
	Policy and Procedure Manual Review CCL-023	Dept: 324318	Critical Care Labs
		Effective Date:	April 2003
		Revised Date:	June 2015
		Contact:	Jane Houska
Name & Title: Gregory Pomper, MD CLIA Laboratory Director		Date:	2/25/19
Signature: 			

1) General Procedure Statement:

- a. **Purpose:** To provide guidelines for creating, modifying, reviewing and discontinuing policies and procedures in the Critical Care Laboratory.
- b. **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) Procedure:


A. Procedure Format: Procedure format should follow WFBMC and the Department of Pathology guidelines. The policies and procedures contained in the OR and ICU Critical Care Labs Section Policy and Procedure Manuals are established by the Clinical Laboratory Director and Lab Section Manager in association with departmental management. All procedures should be written in compliance with NCCLS GP2-A3 (copy available in the Manager, Regulations /QA office).

B. Authorization: All new procedures should be authorized by the CLIA Director and signed/dated when placed into use.

C. Policy and procedure review: Policies and procedures are reviewed at least biennially by the Section Medical Director or designee. All new or procedures with major revisions are signed by the CLIA Director.

D. Document control:

1. New procedures are logged on the *CCL-F071 Procedure Tracking* spreadsheet located under (G:\Lab_Shared\Houska_Shoffner\PolProcGuidCHKLst\PolProc\ProcedureTracking_3_2013). A sequential number is assigned as each procedure is logged. This number serves to identify the procedure.

			
Critical Care Laboratories		CCL-F071 Procedure Tracking - Procedure Log	
Procedure #	Procedure Name	written	In use
CCL-001	CCL-001 Critical Care Labs Quality Improvement Plan		Aug-91
CCL-002	CCL-002 Quality Control (QC) Plan		Jun-95
CCL-003	CCL-003 Critical Care Lab General Procedures		Sep-91
CCL-004	CCL-004 Calibration Verification/Analytical Measurement Range		Mar-13
CCL-005	CCL-005 Proficiency Testing Procedure - Critical Care Labs		Jan-13
CCL-006	CCL-006 hCG Rapid Test, qualitative serum/urine by SP Brand Combo Rapid Test		Oct-07

2. **Procedure revisions** will be logged under the *Revisions* tab on the *CCL-F071 Procedure Tracking* spreadsheet. Any revisions or additions to the manuals will be communicated to the lab by email along with a "read and initial" copy of the revisions which will be filed in the Laboratory's "Read & Initial" note book.

3. **Discontinued procedures** will be logged under the *Retired* tab on the *CCL-F071 Procedure Tracking* spreadsheet. When a policy or procedure is discontinued, a paper or electronic copy is retained for at least two years, recording initial date of use, and retirement date.

E. Staff Policy and Procedure Responsibilities: Policy & Procedure manuals and quick reference guides are available in both paper and electronic forms (electronically under the ICU_OR Lab folder). Staff members working in the Critical Care Labs are responsible for being familiar with and having a clear understanding of the contents of the lab manuals. Staff members should notify lab management if it is recognized that a policy or procedure is unclear, incorrect or incomplete so it can be corrected. Lab management or their designee may note corrections, additions or deletions in the manual. These notations must be initialed by the lab manager or medical director. Staff members will read each manual on an annual basis. Staff will sign on their respective annual competency assessment form(s) as documentation that they are familiar with the contents.

F. Exceptions to Policy and Procedure: Individual exception to lab policies and procedures must be approved by the laboratory medical director, laboratory section manager, pathologist on-call or the designee of the section manager.

3) Related Procedures:

Department of Pathology – Policy on Creating and Amending Policy

4) Attachments: none

5) Related Forms:

- *CCL-F071 Procedure Tracking Form.* (G:\Lab_Shared\Houska_Shoffner\PolProcGuidCHKLst\PolProc\Procedure Tracking 3_2013.xlsx)

6) References: none

7) Related CAP Standards: COM.10000, COM.10300, COM.10500

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): 3/11, 6/14

10) Revised/Reviewed Dates and Signatures:

Reviewed/Revision Date: _____	Signature: _____
Reviewed/Revision Date: _____	Signature: _____
Reviewed/Revision Date: _____	Signature: _____