Wake Forest Baptist Medical Center	Activated Clotting Time (ACT) using the Hemochron Response and FTCA510 Tubes CCL-007	Dept: 324318	Critical Care Labs
		Effective Date:	March 2013
		Revised Date:	Feb 2019
		Contact:	Ann Shoffner
Name & Title: Gregory Pomper, MD CLIA Laboratory Director		Date:	2/25/19
Signature:			

1) **General Procedure Statement:**
   a. **Purpose:** To provide a procedure and guidelines for lab staff in performing ACT testing using the Hemochron Response.
   b. **Principle:** Activated Clotting Time (ACT) testing involves adding fresh, non-anticoagulated whole blood to a test tube containing clot activator and timing the formation of a clot. The test tube is inserted into a Hemochron Response instrument and mechanical detection of a fibrin clot in the blood sample automatically terminates the test causing the instrument's digital timer to display the coagulation time in seconds.
   c. **Responsible Department/Party/Parties:**
      i. Procedure owner: Ann Shoffner
      ii. Procedure: Critical Care Lab (CCL) Staff
      iii. Supervision: Ann Shoffner
      iv. Implementation: Ann Shoffner and Critical Care Lab (CCL) Staff

2) **PPE Requirements:** Lab Coat. Gloves.

3) **Procedure:**
   A. SUPPLIES NEEDED:
      1. Hemochron Response ACT timer.
      2. FTCA 510/HRFTCA 510 tube (celite/diatomaceous earth activator 12m) used for monitoring moderate to high dose heparin therapy up to 6.0 units/ml of blood. ACT tubes are stable when stored at room temperature and can be stored at 15-30°C. Tubes are stable and should be used prior to the package expiration date.

   B. SPECIMEN REQUIREMENTS:
      2mL of whole blood without anticoagulant.
      1. NOTE: syringes without heparin are clear. Heparinized syringes are white.
      2. Samples with visible clotting or debris accumulation should be rejected and recollected.
      3. Samples should be tested as soon as possible after collection.

   C. QUALITY CONTROL:
   Both electronic and liquid types of quality control material are performed on the Hemochron Response. When a test is initiated by pressing START, system checks are automatically performed. These checks include verification of adequate battery power, test well function, correct temperature and internal timers.

   1. DAILY QC - Electronic Quality Control
   Electronic QC is performed using the Hemochron Electronic System Verification (ESV) Probe. This multi-level QC device contains 3 levels of QC on one probe (100, 300 and 500 seconds). The 100 and 500 second settings are used for QC in the Critical Care Laboratories.

DAILY QC - Electronic Quality Control continued...

Frequency: Two levels of ACT electronic QC (100 and 500 seconds) are performed every 8 hours the analyzer is in use. Both levels of electronic QC should be run in both well 1 and well 2.

a. Electronic QC Procedure:

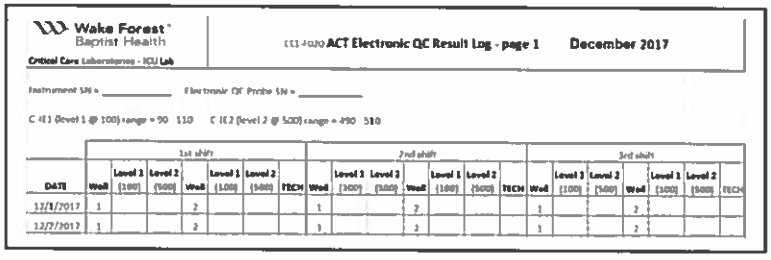
1. If the Hemochron analyzer is in standby, power on the instrument by pressing the START 1 or START 2 button.
2. Press the appropriate level button (100 or 500 seconds) on the ESV. A red light will illuminate on the ESV device.
3. Press either the START 1 (Well 1) or START 2 (Well 2) button on the Hemochron analyzer which corresponds to the well to be QC'd. A green light will illuminate on the analyzer.
4. Insert the QC probe into the appropriate test well. Turn the ESV device or tap the ESV device on its side.
5. If the incorrect level is chosen on the multi-level QC probe, the correct level may be re-selected and performed during counting by pressing the appropriate level button. The ESV will automatically STOP the first test and initiate performance of the newly selected level. When the verification tube reaches its pre-programmed time, it will electronically simulate a test endpoint and the instrument will beep and display the test result. If the instrument's detection system is functioning correctly, the time displayed should be within the acceptable range, shown on the verification tube label.
6. When the test is completed, remove the QC probe from the test well. The results will print.
7. QC results will disappear when the QC probe is removed from the test well. Results can be obtained from the Quality Control database. See the Operator Manual for details. An electronic copy of the Hemochron Manual can be found under *G:\Lab_Shared\ICU_ORLab\ GUIDES, MANUALS, PROCEDURES\Hemochron Response Manual.*

b. Evaluation of Electronic QC results:

1. If an EQC value exceeds acceptable limits, repeat the same EQC level in the same test well.
2. If the EQC value is still unacceptable, change the batteries in the EQC probe and repeat QC testing. You may also try a different EQC probe if available.
3. If the problem persists, run both levels of liquid QC in each testing well. If the liquid QC is acceptable, the Hemochron analyzer is suitable for patient testing. Suspect that the QC probe is faulty. Notify the lab manager.
4. If either level of liquid QC does not fall within acceptable limits, the unit should be removed from service. See *Evaluation of Liquid QC results* found in section B of this procedure.
5. Results should NOT be reported from the Hemochron until QC problems are resolved.
6. Battery Depletion: If a fault message is illuminated next to the test result, and/or the red light on the verification tube is flashing, the battery in the verification tube is nearly depleted and should be replaced.
7. Document all troubleshooting actions on the instrument log sheet located in the *Current Year's Maintenance, QC and Patient Logs* notebook.

c. Documentation of Electronic QC results:

1. Record the Electronic QC results on CCL-F020 *ACT Electronic QC Result Log* located in the *Current Year's Maintenance, QC and Patient Logs* notebook.



Wake Forest Baptist Health
Critical Care Laboratories - ICU Lab

CCL-F020 ACT Electronic QC Result Log - page 1 December 2017

Instrument SN# = _____ Electronic QC Probe SN# = _____

C #1 (level 1 @ 100) range = 90 110 C #2 (level 2 @ 500) range = 490 510

	1st shift							2nd shift							3rd shift						
DATE	Well	Level 1 (100)	Level 2 (500)	Well	Level 1 (100)	Level 2 (500)	TECH	Well	Level 1 (100)	Level 2 (500)	Well	Level 1 (100)	Level 2 (500)	TECH	Well	Level 1 (100)	Level 2 (500)	Well	Level 1 (100)	Level 2 (500)	TECH
12/1/2017	1			2				1			2				1			2			
12/2/2017	1			2				1			2				1			2			

2. Order and result the QC in Beaker using the Quality Control function. For assistance, refer to *Ordering and Resulting QC or How to Result ACT QC when it is automatically ordered* in the *Beaker Quick Reference Guide*.
3. Place the instrument QC tapes in the requisition file box under "A"
4. The tech performing QC is responsible for reviewing and verifying that the QC is acceptable prior to reporting patient testing. The tech initials CCL-F088 or CCL-F089 Daily QC Verification Log as documentation that they have reviewed QC and deem each respective instrument either acceptable or not acceptable for reporting patient testing.

2. WEEKLY QC – Liquid Quality Control

Liquid QC is performed using ITC Normal and Abnormal whole blood quality control material (CPL2) for FTCA510 tubes. Each level of QC consists of a dried whole blood vial and its corresponding diluent for reconstitution. Diluents are lot matched to the whole blood vials. Do not use diluents from one lot of control with whole blood vials from a different lot.

a. Frequency: Two levels of liquid QC should be performed weekly, with each new box of FTCA510 tubes prior to placing into use and anytime instrument performance is in doubt. Before performing liquid QC on ACT tubes that are currently in use, one should first check the lab for any non QC'd boxes of tubes. Weekly liquid QC should be performed on a non QC'd box of tubes first before running QC on a box that is currently in use and has already been QC'd. Following this process will minimize the use of QC material. It is acceptable to run one QC level in one well and run the other QC level in the other well. At the next QC performance the sequence should be switched. Refer to *CCL-F023 ACT Liquid QC Result Log* for the well sequence.

b. Liquid QC Procedure:

1. Allow ACT tubes, dried whole blood vials and diluents vials to reach room temperature for at least 20-60 minutes if removed from refrigeration.
2. Ensure that the Level printed on the diluent vial matches the Level on the dried whole blood QC vial.
3. Program the Hemochron Response to run in QC mode...from the Main Menu (Main Page 1) select option *2 – QC Selects*.
4. Select option *1-QC Normal* or option *2-QC Abnormal* depending on the QC level you wish to run.
5. Refer to the QC ranges printed on the QC package insert and verify that the Lower and Upper range values in the instrument are correct. If the values are correct, press YES (ENTER) x 2. If the values are not correct, change the range by selecting option *1-Lower* or option *2-Upper* and entering the appropriate values then press YES (ENTER) x 2.
6. Using a 3mL syringe with a blunt needle, withdraw exactly 3.0 mL from the diluent vial. Transfer the diluent into the whole blood vial by direct puncture of the stopper.
7. Remove the syringe and needle from the whole blood vial. Do not discard the syringe and needle.
8. Using moderate end-to-end inversion, mix the control vial for exactly 15 seconds.
9. Using the same syringe, withdraw exactly 2.0 mL of the rehydrated whole blood control.
10. Flip the cap on the FTCA510 tube open.
11. Depress the Hemochron START button and immediately transfer the 2.0 mL of control into the FTCA510 tube.
12. Close the cap on the FTCA510 tube. Hold your thumb over the cap and vigorously shake the tube 10 times to disperse the activator. Adequate mixing is important for accurate results.
13. Insert the tube into the Hemochron. Turn the tube clockwise until the green light appears. Turn one additional revolution to assure illumination of the green light.
14. When the test is completed, remove the tube from the test well. The results will print.

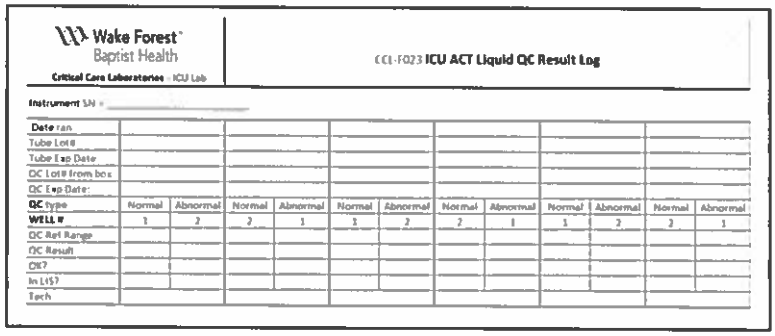
15. QC test results are automatically stored when the test is completed. The QC tag, date and time each test was run are stored with the results for the test.
16. Repeat steps 3 -15 for the 2nd level of QC.
17. After the QC is finished, the analyzer will return to the patient testing prompt.

c. Evaluation of Liquid QC results:

1. If a liquid QC result exceeds the established QC range, repeat that same level and lot # of QC.
2. If the liquid QC result is still unacceptable, repeat QC testing using the same lot # of QC but use a different box of tubes (if available).
3. If the QC result is still unacceptable, obtain a different lot of control material and repeat the testing. If all control material is of the same lot #, use a different box of control material.
4. If the QC result is still unacceptable, DO NOT use the Hemochron instrument for patient testing until a resolution is made. Notify the lab manager. The instrument may be sent to NCBH Facility Services/Clinical Equipment Support (Bio-Med) for repair. ITC Technical Support can also be contacted at 1-800-631-5945 for assistance.
5. The Critical Care Labs has a loaner Hemochron device that can be placed into use. This device is maintained in the ICU Lab. Both levels of electronic QC and liquid QC must be performed and those QC results acceptable before placing the loaner instrument into use.
6. Document all troubleshooting actions on the instrument log sheet located in the *Current Year's Maintenance, QC and Patient Logs* notebook.

d. Documentation of Liquid QC results:

1. Record the Liquid QC results on CCL-F023 *ACT Liquid QC Result Log* located in *Current Year's Maintenance, QC and Patient Logs* notebook.



Wake Forest Baptist Health
Critical Care Laboratories – ICU Lab

CCL-F023 ICU ACT Liquid QC Result Log

Instrument SN: _____

Date ran												
Tube Lot #												
Tube Exp Date												
QC Lot # from box												
QC Exp Date:												
QC type	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
WELL #	1	2	2	1	1	2	2	1	1	2	2	1
QC Ref Range												
QC Result												
OK?												
In LIS?												
Tech												

2. Order and result the QC in Beaker using the Quality Control function. For assistance, refer to *Ordering and Resulting QC* in the *Beaker Quick Reference Guide*.
3. Place the instrument QC tapes in the requisition file box under "A"

D. PATIENT SAMPLE ANALYSIS:

1. If the instrument is in Standby, power ON the Hemochron analyzer by pressing START 1 or START2.
2. Samples should be analyzed immediately after specimen receipt.
3. Verify the patient's name and MR# on the requisition matches the patient's name and MR# on the sample.
4. Prepare the collection syringe to dispense exactly 2.0 ml of blood.
5. Open the flip top of the FTCA510 tube.
6. Depress the Hemochron START 1 or START 2 button that corresponds to the appropriate testing well. Immediately dispense exactly 2.0 ml of blood into the FTCA510 test tube.
7. Close the flip top and hold your thumb over the top of the tube. Immediately shake the test tube **vigorously** from end-to-end ten times to disperse the activator. Adequate mixing is important for accurate results. Quickly tap, tap, tap the bottom of the tube on your finger to make sure the magnet is free and loose.

8. Insert test tube into the Hemochron test well and rotate the tube clockwise until green "Detector" light is illuminated. Turn at least one additional revolution to assure that the green light remains lit.
9. **Enter the patient's Medical Record #** using the numeric keypad and press **YES (ENTER).** Note: The analyzer will begin running the test, but the results will not display or be stored in the database until the MR# is entered into the analyzer.
10. You may edit the MR# by accessing MENU, ID SELECTS and PID. Enter the correct ID when prompted.
11. Results for Well 1 appear in the upper portion of the of the display panel, while results for Well 2 are shown in the lower portion of the display panel.
12. The timer will stop when the test is completed. The result in seconds will remain displayed until the tube is removed from the analyzer.
13. Remove the tube from the analyzer. The results will print when the tube is removed.
14. Tear the printed tape from the Hemochron. Re-verify that the MR# on the tape and the MR# on the requisition match then staple the result tape to the lab requisition.
15. Hemochron Response ACT results will disappear when the tube is removed from the test well. Results can be obtained from the patient database. See the Operator Manual for details.
16. If there is an analyzer error, the error should be evaluated and the sample recollected and re- tested. The ACT tube cannot be re-mixed and used again. Results will not be accurate, since the blood will have already started the clotting process.
17. Patient test results are automatically stored when the test is completed. The PID, date and time each test was run are stored with the results for the test.

E. EVALUATION OF PATIENT RESULTS:

Reportable range = 80 – 600 seconds.
Normal range is patient location dependent.
Post CABG = 102 – 142 seconds
OR Vascular = >200 seconds
Critical Value = n/a

2. Unexpected results of >600 seconds should be evaluated for correct analyzer/tube performance and repeated with a freshly drawn sample to rule out heparin or other sample contamination.
3. Verified results of > 600 seconds should be reported as >600 seconds.
4. Results of 80 seconds or less may indicate improper instrument starting technique. The sample should be credited as LPROB (Lab Problem) and a new sample requested.
5. When questionable results are repeatedly obtained, proper instrument and tube performance should be verified by performing quality control (QC) checks. Do not use the analyzer or tubes for patient testing if QC results are not within acceptable limits. Consideration should be taken that an appropriate uncontaminated sample was used for test analysis. e.g.: If the sample was collected from a line, was the line free and clear of any contaminant fluid?

F. HOW To RECALL a PATIENT or QC RESULT IN THE ANALYZER:

1. **Menu**
2. **4 - Database.**
3. Press **1-Query Pat Rec** to look for a patient result or **3-Query QC Rec** to look for a QC result
4. Press **YES (Enter)** and bypass this screen: **Patient Database**
Records = 12
□ □ □
5. This screen appears: **1 = Search** (Lets you search by patient MR#)
0 = ↑ Record
9 = ↓ Record } Lets you move up and down the database

G. LIS ORDERING and RESULT REPORTING:

1. ACT testing is requested using a paper requisition in the OR and ICU Blood Gas Labs.
2. Order patient testing in Beaker. For assistance, refer to *Manual Ordering via Manage Orders and Order Inquiry* in the *Beaker Quick Reference Guide*.
3. Report results via the *Outstanding List* in Beaker. For assistance refer to *Manually Entering Results* in the *Beaker Quick Reference Guide*.
4. Document called results appropriately.
5. All Lab staff should place a specimen taglet on the *CCL-F003 ACT Patient Result Log* and record the results. The current log in use can be found on the clipboard on the counter.

Wake Forest Baptist Health
Critical Care Laboratories - OR Lab

CCL-F003 **ACT Patient Result Log**

LIS Tag/Pt. ID/Date	Room #	ACT Result	Initial	LIS Tag/Pt. ID/Date	Room #	ACT Result	Initial

I. LIMITATIONS OF THE PROCEDURE:

1. Improper storage of test tubes (exposure to prolonged heat) may affect results.
2. ACT's may be affected by hemodilution, cardiopledgic solutions, hypothermia, platelet dysfunction, hyopfibrinogenemia and other coagulopathies and certain medications.
3. ACT's are affected by poor technique, including venipuncture and test procedure.
4. Inadequate specimen/reagent mixing may result in reduced precision and accuracy.
5. Celite ACT's (FTCA510 tubes) are affected by protease inhibitors which may be administered to reduce post-operative bleeding, especially during cardiopulmonary bypass surgery. Celite ACT's can be prolonged in the presence of these inhibitors.

J. INSTRUMENT MAINTENANCE:

Weekly: Clean the air filter on the bottom of the instrument. Record your initials on the respective general maintenance log: *CCL-F028, CCL-F029 ICU Temp and General Maintenance Log*

K. INSTRUMENT TROUBLESHOOTING:

1. A complete list of fault codes, explanation and corrective actions can be found in the Troubleshooting section of the Hemochron 401/801 Operator's Manual, p. 25 and in the Hemochron Response Operator's Manual p. 28-30.
2. Any questions regarding use of the Hemochron or special handling techniques are referenced to in the instrument specific Hemochron Operating Manual.
3. Technical assistance is available from International Technidyne-Technical Service at 1-800-631-5945.
4. Paper Feed Problem - If you encounter a paper feed problem, place the instrument in standby by pressing and holding the START button. Do NOT poke an object into the printer slot. Turn the instrument back on and allow the paper to feed automatically. When loading a new roll of paper, cut the corners of the paper to form a pointed end. Thread the pointed end into the paper slot until it appears at the top of the printer. Load only a half role of 1265 paper onto the instrument. A full roll is too heavy for the printer to handle.
5. Document all instrument problems and troubleshooting on the ACT Problem Log located in the *Current Year's Maintenance, QC and Patient Logs* notebook. If the instrument problem cannot be resolved,

contact the lab manager and NCBH Facility Services/Clinical Equipment Support (Bio-Med) for repair assistance.

6. IMPORTANT: Hemochron Response analyzers must cleared of all patient data before leaving our facility. To erase patient and QC data, select the Supervisor menu, select Option 1 for patient data and option 2 for QC data.
7. To "hack" a hemochron that has been locked requiring an Operator ID:
   Go to Menu.
   Select 2nd page by pressing 0.
   Select number 4 for Supervisor.
   Enter in the number 7, the first number of the minute of the time that is showing on the analyzer, followed by the number 8, and the second number in the minute showing the time on the analyzer.

L. TURNING THE INSTRUMENT OFF:

Press START 1 or START2.

4) Related Guides/Procedures: CCL-QRG-010 Beaker Quick Reference Guide

5) Attachments: none

6) Related Forms:

CCL-F003 ACT Patient Result Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\RESULT LOGS\CCL-F003 ACT patient result log OR Lab.xlsx)

CCL-F020 ICU ACT Electronic QC Result Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\Maintenance and QC Forms\2017\ACT QC logs ICU.xlsx)

CCL-F021 ICU ACT Liquid QC Result Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\Maintenance and QC Forms\2017\ACT QC logs ICU.xlsx)

CCL-F022 OR Lab ACT Electronic QC Result Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\Maintenance and QC Forms\2017\ACT QC logs OR .xlsm)

CCL-F023 OR ACT Liquid QC Result Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\Maintenance and QC Forms\2017\ACT QC logs OR .xlsm)

CCL-F025 Loaner Hemochron Tracking Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\Maintenance and QC Forms\ACT QC logs Loaner Instrument.xlsx)

CCL-F026 Loaner ACT Electronic QC Result Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\Maintenance and QC Forms\ACT QC logs Loaner Instrument.xlsx)

CCL-F027 Loaner ACT Liquid QC Result Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\Maintenance and QC Forms\ACT QC logs Loaner Instrument.xlsx)

CCL-F088 and CCL F089 Daily QC Verification Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\Maintenance and QC Forms)

7) References:

A. ACT HEMOCHRON Operator's Manual--Models 801 & 401. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. P801:2-2. Rev 7:93. and Rev HD2525 R3 8/99

B. HEMOCHRON Whole Blood Coagulation System Activated Clotting Time (ACT) Package Insert for A510/FTCA510/HRFTCA510, P214/P215 and FTK-ACT/HRFTK-ACT Tubes. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. HM0459. RS 5/99.

C. HEMOCHRON Whole Blood Coagulation Systems Quality Control Package Insert CPL1, CP2, Q101 and Q101-H. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. HL0750 R3 6/98.

D. HEMOCHRON Whole Blood Coagulation Systems Celite ACT (CA510/FTCA510) and P214 ACT NCCLS Formatted Procedures. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. MRES:33 7/99 and MRES:34 2/00.

E. HEMOCHRON Whole Blood Coagulation System Electronic System Verification Tube Package Insert. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. HR1114 RO 4/99.

F. HEMOCHRON Whole Blood Coagulation System Response Operator's Manual. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. P/N HR1250 R0 11/99 and HR 1250 R1 12/00.

References continued:

G. NCCLS Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood Body Fluids and Tissue; Approved Guideline. 940 West Valley Road Suite 1400, Wayne, PA 19087. 1997 M29-A Volume 17 # 20.

H. NCBH-Department of Nursing, Policy and Procedure Manual-10 Reynolds, 7 Ardmore, and CCU. "Sheath Removal, Arterial and Venous". NCBH, Medical Center Boulevard, Winston-Salem, NC 27157. Effective 5/94 Rev. 11/97.

I. HEMOCHRON Whole Blood Coagulation System P214 Test Tubes HepCheck Whole Blood Control Package Insert. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. HL 1138 R1 02/01.

J. HEMOCHRON Whole Blood Coagulation System Electronic System Verification Tubes Package Insert. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. PQC:41 Rev 6/94

K. HEMOCHRON Whole Blood Coagulation Systems HE-CAL Calibration Tube Instructions. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. HR1029 R0 10/00.

8) Review/Revision/Implementation:

- Review Cycle: All procedures must be reviewed at least every 2 years.
- Office of Record: Department of Pathology, Critical Care Laboratory

9) Previous Revision Date(s): 03/05, 04/09, 7/10, 3/11, 1/13, 6/14, 5/15, 12/16, 9/18

10) Revised/Reviewed Dates and Signatures:

Reviewed/Revision Date:_____ Signature:_____

Reviewed/Revision Date:_____ Signature:_____

Reviewed/Revision Date:_____ Signature:_____