| **Creatine Kinase** |
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| **Purpose** | This procedure provides instructions CREATINE KINASE (CK) on ABBOTT INSTRUMENTATION.The Alinity c Creatine Kinase assay is used for the quantitation of creatine kinase (CK) in human serum or plasma on the Alinity c analyzer |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Abbott Alinity c at Children’s Minnesota Laboratory. |
| **Principle** | Creatine kinase (CK), present in the patient sample, catalyzes the transfer of a high energy phosphate group from creatine phosphate to ADP. The ATP produced in this reaction is subsequently used to phosphorylate glucose to produce glucose-6-phosphate (G-6-P) in the presence of hexokinase. G-6-P is then oxidized by glucose- 6-phosphate dehydrogenase (G-6-PDH) with the concomitant reduction of nicotinamide adenine dinucleotide phosphate (NADP) to nicotinamide adenine dinucleotide phosphate reduced (NADPH). The rate of formation of NADPH is monitored at 340 nm and is proportional to the activity of CK in the sample. These reactions occur in the presence of N-acetyl-L-cysteine (NAC) which is present as an enzyme reactivator. **Methodology:** NAC (N-acetyl-L-cysteine) For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3. |
| **Clinical Significance** | Measurements of creatine kinase are used in the diagnosis and treatment of myocardial infarction and muscle diseases. Creatine kinase (CK) may also be elevated following muscle injury or strenuous exercise. This enzyme catalyzes the transfer of phosphate groups from creatine phosphate to ADP. One of the end products of the reaction, ATP, serves as an important energy source. CK is found primarily in muscle (skeletal, heart, and uterus), but it is also present in brain tissue. There are at least three molecular species, or isoenzymes, of CK that can be separated by electrophoresis. |
| **Analyzer** | **Minneapolis: Abbott Alinity ci (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code: SALIC)** |
| **Sunquest Test Codes** | **CPK** |
| **Specimen** | Sample: **Preferred:** Plasma (lithium heparin with or without gel)**Alternative:** NaHep, SSTFor 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.**Minimum sample volume:** 200 µL preferred. 150 µL minimum.**Stability when separated from cells/gel:** RT / 2 days; 2 to 8°C/ 7 days; -20°C/ 7 days **Rejection criteria:** Unlabeled tube, sample type other than serum or acceptable 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 directly to a properly labeled pilot tube.
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** | **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 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.
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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Abbott Alinity c Creatinine Kinase Reagent Kit | 08P4220 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**On-board**: System temperature for 30 days |

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| **Risk and Safety** | 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.R1 and R2 Reagent: Contains imidazole and sodium azide. May damage fertility or the unborn child.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | 10 to 4267 U/L |
| Reference Material: | Onboard water |
| Suggested Calibration Levels: | The calibration factor for the Alinity c Creatine Kinase assay is 9081. |
| Calibration Scheme: | Factor data reduction method |
| Calibration Frequency: | 30 days |
| AMR | AMR is verified twice annually using the Maine Standards GC# Product # 1300ab 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** | **Quality Control Material**: Bio-Rad Liquichek Multiqual 1,2,3 Unassayed Control Levels 1 & 3**Frequency:** Two levels each day of use **Stability:** Once thawed, opened, and stored tightly capped at 2 to 8°C, **Multiqual Unassayed Chemistry Control** 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)
* After thawing, the products **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 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** | **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”Potentially Interfering Endogenous Substances:Interference studies were conducted using NCCLS EP7-P.14Hemoglobin: up to 2000 mg/dLBilirubin: up to 60 mg/dLLipemia: up to 1000 mg/dL Interferences from medications or endogenous substances may affect results |
| **Reference Intervals** | **Female:** 0 to 12 years: 68 to 293 U/L 13 to 18 years: 48 to 200 U/L Adult: 29 to 168 U/L **Male:** 0 to 12 years: 68 to 293; U/L13 to 18 years: 80 to 354 U/L Adult: 30 to 200 U/L |
| **Critical Values** | **>4000 U/L**Critical values must be called according to the Critical Limit Test Value Policy. |
| **Limitations** | Moderate or severely hemolyzed specimens can liberate adenylate kinase, ATP, and G-6-P which may affect the lag phase and side reactions of the CK assay system. Request redraw if unable to obtain a numerical value without assay flags. |
| **Dilutions** |

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| Available Auto Dilutions: | 1:10, 1:20 |
| Max Auto Dilution: | 1:20 dilution  |
| Maximum Manual Dilution: | 1:100 dilution, by serial dilutionCreate a 1:10 dilution (20 ul patient sample with 180 ul saline) and mix well. Next, create the 1:100 dilution by adding 20 uL from the 1:10 to 180 uL saline and mix well. |
| Diluent: | Auto Dilution: Onboard Saline; Manual dilution: 0.85% - 0.9& Saline |
| Manual Dilution: | Follow Abbott [Alinity Operator’s Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) instructions for programming automated and manual dilutions. The system will automatically calculate the concentration of the sample and report the result. If a diluted sample result is less than the lower value of the measuring interval of 10 U/L, do not report the result. Rerun and/or investigate for other possible causes of error. |

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| **Result Reporting** | * Results between 10 and 4267 U/L without error messages are released
* Results below 10 without error messages are reported as < 10 U/L.
* Results > 4267 should be diluted using the onboard automated 1:10 dilution.
* Results > 42670 should be diluted using the onboard automated 1:20.
* Results > 85340 following automated dilution are manually diluted at a 1:100 dilution. Release results without error messages following this dilution.
* Results > 426700 following manual dilution are reported as >426700.
* If absorbance read errors persist after following dilution protocols and no numerical result can be obtained, contact technical specialist or pathology department for further guidance.
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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. Abbott Alinity c Creatine Kinase Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL, USA. Revised February 2018
2. Bio-Rad Liquichek Multiqual 1,2,3 Unassayed Chemistry Control Package Insert, Bio-Rad Laboratories.
3. [CALIPER Reference Range Study](https://caliper.research.sickkids.ca/#/) accessed October 27, 2020
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Michelle Anton |  | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | 10/28/2020 | Added correct Alinity ci Mpls, AMR, QC product, dilutions, interferences section, cal ver product, reference range, references, title/number, product numbers |
|  | 2 | Matt Johnson | 8/4/2022 | Reviewed, added 1:20 automated dilution  |
|  | Matt Johnson | 3/10/2023 | Reviewed, no changes. |
|  | 3 | Matt Johnson | 3/8/2024 | Added 1:100 manual dilution. Edited reporting section to reflect dilution change. |