| **CO2** |
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| **Purpose** | This procedure provides instructions for CO2 (CARBON DIOXIDE) ON ABBOTT INSTRUMENTATION. The CO2 method is an *in vitro* diagnostic test for the quantitative measurement of CO2 in human serum and plasma on the Abbott Architect c4000 or Abbott Alinity c automated chemistry analyzers. |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Abbott Architect c4000 or Abbott Alinity c at Children’s Minnesota Laboratory.  |
| **Principle** | Carbon dioxide, as bicarbonate (HCO3–), and phospho(enol)pyruvate (PEP) are converted to oxalacetate and phosphate in the reaction catalyzed by phospho(enol)pyruvate carboxylase (PEPC). Malate dehydrogenase (MDH) catalyzes the reduction of oxalacetate to malate with the concomitant oxidation of reduced nicotinamide adenine dinucleotide (NADH) analog.2 The resulting decrease in absorbance at 404 nm is proportional to the CO2 content in the sample.Methodology: PEP Carboxylase |
| **Clinical Significance** | The determination of serum carbon dioxide total (CO2) in conjunction with other clinical and laboratory information is necessary for the evaluation of acid-base status. A high CO2 content may be observed in compensated respiratory acidosis and metabolic alkalosis. A low CO2 content may be observed in compensated respiratory alkalosis and metabolic acidosis. Additional laboratory determinations will permit differentiation between metabolic and respiratory conditions. |
| **Analyzer** | **Minneapolis: Abbott Alinity c (Sunquest method code: MALIC), Abbott Alinity ci (Sunquest test code: MACC)****St. Paul: Abbott Architect c4000 (Sunquest method code: ARCH4), Abbott Alinity c (Sunquest method code: SALIC)** |
| **Sunquest Test Codes** | TCO2: CO2 in serum and plasma. |
| **Specimen** | Sample: Plasma (lithium heparin with or without gel) preferred. Sodium heparin plasma or serum (with or without gel) also acceptable. Refer to specimen collection procedures.**Minimum sample volume:** 200 µL preferred, 150 µL minimum**Stability when separated from cells/gel:** RT/ 1 hour after draw. After 1 hour, all results must have STABX comment attached to results.**Rejection criteria:** Unlabeled tube, sample type other than serum or heparinized plasma**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. Specimens should be free of particulate matter.
4. Transfer serum or plasma to a properly labeled sendout tube. Short samples should be pipetted into an Abbott sample cup and nested on a sendout tube; any amount remaining after sampling should be pipetted into the sendout tube and tightly capped.
5. Architect and Alinity systems utilize a specimen level detect mechanism, so special racks specific to tube-type are not required.
6. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
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| **Reagents** | **Alinity c and Architect c4000:****Reagent Handling** 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 1 hour 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. Use a pipette to remove all bubbles prior to loading on the Alinity or Architect system.* Do not use reagents beyond the expiration date.
* Do not pool reagents within a kit or between kits.
* Do not use components from one lot with components from another lot.

**Alinity c:**Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.**Alinity c:**

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Abbott Alinity c Carbon Dioxide ReagentCHC# 32623 | 07P72-20 | **Store at:** 2 – 8 °C**Unopened:** Manufacturer’s printed expiration date**On-board**: 14 days**Opened, off the analyzer (with clean caps):** Manufacturer’s printed expiration date. (Reagents may be stored on or off the system. The system tracks time onboard.) |
| Abbott Alinity c Carbon Dioxide CalibratorCHC# 32634 | 08P72-01 | **Store at:** 2 – 8 °C**Unopened:** Manufacturer’s printed expiration date**Opened expiration: 30 days** when opened and stored off the system. |

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|  | **Architect c4000:**

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Abbott Architect Carbon Dioxide ReagentCHC# 32544 | 03L80-21 | **Store at:** 2 – 8°C**Unopened:** Manufacturer’s printed expiration date.**On-board:** 14 Days |
| Abbott Architect Carbon Dioxide CalibratorCHC# 32558 | 01E64-02 | **Store at:** 2 – 8°C**Unopened:** Manufacturer’s printed expiration date**Opened:** 30 Days when tightly capped after use |

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| **Risk and Safety** |

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| **CAUTION:** For in vitro diagnostic use. This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Appropriate Personal Protective Equipment (PPE) must be worn according to Children’s Minnesota Laboratory policies. Current SDSs are kept on the [Children’s StarNet](https://msdsmanagement.msdsonline.com/a07dc954-23d8-42a9-b591-ef5763cdfd33/ebinder/?nas=True) pageR1 reagents: Contains Tris hydroxymethyl aminomethane: Causes mild skin irritation. Contains sodium azide: Contact with acids liberates very toxic gas. Recap and dispose of used reagent in regulated medical waste (red trash).Abbott Carbon Dioxide Calibrators: Contains sodium azide: Contact with acids liberates very toxic gas. Recap and dispose of in regulated medical waste (red trash). |

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| **Calibration** | **Alinity c** and **Architect c4000:**

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| Assay Range: | 8 – 50 mEq/L/mmol/L |
| Reference Material: | Abbott Alinity and Architect Carbon Dioxide Calibrators |
| Suggested Calibration Levels: |  See lot-specific assay set point documentation |
| Calibration Scheme: | 2 levels, Linear data reduction method |
| Calibration Frequency: | 14 Days |
| AMR | AMR is verified twice annually using the Maine Standards GC2 Product # 1200ab by running all applicable levels in triplicate. Assay results are submitted to Maine Standards for compilation and comparison to peers. Results are reviewed and approved by the Technical Specialist. Questionable results are investigated and corrective actions documented. |

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| **Quality Control** | **Alinity c and Architect c4000:** Bio-Rad Liquichek™ Unassayed Multiqual Chemistry Control (Human) Levels 1 & 3**Frequency:** Two levels each shift (days, evenings, nights) **Stability:** Once thawed, opened, and stored tightly capped at 2 to 8°C, this product will be labeled with an expiration date equal to the shortest stability of the included analytes, which is **7 days.****Preparation**: This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used. * To thaw the product, allow it to stand at room temperature (18° to 25°C) until completely thawed but no longer than one (1) hour.
* After thawing, the product **MUST** be gently swirled and inverted several times to ensure homogeneity.
* For optimal analyte stability in the thawed state, promptly return to 2 to 8°C storage after each use and minimize the time at room temperature to no more than 20 minutes daily.
* **Before each use**, gently swirl the contents until homogeneous with no visible signs of precipitate.

**Acceptable ranges:** * Non-Bio-Rad controls will utilize manufacturer ranges and 2 SD Westgard rules.
* New lots of Bio-Rad controls should be run for 20 days in parallel with the current lot whenever possible prior to switching to the new lot.
* Refer to the Westgard Rules in Chemistry procedure (insert hyperlink) for current Westgard rules in place for each analyte.
* **Acceptable ranges are current in Unity Real Time only.** Quality Control results must be rejected in Sunquest when the results cross the interface.
* In the event of a QC failure, refer to the [Unity Real Time QC Review, General User](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.17-unity-real-time-qc-review-general-user.pdf) and navigate to the QC Troubleshooting section.
* Do not load or release patients until QC is acceptable in Unity Real Time.
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| **Interferences** | **Alinity c and Architect c4000:** **Hemolysis, Icterus & Lipemia (HIL) Index Values:**

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At HIL levels at or above the specified cutoff value, append the appropriate comment AFTER visually confirming presence of interferent: -HP for “Hemolysis present, may affect results.” -BIN for “Bilirubin Interference”-LINT for “Lipid Interference” Interference studies were conducted by Abbott Diagnostics Division based on guidance from CLSI EP06-A. Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte. Interference is less than 5% at two CO2 medical decision levels for:* Hemoglobin: up to 2000 mg/dL
* Bilirubin: up to 60 mg/dL
* Lipemia (Intralipid®): up to 2000 mg/dL

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.  |
|  | **Alinity c and Architect c4000:**  |
| **Reference Intervals** |

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| Age | CO2 |
| 0 - 14 days | 5 – 20 mEq/L |
| 15 days – 364 days | 10 – 24 mEq/L |
| 1 - 4 years | 14 – 24 mEq/L |
| 5 - 14 years | 17 - 26 mEq/L |
| 15 – 18 years female | 17 – 26 mEq/L |
| 15 – 18 years male | 18 – 28 mEq/L |
| 19 to 59 years | 22 - 29 mEq/L |
| 60 years and greater | 23 - 31 mEq/L |
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| **Critical Values** | <10 or >40 mEq/LCall and document according to Critical Values policy. |
| **Limitations** | The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in CO2 results. Refer to the [Abbott Architect](https://starnet.childrenshc.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) or [Alinity](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) Operator’s Guides for the meaning of report flags and comments, and instructions for addressing them. Do not report results until a report containing flags and/or comments is resolved.CO2 values can change by 6 mEq/L within 1 hour after draw and exposure to ambient air. The Sunquest comment STABX must be attached to all results greater than 1 hour past uncapping.Interferences from medication or endogenous substances may affect results.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.  |
| **Dilutions** | Do not dilute. |
| **Result Reporting** | **Alinity c and Architect c4000:** * Results between 10 – 40 mEq/L without error messages are released
* Results below 8 mEq/L: report as < 8 mEq/L rather than the numerical value.
* Results greater than 50 mEq/L: report as > 50 mEq/L rather than the numerical value.
* Results less than 10 mEq/L and greater than 40 mEq/L must be called and documented according to the Critical Values policy.
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| **Specimen Storage** | Promptly stopper tested specimen and store upright in a specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer. |
| **References** | 1. Jacobs & DeMott Laboratory Test Handbook, Lexi-Comp, Inc., Hudson, OH, 5th Edition, 2001
2. Architect Carbon Dioxide Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, March 2017.
3. Alinity Carbon Dioxide Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, February 2018.
4. CALIPER pediatric reference range database. (2019). Retrieved October 3, 2019, from https://caliper.research.sickkids.ca/#/
5. Alinity Carbon Dioxide Calibrator Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, February 2018.
6. Architect Carbon Dioxide Calibrator Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, March 2015.
7. Bio-Rad Liquichek Unassayed Multiqual Chemistry Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Erin Bartos | 10/15/2019 | New Procedure for Abbott analyzers |
| 2 | Erin Bartos | 11/25/2019 | Changed CO2 QC to “each shift” |
| 3 | Erin Bartos, Elauteria Earnhardt | October 28, 2020 | Added St. Paul Alinity c as an analyzer; added mpls Alinity c, changed QC type, added HIL box, changed AMR |
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