| **PTH, Intact** |
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| **Purpose** | This procedure provides instructions for performing INTACT PARATHYROID HORMONE (PTH) on the Abbott Architect i1000SR. |
| **Policy Statements** | This procedure applies to all personnel responsible for performing testing on the Abbott Architect i1000SR. |
| **Principle** | 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. Sample, assay diluent, and anti-PTH coated paramagnetic microparticles are combined. Intact PTH present in the sample binds to the anti-PTH coated microparticles. After washing, anti-PTH acridinium-labeled conjugate is added to create a reaction mixture. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture. 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. The ARCHITECT Intact PTH assay can be used with both STAT and Routine protocols. The STAT protocol has a shorter incubation time in comparison to the Routine protocol. STAT and Routine protocols require separate calibrations but require only one reagent kit. To account for differences between the STAT and Routine protocols, a correction factor has been added to the STAT protocol. The correction factor ensures that patient specimen results are consistent between the STAT and Routine protocols. As a consequence of the correction factor, controls read differently between the STAT and Routine protocols. |
| **Clinical Significance** | 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. 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 (Cai). The biological activity of PTH is to increase absorption of dietary calcium, decrease renal clearance and mobilize skeletal calcium stores. Abnormally high Cai concentrations suppress secretion of PTH. 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. |
| **Instrument** | **PRIMARY METHOD:** Abbott Architect i1000SR**SECONDARY (BACKUP) METHOD:** Send out to Esoterix Lab |
| **Sunquest Test Code** | IPTHC, PTH with Calcium |
| **Specimen** | Plasma (Potassium EDTA), Lithium Heparin (no gel) for intraoperative PTH specimens. Refer to specimen collection procedures.**Minimum volume:** 200 µL of potassium EDTA plasma, 100 µL of lithium heparin plasma for Ca**Stability:** 2-8 °C / ≤2 days, < -20°C / 6 months (centrifuge thawed samples prior to use). Avoid more than 5 freeze thaw cycles.**Rejection criteria:** Unlabeled tube, other than potassium EDTA for Intact PTH. Grossly hemolyzed (> 500 mg/dL)**Preparation:** 1. Whole blood specimens should be centrifuged following complete clot formation, according to Specimen Processing procedures prior to analysis.
2. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
3. Lipemic samples should be ultrafuged.
4. Specimens should be free of particulate matter.
5. Transfer serum or plasma to a properly labeled sendout tube. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
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| **Reagents****r** |

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Intact PTH Reagent | 8K25 | **Store at:** 2 – 8 °C**Unopened/Opened:** Manufacture expiration date.**On-board:** 30 Days |
| Intact PTH Calibrator | 8K25-01 | **Store at:**  <-20°C**To Use**: Thaw completely at Room Temp**Unopened**: Manufacture espiration date.**Opened**: Store at 2 – 8 °C and store for 30 days. |
| Multiasay Diluent | 7D82-50 | Refer to Supply Status on Analyzer |
| Pre-Trigger Solution | 06E23-65 | Refer to Supply Status on Analyzer |
| Trigger Solution | 06C55-60 | Refer to Supply Status on Analyzer |
| Wash Buffer | 06C54-58 | Refer to Supply Status on Analyzer |
| Reaction Vessels  | 07C15 (-02 or -03) | N/A |

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| **Risk and Safety:** | Contains polyethylene glycol octylphenyl ether and sodium azide.Avoid contact with skin and eye. Causes serious eye irritation. Wear gloves. Contact with acids liberates very toxic gas. Dispose of in appropriate Hazardous Waste Container. |
| Calibration/ Verification/AMR |

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| Analytical Measuring Range: | 4.0 – 2500.0 pg/mL |
| Reference Material: | Intact PTH Calibrator 8K25-01 |
| Suggested Calibration Levels | A – 0.0 pg/mLB – 4.8 pg/mLC – 24.0 pg/mLD – 120.0 pg/mLE – 600.0 pg/mLF – 3000 pg/mL |
| Verification Scheme: | n=6 |
| Verification Frequency: | * For each new lot of reagent
* After major maintenance or service, if indicated by quality control results
* As indicated in laboratory quality control procedures
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| AMR | Verification of AMR is accomplished with each calibration.* Cal Verification and AMR verification are performed at least once every six (6) months.
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| **Quality Control** | BioRad Lyphochek Specialty Immunoassay Levels 1,2 and 3**Frequency:** Three levels each day of use.**Stability:** 30 Day at -20 to -70°C.**Preparation**: Reconstitute with 2mL of DI water let vials sit for 15 minutes and gently swirl. Aliquot controls into 5 aliqots.**Sunquest Control names:** Level 1 = C-LYSI1, Level 2 = C-LYSI2, Level 3= C-LYSI3**Acceptable ranges:** * Ranges are current in Sunquest and the instrument. Refer to the Quality Control in Chemistry procedure for QC exception codes.
* If a control value is outside the confidence interval, the determination must be repeated. If the repeat determination confirms the deviation, a new reference curve should be established.
* Do not release patient results until the cause of deviation has been identified and corrected
* When a new lot of assayed control is received, validate the manufacturer’s insert range by running the new lot in parallel with the current lot, and confirming that the results obtained are within the stated range
* When a new lot of unassayed control is received, verify new ranges by running the new lot in parallel with the current lot 30 times, and calculate a new range using the method mean ± 3 SD. Ranges are current in Sunquest and the instrument. Refer to the Quality Control Procedure for QC exception codes.
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| **Interferences** | * Use of serum separator tube may result in a decrease concentration of up to 20% when compared with serum collected in tubes without additives.
* PTH degradation may be observed when using thrombinmediated serum tubes.
* Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.
* Do not use specimens with the following conditions: heat-inactivated, pooled, or gross hemolysis (>500mg/dL)
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| **Reference Range** |

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| **Age** | **Lower Limit** | **Upper Limit** |
| Birth to < 1 year | 6 pg/mL | 88 pg/mL |
| 1 year to < 9 years | 16 pg/mL | 63 pg/mL |
| 9 years to <17 years | 22 pg/mL | 88 pg/mL |
| 17 years to < 19 years | 15 pg/mL | 65 pg/mL |

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| **Critical Values** | None specified |
| **Limitations** | The instrument reporting system contains error messages to warn the operator of specific malfunctions. Refer to Operator’s Manual for troubleshooting specific error messages. |
| **Dilutions** | Do not dilute Intact PTH assay. |
| **Result Reporting** | * Results between 4 – 2500 pg/mL without error messages are released
* Results less than 4 are reported as < 4 rather than the numerical value
* Results greater than 2500 pg/mL are reported as >2500 pg/mL rather than the numerical value
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| **Specimen Storage** | Promptly stopper tested specimen and store upright in specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer. |
| **References** | 1. Abbott Architect Intact PTH reagent cartridge insert sheet Abbott Laboratories, Abbott Park, IL, 60064. Revised Date Janurary 2016
2. Abbott Architect Intact PTH calibrator insert sheet Abbott Laboratires, Abbott Park, IL 60064. Revised November 2015.
3. Abbott Architect Safety Data Sheet, Abbott Diganostics, Abbott Park, IL 60064. Revised 2016-04-09.
4. Biorad Lyphochek Specialty Immunoassay Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 Janurary 2018
5. Caliper Paediatric Reference Intervals. The Hospital for Sick Children, Toronto, Ontario.
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| **Historical Record** |

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| **Version** | **Written/Revised By** | **Effective Date** | **Summary of Revisions** |
| 1 | Kelsi Brown | 03/29/2018 | New Procedure |
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