| **Ridgeview Medical Center Laboratory Services** | | | **Department of Origin**  **COAG** | | | **Effective Date** | |
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| **Purpose**  This procedure provides information about Quality Control including supplies, reagents, storage, stability, safety measures and use. It gives directions for performing QC including frequency and daily review, starting new lots, establishing target/limit, using QAP program and storage of QC reports. | | | | | | | |
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| **Reagents** | | **Supplies** | | **Equipment** | | | |
| * Berichrom Heparin kit * Berichrom®Heparin Unfractionated Control 1 * Berichrom®Heparin Unfractionated Control 2 * CA Clean I * CA Clean II | | * 4.0 mL Sample Cups * 2.0 mL sample cups * Reaction Tubes * Preservative-free distilled water | | * Sysmex® CA-1500 System | | | |
| 1. **Berichrom Heparin kit:**  * **Dextran Sulfate Reagent** * **Factor Xa Reagent** * **AT III Reagent (HUMAN)** * **Substrate Reagent**   **Storage and Stability**:   * Store the test kit unopened at 2 to 8 °C. Use before the expiration date given on the label. * **After reconstitution:**  |  |  |  |  | | --- | --- | --- | --- | | **Temperature** | **Factor Xa** | **AT III** | **Substrate Reagent** | | +15 to +25°C | 3 days | 1 week | 2 weeks | | **+2 to +8°C** | **2 weeks** | **2 weeks** | **6 weeks** | | -20°C | 2 months | 2 months | 6 months | | Onboard | 8 hours | 8 hours | 8 hours |  1. **CA Clean I** is liquid and ready to use.   Store at 2-8°C. Do Not Freeze.  Stable unopened at 2-8°C until expiration date on bottle.  Opened bottle stable for **30 days** at 2-8°C.   1. **CA Clean II** is liquid and ready to use.   Stable unopened at 5-35°C until expiration date on cubitainer.  Opened cubitainer is stable for **60 days.**   1. **Berichrom® Heparin Unfractionated Control 1**   Contains unfractionated heparin from porcine intestine (≤ 0.3 IU/mL) and buffered human plasma. The control is lyophilized. Dissolve in 1mL deionized water.   1. **Berichrom® Heparin Unfractionated Control 2**   Contains unfractionated heparin from porcine intestine (≤ 0.7 IU/mL) and buffered human plasma. The control is lyophilized. Dissolve in 1mL deionized water.   * Mix carefully to dissolve (without foam formation) * Allow to stand at +15 to +25°C for at least 15 minutes. * Mix gently once more before use.   **Stability after reconstitution:**   |  |  |  | | --- | --- | --- | | **Temperature** | **UF Ct. 1** | **UF Ct. 2** | | +15 to +25°C | 24 hours | 24 hours | | **+2 to +8°C** | **48 hours** | **48 hours** | | -18°C | 4 weeks | 4 weeks | | Onboard | - | - |   **These products are for in vitro diagnostic use only.**  Reagent Integrity:  Indication of deterioration: No evidence of vacuum in vial upon opening, difficulty in reconstituting reagent, control values outside of determined range  **WARNING:** Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. If discarded into a sink, flush with a large volume of water to prevent azide build up.  QUALITY CONTROL POLICY  **Berichrom Heparin Unfractionated Controls 1 & 2**   1. **Frequency**: Controls should be tested at the initiation of testing, upon reagent changes, and at least once each 8 hour shift. 2. **Performance**: Controls should be run in the same manner as the test samples.   3. **Review**: Controls should be within the tolerance limits established for the specific lot number of control. If control values are outside of determined range:   * Check controls, reagents and instrument performance. * Document actions taken to identify and correct the problem before reporting any patient data. * New control ranges should be established for unassayed controls with changes in each lot of reagent or control material.  1. **QAP** program will be utilized for peer review consistent with current CA1500 coagulation testing. | | | | | | | |
| QC PROCESSING | | | | | | | |
| **Step** | **Action** | | | | | | |
|  | Manually Register QC | | | | | | |
| 1 | From the Main Menu, press [Work List]. | | | | | | |
| 2 | Verify that <**Register Rack>** is displayed above the parameter keys. If not, press [Rack]. | | | | | | |
| 3 | Verify that the next available rack is displayed (white background). Use the [Prev] or [Next] key to locate the next available rack. | | | | | | |
| 4 | Use the up and down arrow keys to select the desired sample rack position, press [ID No. Entry]. | | | | | | |
| 5 | The numeric keypad is displayed. Enter the QC and file number. (**QC7, QC8**) respectively for levels 1 & 2. | | | | | | |
| 6 | Press the blue test key, [**HepU**], for each level. | | | | | | |
| 7 | Press [**Enter**]. Each QC test selected should show the symbol “O” and will be automatically performed in the “micro” mode. Micro mode will display an “M” in the “opt.” column in the respective Work List position on the screen. | | | | | | |
| 8 | Load both levels of control material in 2mL cups and place in the respective “cup” rack positions. | | | | | | |
| 9 | When all levels are programmed and loaded in the respective “cup” rack position, press [**Quit**] on the numeric keypad. | | | | | | |
| 10 | With all reagents and consumables on board, place the rack into the right rack pool of the sampler (input tray). | | | | | | |
| 11 | Press [**Start**] to begin processing. | | | | | | |

REPORTING RESULTS

QC results are reported as heparin concentration in IU/mL. Results will cross the LIS, follow Westgard rules when accepting and rejecting QC results. Refer to current lot QC range chart for control ranges.

Hep UF 1 (QC7) range: **0.08 – 0.34**

Hep UF 2 (QC8) range: **0.37 – 0.77**

**PROCEDURE NOTES**

Overall performance of Berichrom® Heparin testing is dependent on reagent and instrument performance. Acceptable variability (imprecision) should be such, that the total coefficient of variation (CV) of the analytic system is less than 15% on the same lot of control plasma.

**SAFETY**

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| Follow RMC Policy-Laboratory Procedure: Infection Control and Laboratory Safety Hygiene Procedure.  Dispose of all biohazard materials in marked biohazard containers. |

Human source material. *Each donor or donor unit was tested and found to be negative for human immunodeficiency virus (HIV) 1 and 2, hepatitis B virus (HBV) and hepatitis C virus (HCV) using either tests found to be in conformance with the In Vitro Diagnostic Directive in the EU or FDA approved tests. Because no known test can offer complete assurance of the absence of infectious agents, all human derived products should be handled with appropriate caution.*

Related Documents/ Backup Procedure

* HepU (anti-Xa)
* HepU (anti-Xa) Calibration

REFERENCES

* 1. Berichrom® Heparin package insert, Siemens Healthcare Diagnostics Inc., Newark, DE, May 2008
  2. Standard Human Plasma package insert, Siemens Healthcare Diagnostics Inc., Newark, DE, August, 2008
  3. Berichrom® Heparin Calibrator and Controls package insert, Siemens Healthcare Diagnostics Inc., Newark, DE, February 2009.
  4. Clinical Laboratory Standards Institute. Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays: Approved Guideline-Fifth Edition. CLSI Publication H21-A5. Wayne, PA, January, 2008.
  5. Application Sheet for Berichrom® Heparin Assay on Sysmex® CA-1500 System
  6. Sysmex® CA-1500 System Operator’s Manual

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| **Date:** | | **Author:** | | | | | **Date:** | | | **Validated by:** | | | | **Date:** | | | **Approved by:** | | |
| 2/5/2013 | | Joan Goetteman, MT(ASCP) | | | | |  | |  | | | | |  | | |  | | |
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| **Annual Review** | | | | | | | | | | | | | | | | | | | |
| **Date:** |  | |  | |  |  | |  | | |  |  |  | |  |  | |  |  |
| **Initials:** |  | |  | |  |  | |  | | |  |  |  | |  |  | |  |  |
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