insert were generated using the Calibration method.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.[22] 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.

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

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (µkat/L)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	1.93	0.014	0.7	0.050 (0.046 – 0.050)	2.6 (2.4 – 2.6)
Control Level 2	80	7.14	0.022	0.3	0.129 (0.125 – 0.140)	1.8 (1.7 – 2.0)
Panel A	80	0.16	0.010	6.5	0.010 (0.010 – 0.017)	6.5 (6.5 – 11.6)
Panel B	80	0.70	0.012	1.6	0.015 (0.015 – 0.020)	2.2 (2.2 – 2.9)
Panel C	80	34.08	0.113	0.3	0.726 (0.675 – 0.726)	2.1 (1.9 – 2.1)
Panel D	80	71.77	0.243	0.3	1.296 (1.296 – 1.645)	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.

Reproducibility

A study was performed based on guidance from CLSI EP05-A3.[22] 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.

			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 repeatability (within-run), between-run, and between-day variability.

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

			Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	n	Mean (µkat/L)	SD	%CV	SD	%CV	SD	%CV
Control Level 1	90	1.88	0.018	0.9	0.043	2.3	0.043	2.3
Control Level 2	90	7.68	0.044	0.6	0.093	1.2	0.109	1.4
Control Level A	90	1.18	0.014	1.2	0.015	1.3	0.017	1.5
Control Level B	90	2.96	0.028	0.9	0.074	2.5	0.074	2.5
Control Level C	90	5.98	0.036	0.6	0.105	1.8	0.117	1.9

[a] Includes repeatability (within-run), between-run, and between-day variability.

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

Accuracy

A study was performed to estimate the bias of the Alkaline Phosphatase2 assay relative to material standardized to the IFCC reference method.[17]

Calibration method

Testing was conducted using 3 lots of the Alkaline Phosphatase2 reagents, 1 lot of the Consolidated Chemistry Calibrator, and 3 instruments. The bias was within ± 0.9%.

Calibration Factor method

Testing was conducted using 3 lots of the Alkaline Phosphatase2 reagents and 3 instruments. The bias was within ± 5.9%.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[23] 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.

	U/L	µkat/L
LoB[a]	4	0.07
LoD[b]	7	0.12
LoQ[c]	9	0.15

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

[b] The LoD presented in the table was generated using the Calibration Factor method and 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.

Linearity

A study was performed based on guidance from CLSI EP06-A.[24] This assay is linear across the analytical measuring interval of 9 to 4522 U/L (0.15 to 75.38 µkat/L).

Analytical Specificity

Interference

A study was performed based on guidance from CLSI EP07, 3rd ed.[25] 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%)		
	Interferent Level	
Potentially Interfering Substance	Default Units	Alternate Units
Bilirubin - conjugated	15 mg/dL	178 µmol/L
Bilirubin - unconjugated	20 mg/dL	342 µmol/L
Hemoglobin	250 mg/dL	2.5 g/L
Total protein	15 g/dL	150 g/L
Triglycerides	1500 mg/dL	17 mmol/L

Interference beyond ± 10% (based on 95% Confidence Interval [CI]) was observed at the concentrations shown below for the following substances.

Interference Beyond ± 10% (Based on 95% CI)					
Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Bilirubin - conjugated	40 mg/dL	474 µmol/L	70 U/L	1.17 µkat/L	28% (27%, 29%)
Bilirubin - conjugated	40 mg/dL	474 µmol/L	200 U/L	3.33 µkat/L	11% (10%, 11%)
Bilirubin - unconjugated	40 mg/dL	684 µmol/L	70 U/L	1.17 µkat/L	21% (20%, 22%)
Bilirubin - unconjugated	60 mg/dL	1026 µmol/L	200 U/L	3.33 µkat/L	10% (10%, 11%)
Hemoglobin	1000 mg/dL	10 g/L	70 U/L	1.17 µkat/L	-33% (-34%, -31%)
Hemoglobin	1000 mg/dL	10 g/L	200 U/L	3.33 µkat/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%)		
	Interferent Level	
Potentially Interfering Substance	Default Units	Alternate Units
Acetaminophen	160 mg/L	1059 µmol/L
Acetylcysteine	150 mg/L	920 µmol/L
Acetylsalicylic acid	30 mg/L	167 µmol/L
Ampicillin-Na	80 mg/L	215 µmol/L
Ascorbic acid	60 mg/L	341 µmol/L
Biotin	4250 ng/mL	17 µmol/L
Ca-dobesilate	60 mg/L	143 µmol/L
Cefotaxime	60 mg/dL	1320 µmol/L
Cefoxitin	6600 mg/L	15 mmol/L
Cyclosporine	2 mg/L	1.7 µmol/L
Desacetylcefotaxime	6 mg/dL	145 µmol/L
Doxycycline	20 mg/L	45 µmol/L
Ibuprofen	220 mg/L	1067 µmol/L
Levodopa	8 mg/L	41 µmol/L
Magnesium sulfate	50 mg/dL	4154 µmol/L
Methyldopa	25 mg/L	118 µmol/L
Metronidazole	130 mg/L	759 µmol/L
Phenylbutazone	330 mg/L	1069 µmol/L
Rifampicin	50 mg/L	61 µmol/L
Sodium heparin	4 U/mL	N/A
Theophylline (1,3-dimethylxanthine)	60 mg/L	333 µmol/L

N/A = Not applicable

Interferences from medication or endogenous substances may affect results.[26]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3[27] using the Passing-Bablok regression method.

Alkaline Phosphatase2 vs Alkaline Phosphatase on the ARCHITECT c System						
	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range[a]
Serum	133	U/L	1.00	0	1.00	14 – 4830
		(µkat/L)		(0.00)		(0.24 – 80.51)

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

BIBLIOGRAPHY

1. Burtis CA, Bruns DE, editors. *Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics.* 7th ed. St. Louis, MO: Saunders Elsevier; 2015.
2. Goldman L, Schafer AI, editors. *Goldman-Cecil Medicine.* 25th ed. Elsevier/Saunders; 2016.
3. Pagana K, Pagana T. *Mosby's Manual of Diagnostic and Laboratory Tests.* 5th ed. Mosby; 2014.
4. Scappaticcio L, Longo M, Maiorino MI, et al. Abnormal liver blood tests in patients with hyperthyroidism: systematic review and meta-analysis. *Thyroid* 2021;31(6):884-894.
5. Josse RG, Hanley DA, Kendler D, et al. Diagnosis and treatment of Paget's disease of bone. *Clin Invest Med* 2007;30(5):E210-E223.
6. Uday S, Högler W. Nutritional rickets & osteomalacia: a practical approach to management. *Indian J Med Res* 2020;152(4):356-367.
7. Migliorini F, Maffulli N, Spiezia F, et al. Potential of biomarkers during pharmacological therapy setting for postmenopausal osteoporosis: a systematic review. *J Orthop Surg Res* 2021;16(1):1-13.
8. Fawley J, Gourlay DM. Intestinal alkaline phosphatase: a summary of its role in clinical disease. *J Surg Res* 2016;202(1):225-234.
9. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
10. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
11. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
12. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition.* CLSI Document M29-A4. Wayne, PA: CLSI; 2014.
13. Cuhadar S, Atay A, Koseoglu M, et al. Stability studies of common biochemical analytes in serum separator tubes with or without gel barrier subjected to various storage conditions. *Biochem Med* 2012;22(2):202-214.
14. Kachhawa K, Kachhawa P, Varma M, et al. Study of the stability of various biochemical analytes in samples stored at different predefined storage conditions at an accredited laboratory of India. *J Lab Physicians* 2017;9(1):11-15.
15. Clinical and Laboratory Standards Institute (CLSI). *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition.* CLSI Document GP44-A4. Wayne, PA: CLSI; 2010.
16. Westgard JO. *Basic QC Practices; Training in Statistical Quality Control for Medical Laboratories.* 4th ed. Westgard QC, Inc.; 2016.
17. Schumann G, Klauke R, Canalias F, et al. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37 °C. Part 9: Reference procedure for the measurement of catalytic concentration of alkaline phosphatase. *Clin Chem Lab Med* 2011;49(9):1439-1446.
18. Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking.* 1st ed. CLSI Guideline EP34. Wayne, PA: CLSI; 2018.
19. Piec ID, Tompkins B, Fraser WD. Interference of asfotase alfa in immunoassays employing alkaline phosphatase technology. *J Appl Lab Med* 2020;5(2):290-299.
20. Kishnani PS, Rush ET, Arundel P, et al. Monitoring guidance for patients with hypophosphatasia treated with asfotase alfa. *Mol Genet Metab* 2017;122(1-2):4-17.
21. Rifai N, Horvath AR, Wittwer C, editors. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics.* 6th ed. St. Louis, MO: Elsevier; 2018.
22. 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.
23. 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.
24. Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. CLSI Document EP06-A. Wayne, PA: CLSI; 2003.
25. Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry.* 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.
26. Young DS. Laboratory test listings. In: *Effects of Drugs on Clinical Laboratory Tests.* 5th ed. AACC Press; 2000:chap 3.
27. 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.

Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
FOR USE WITH	Identifies products to be used together
PRODUCT OF IRELAND	Product of Ireland
R1	Reagent 1
R2	Reagent 2
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

The ARCHITECT c System family of instruments consists of c4000, c8000, and c16000 instruments.

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For customers in the European Union: if, in the course of using this device, you have reason to believe that a serious incident has occurred, report it to the manufacturer and to your national authority.

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