ARCHITECT Intact PTH

REF 8K25-28
REF 8K25-21

en
Intact PTH
8K25
G94306R01
B8K2U0

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

NAME

ARCHITECT Intact PTH

INTENDED USE

The ARCHITECT Intact PTH assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of intact parathyroid hormone (PTH) in human serum and plasma on the ARCHITECT iSystem.

SUMMARY AND EXPLANATION OF THE TEST

PTH is a single chain polypeptide of 84 amino acids produced by the parathyroid gland. Intact PTH1-84 is secreted into the blood stream and undergoes extensive proteolytic modifications. In contrast to its degradation products, the concentration of intact PTH is relatively independent of glomerular filtration rate and reflects the biologically active portion of the hormone.[1]

The primary role of PTH is to regulate the blood calcium level. PTH synthesis and secretion are stimulated within a few minutes by low concentrations of ionized calcium (Ca_i). The biological activity of PTH is to increase absorption of dietary calcium, decrease renal clearance and mobilize skeletal calcium stores. Abnormally high Ca_i concentrations suppress secretion of PTH.[1]

In conjunction with serum calcium levels, the ARCHITECT Intact PTH assay may be used as an aid in the differential diagnosis of hypercalcemia, hypocalcemia and parathyroid disorders. PTH determination is important in monitoring dialysis patients to manage renal osteodystrophy.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Intact PTH assay is a two-step sandwich immunoassay for the quantitative determination of intact PTH in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample, assay diluent, and anti-PTH coated paramagnetic microparticles are combined. Intact PTH present in the sample binds to the anti-PTH coated microparticles.
2. After washing, anti-PTH acridinium-labeled conjugate is added to create a reaction mixture.
3. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
4. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of intact PTH in the sample and the RLUs detected by the ARCHITECT iSystem optics.

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

REAGENTS

Kit Contents

ARCHITECT Intact PTH 8K25

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

REF	8K25-28	8K25-21
Σ	100	400
MICROPARTICLES	1 x 6.6 mL	4 x 6.6 mL
CONJUGATE	1 x 5.9 mL	4 x 5.9 mL
ASSAY DILUENT	1 x 10.0 mL	4 x 10.0 mL

MICROPARTICLES Anti-PTH (goat, polyclonal) coated microparticles in TRIS buffer. Minimum concentration: 0.05% solids. Preservative: sodium azide.

CONJUGATE Anti-PTH (goat, polyclonal) acridinium-labeled conjugate in MES buffer with protein (bovine, goat) stabilizer. Preservative: sodium azide.

ASSAY DILUENT Intact PTH Assay Diluent containing phosphate buffer with protein (bovine, goat) stabilizer. Preservative: sodium azide.

Other Reagents

MULTI-ASSAY MANUAL DILUENT 1 x 100 mL ARCHITECT Multi-Assay Manual Diluent, REF 7D82-50, containing phosphate buffered saline solution. Preservative: antimicrobial agent.

PRE-TRIGGER SOLUTION ARCHITECT Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

WASH BUFFER ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[2-5]

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

The following warnings and precautions apply to: CONJUGATE	
	
WARNING:	Contains polyethylene glycol octylphenyl ether and sodium azide.
H319	Causes serious eye irritation.
H316*	Causes mild 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.
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.
P332+P313*	If skin irritation occurs: Get medical advice / attention.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EU 1272/2008 (CLP) or OSHA Hazard Communication 29CFR 1910.1200 (HCS) 2012 have been implemented.

Safety Data Sheets are available at www.abbottdiagnostics.com 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 use reagent kits beyond the expiration date.
- **Do not pool reagents within a kit or between kits.**
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. For microparticle mixing instructions, refer to the **PROCEDURE, Assay Procedure** section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
  - To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
  - Once a septum has been placed on an open reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
  - Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.

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

Reagent Storage

When stored and handled as directed, reagents are stable until the expiration date.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened/ Opened*	2-8˚C	Until expiration date	May be used immediately after removal from 2-8˚C storage. Store in upright position.
On board	System temperature	30 days	Discard after 30 days. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

* Reagents may be stored on or off the ARCHITECT iSystem. If reagents are removed from the system, store them at 2-8˚C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. 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 ARCHITECT Intact PTH assay file (assay number 581) must be installed on the ARCHITECT iSystem from an ARCHITECT iSystem Assay CD-ROM prior to performing the assay.
- The ARCHITECT Intact PTH STAT assay file (assay number 585) must be installed on the ARCHITECT iSystem with STAT protocol capability from an ARCHITECT iSystem Assay CD-ROM prior to performing the assay.
- The Routine assay may not be available on all ARCHITECT iSystems.

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

Edit assay parameter "Result concentration units" to select an alternate unit.

Conversion formula:

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

Default result unit	Conversion factor	Alternate result unit
pg/mL	0.106	pmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Verified specimen types to be used with this assay:

Specimen Types	Collection Tubes
Human serum	Serum (use of serum separator tubes may result in a decrease in concentration)
Human plasma	Lithium Heparin Sodium Heparin Potassium EDTA

- PTH degradation may be observed when using thrombin-mediated serum tubes.[6]
- Performance has not been established for the use of cadaveric specimens or the use of body fluids other than human serum and plasma.
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.
- The instrument does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.
- Sodium Citrate, Sodium Fluoride/Potassium Oxalate, and Ammonium Heparin tubes cannot be used with the ARCHITECT Intact PTH assay.

Specimen Conditions

- Do not use specimens with the following conditions:
  - heat-inactivated
  - pooled
  - grossly hemolyzed (> 500 mg/dL)
  - obvious microbial contamination
- 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.
- PTH is relatively unstable: optimization of pre-analytical conditions, including specimen type, sampling time and storage conditions is essential.[7] In order to minimize changes in PTH concentration, it is necessary to select the appropriate tube type and size and avoid multiple tube-to-tube transfers.[8]

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at ≥ 10,000 RCF (Relative Centrifugal Force) for 10 minutes before testing if
  - they contain fibrin, red blood cells, or other particulate matter, or
  - they require repeat testing.
- 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.
- Inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

Specimen Storage

Specimen Type	Storage Temperature	Maximum Storage Time
Serum/plasma	2-8°C	≤ 2 days
	Frozen	6 months

Specimens may be stored on or off the clot, or red blood cells.

If testing will be delayed more than 2 days, remove serum or plasma from the clot, or red blood cells and store frozen.

Specimens stored frozen for 6 months showed no performance difference.

Avoid more than 5 freeze/thaw cycles.

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

8K25 ARCHITECT Intact PTH Reagent Kit

Materials Required but not Provided

- ARCHITECT Intact PTH Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
- 8K25-04 ARCHITECT Intact PTH Calibrators
- 8K25-13 ARCHITECT Intact PTH Controls
- 7D82-50 ARCHITECT Multi-Assay Manual Diluent
- ARCHITECT Pre-Trigger Solution
- ARCHITECT Trigger Solution
- ARCHITECT Wash Buffer
- ARCHITECT Reaction Vessels
- ARCHITECT Sample Cups
- ARCHITECT Septum
- ARCHITECT Replacement Caps
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

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

Assay Procedure

- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.
  - **Invert the microparticle bottle 30 times.**
  - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
  - **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
  - Once the microparticles have been resuspended, place a septum on the bottle. For instructions about placing septums on bottles, refer to the **Reagent Handling** section of this package insert.
- Load the reagent kit on the ARCHITECT iSystem.
  - Verify that all necessary reagents are present.
  - Ensure that septums are present on all reagent bottles.
- Order calibration, if necessary.
  - For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.

- Order tests.
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- Minimum sample cup volume is calculated by the system and printed on the Orderlist report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

  Maximum number of replicates sampled from the same sample cup: 9
  - Priority:

    Sample volume for first test: 200 µL

    Sample volume for each additional test from same sample cup: 150 µL
  - ≤ 3 hours on board:

    Sample volume for first test: 200 µL

    Sample volume for each additional test from same sample cup: 150 µL
  - > 3 hours on board: Additional sample volume required. For information on sample evaporation and volumes, refer to the ARCHITECT System Operations Manual, Section 5.
  - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- Prepare ARCHITECT Intact PTH Calibrators and Controls.
  - Mix calibrator(s) and controls by gentle inversion before use.
  - Hold bottles **vertically** and dispense recommended volumes into each respective sample cup.
  - Recommended volumes:

    for each calibrator: 15 drops

    for each control: 10 drops
- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN.
- For additional information on principles of operation, refer to the ARCHITECT System Operations Manual, Section 3.
- 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.

Specimen Dilution Procedures

Specimens with an intact PTH concentration of > 3000.0 pg/mL (Routine protocol) or > 2500.0 pg/mL (STAT protocol) will be flagged as "> 3000.0 pg/mL" or "> 2500.0 pg/mL" and may be diluted with the Manual Dilution Procedure.

Manual Dilution Procedure

Suggested dilution: 1:2

1. Add 150 µL of the patient specimen to 150 µL of ARCHITECT Multi-Assay Manual Diluent.
2. The operator must enter the dilution factor in the Patient or Control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution and report the result. The result should be > 1.0 pg/mL before the dilution factor is applied.

For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

- Test calibrators A - F in replicates of two. The calibrators should be priority loaded.

  A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.
- Calibration Range:
  - STAT protocol: 0.0 – 2500.0 pg/mL
  - Routine protocol: 0.0 – 3000.0 pg/mL
- Once an ARCHITECT Intact PTH calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
  - A reagent kit with a new lot number is used or
  - Controls are out of range.
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Quality Control Procedures

The recommended control requirement for the ARCHITECT Intact PTH assay is that a single sample of each control level be tested once every 24 hours each day of use. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures.

The ARCHITECT Intact PTH Control values must be within the acceptable ranges specified in the control package insert. If a control is out of its specified range, the associated test results are invalid and samples must be retested. Recalibration may be indicated.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B.

The ARCHITECT Intact PTH assay belongs to method group 1.

RESULTS

Calculation

The ARCHITECT Intact PTH assay uses a point to point data reduction method to generate a calibration curve.

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.

Measurement Range (Reportable Range)

The measurement range for the ARCHITECT Intact PTH assay is

- STAT protocol: 4.0 pg/mL to 2500.0 pg/mL
- Routine protocol: 3.0 pg/mL to 3000.0 pg/mL

Results below the range of measurement should be reported as < 4.0 pg / mL or < 3.0 pg/mL, respectively.

LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- If the Intact PTH results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference, and anomalous values may be observed. Additional information may be required for diagnosis.[9]

EXPECTED VALUES

It is recommended that each laboratory establish its own reference range, which may be unique to the population it serves depending on the geographical, dietary, or environmental factors.

A study was performed for the ARCHITECT Intact PTH assay to establish the reference range using plasma specimens from apparently healthy adults. Data from this study are summarized in the following table.*

		Intact PTH (pg/mL)		
	n	Median	2.5th percentile	97.5th percentile
Healthy Adults	143	35.6	15.0	68.3

* Representative performance data are shown. Results obtained at individual laboratories may vary.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT Intact PTH assay is designed to have precision of ≤ 9% total CV for the Low Control and of ≤ 7% total CV for the Medium and High Control. A study was performed for the ARCHITECT Intact PTH assay, based on guidance from the National Committee for Clinical Laboratory Standards Institute (NCCLS) Protocol EP5-A.[10] Multiple ARCHITECT Intact PTH control lots were assayed using two lots of reagents in replicates of two at two separate times per day for 20 days at one site on two instruments using the STAT protocol and at a second site on two instruments using the Routine protocol.

In addition, a second precision study was performed, where two lots of reagents were assayed in four replicates per run at two separate times per day over 10 days on one instrument at a third site using the STAT protocol and on one instrument at a fourth site using the Routine protocol. Each reagent lot used a single calibration curve throughout the study. Data from both studies are summarized in the following tables.*

ARCHITECT Intact PTH Precision Using STAT Protocol

		Mean Conc.	Within Run		Total[a]	
Sample	n	(pg/mL)	SD	%CV	SD	%CV
Low Control	878	8.5	0.74	8.7	0.74	8.7
Medium Control	880	56.5	2.34	4.1	2.35	4.2
High Control	880	208.9	8.62	4.1	8.62	4.1

ARCHITECT Intact PTH Precision Using Routine Protocol

		Mean Conc.	Within Run		Total[a]	
Sample	n	(pg/mL)	SD	%CV	SD	%CV
Low Control	880	10.7	0.65	6.1	0.69	6.4
Medium Control	880	69.6	2.28	3.3	2.31	3.3
High Control	880	255.8	7.40	2.9	7.56	3.0

[a] Total assay variability contains within run, run to run and day to day variability.

* Representative performance data are shown. Results obtained at individual laboratories may vary.

Recovery

The ARCHITECT Intact PTH assay is designed to have a mean recovery of 100 ± 10%. A study was performed where known concentrations (0, 4.8, 24, 120, 600 pg/mL) of intact PTH were added to 10 aliquots of human plasma with endogenous levels ranging from 22.9 pg/mL to 162.8 pg/mL of intact PTH. The concentration of intact PTH and the percent recovery were calculated for each sample. The percent recovery of the ARCHITECT Intact PTH assay resulted in a mean of 101%. Data are representative performance data, but results obtained at individual laboratories may vary.

Linearity

The ARCHITECT Intact PTH assay is designed to recover diluted specimens within ± 10% of the expected result in the dilution range from 20% to 80%. A dilution linearity study was performed using specimens with undiluted intact PTH values that ranged between 65.6 pg/mL and 2257.0 pg/mL. These specimens were diluted manually using ARCHITECT Multi-Assay Manual Diluent at various dilution factors (0.2 to 0.8) to result in 80% to 20% of the endogenous intact PTH level. Data from this study are summarized in the following tables.*

Sample	Dilution Factor	Observed values (pg/mL)	% Mean Recovery[a]
1	undiluted	65.6	–
	0.2 - 0.8	53.8 - 12.4	97
2	undiluted	779.9	–
	0.2 - 0.8	644.7 - 163.2	103
3	undiluted	2257.0	–
	0.2 - 0.8	1860.5 - 435.2	98

In addition, a dilution study was performed using specimens with different high and low intact PTH concentration values ranging between 19.1 pg/mL and 2038.8 pg/mL. The low level sample was used to dilute the high level sample to different concentrations (dilution factors of 0.25, 0.50 and 0.75). Data from this study are summarized in the following table.*

Sample	Undiluted Concentration Level (pg/mL)	Diluted Concentration Range (pg/mL)	% Mean Recovery[a]
1	Low 19.1 High 615.0	168.3 to 477.1	101
2	Low 21.5 High 1271.9	339.5 to 989.4	104
3	Low 22.8 High 2038.8	522.6 to 1580.8	102

$$^{a}\ \%\ \text{Recovery} = \frac{\text{Observed Value (pg/mL)}}{\text{Expected Value (pg/mL)}} \times 100$$

% Mean Recovery = Mean of % Recovery of all dilutions of a sample

* Representative performance data are shown. Results obtained at individual laboratories may vary.

Functional Sensitivity

The ARCHITECT Intact PTH assay is designed to have a functional sensitivity of ≤ 5 pg/mL at a total CV of 20%. A study was performed using human samples with concentrations targeted at 3 pg/mL, 4 pg/mL and 5 pg/mL of intact PTH. Those samples were tested in replicates of two over 10 days using two reagent lots on two instruments using the STAT protocol and on one instrument using the Routine protocol.

Functional sensitivity was determined to be ≤ 4 pg/mL for the STAT protocol and ≤ 3 pg/mL for the Routine protocol.*

* Representative performance data are shown. Results obtained at individual laboratories may vary.

Analytical Sensitivity

The ARCHITECT Intact PTH assay is designed to have an analytical sensitivity of ≤ 1 pg/mL. Analytical sensitivity is defined as the concentration at two standard deviations above the calibrator A (0.0 pg/mL). In a study (n = 12 runs, 20 replicates of calibrator A and 10 replicates of calibrator B, using three instruments and two reagent lots), the analytical sensitivity was calculated to be 0.23 pg/mL* using the Routine protocol and 0.31 pg/mL* using the STAT protocol at a 95% level of confidence.

* Representative performance data are shown. Results obtained at individual laboratories may vary.

Specificity

The specificity of the ARCHITECT Intact PTH assay is designed to have a cross-reactivity of ≤ 0.01% when tested with structurally similar compounds listed in the table below. A study was performed with the ARCHITECT Intact PTH assay based on guidance from NCCLS Protocol EP7-A.[11] Aliquots of ARCHITECT Intact PTH Calibrator A were supplemented with potential cross-reactants at the concentrations listed and tested for intact PTH. Data from this study are summarized in the following table.*

PTH fragment	Concentrations	% Cross-Reactivity[a]
1-34	100000 pg/mL	0.00
39-68	100000 pg/mL	0.00
53-84	100000 pg/mL	0.00
44-68	100000 pg/mL	0.00
39-84	100000 pg/mL	0.00

$$^{a}\%\ \text{Cross-Reactivity} = \frac{\text{Mean Value spiked - Mean Value non spiked (pg/mL)}}{\text{Concentration of Cross-Reactant (pg/mL)}} \times 100$$

* Representative performance data are shown. Results obtained at individual laboratories may vary.

Interference

Potential interference in the ARCHITECT Intact PTH assay from hemoglobin, bilirubin, triglycerides, and protein at the levels indicated below is designed to be ≤ 10%. Interference was demonstrated by a study based on guidance from the NCCLS Protocol EP7-A.[11] There was no significant interference observed since the % mean recovery is within ± 10% of the expected value. Data from this study are summarized in the following table.*

Potentially Interfering Substance	Concentration	% Mean Recovery[a]
Hemoglobin	500 mg/dL	102
Bilirubin	20 mg/dL	98
Triglycerides	5000 mg/dL	105
Protein low	4 g/dL	106
Protein high	9.5 g/dL	93
Protein high (Routine protocol)	10.5 g/dL	94**

$$^{a}\%\ \text{Recovery} = \frac{\text{Observed Value (pg/mL)}}{\text{Expected Value (pg/mL)}} \times 100$$

% Mean Recovery = Mean of % Recovery of all tested samples

* Representative performance data are shown. Results obtained at individual laboratories may vary.

** For using the STAT protocol, interference with high levels of protein may be observed.

Method Comparison

The ARCHITECT Intact PTH assay is designed to have a correlation coefficient of ≥ 0.95 when evaluated against a comparison assay. A study was performed with the ARCHITECT Intact PTH assay, where regression analysis was performed using the Passing-Bablok and Least Squares regression methods. Data from this study are summarized in the following table.*

ARCHITECT Intact PTH vs. Comparison Assay				
Regression Method	n	Slope	Intercept	Correlation Coefficient
Passing-Bablok [a]	199	1.02	0.61	0.99
Least Squares	199	0.98	9.00	

[a] A linear regression method with no special assumptions regarding the distribution of samples and measurement errors.[12]

In this evaluation, specimen concentrations ranged from 5.9 pg/mL to 1277.0 pg/mL with the ARCHITECT Intact PTH assay and from 7.5 pg/mL to 1344.3 pg/mL with the comparison assay.

Another study was performed comparing the ARCHITECT Intact PTH assay to a diagnostic assay commercially available. In the study 709 specimens were analyzed resulting in a correlation coefficient of 0.99*. The specimen concentrations ranged from 1.5 to 2326.9 pg/mL with the ARCHITECT Intact PTH assay and from 1.2 to 1813.0 pg/mL with the commercially available diagnostic kit. The specimen categories included in the study are as follows: normal adults (285), series of intraoperative measurements of parathyroidectomy (32), Hypoparathyroidism (20), Primary Hyperparathyroidism (39), Chronic Renal Failures (93), Hypercalcemia of malignancies (40), randomized PTH levels (200).

* Representative performance data are shown. Variables such as differences in sampling size and sample population may impact the correlation of the assay, therefore, results obtained at individual laboratories may vary from these data. Inconsistent specimen handling within method comparison studies can contribute to both negative and positive bias variability.

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Key to Symbols

	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
ASSAY DILUENT	Assay Diluent
CONJUGATE	Conjugate
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
CONTROL NO.	Control Number
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
MICROPARTICLES	Microparticles
MULTI-ASSAY MANUAL DILUENT	Multi-Assay Manual Diluent
PRE-TRIGGER SOLUTION	Pre-Trigger Solution
PRODUCED FOR ABBOTT BY	Produced for Abbott by
PRODUCT OF SPAIN	Product of Spain
REACTION VESSELS	Reaction Vessels
REAGENT LOT	Reagent Lot
REF	List Number
REPLACEMENT CAPS	Replacement Caps
SAMPLE CUPS	Sample Cups
SEPTUM	Septum
SN	Serial number
TRIGGER SOLUTION	Trigger Solution
WASH BUFFER	Wash Buffer


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