Wake Forest Baptist Medical Center	**Critical Results of Tests and Diagnostic Procedures** Formerly: PPB-NCBH-10	**Type:**	**TIER # 2**
		Original Effective Date:	**4/04**
		Current (Revised) Date:	**9/17**
		Contact:	**Clinical Compliance and Regulatory Services**
Name and Title: Russell M. Howerton, MD, Senior VP Clinical Operations, Chief Medical Officer			
Signature: Signature on file		**Date:**	9/11/17
Name and Title: Cathleen A. Wheatley, Senior VP Clinical Operations, Chief Nurse Executive			
Signature: Signature on file		**Date:**	9/11/17
Name and Title: Gregory Pomper, MD, Clinical Laboratory Medical Director			
Signature: Signature on file		**Date:**	9/6/17

1) General Procedure/Guideline Statement:

It is the policy of Wake Forest Baptist Medical Center (WFBMC) to establish the procedure and time frames for reporting critical tests and critical values to the ordering Provider. Critical values are a discrete subset of abnormal diagnostic results that require immediate action by the clinician.

a) **Scope**: All WFBMC staff that receive telephonic reporting of critical tests and critical values are responsible for complying with this policy.

b) R**esponsible Department/Party/Partie**s:

i. Policy Owner: Director of Clinical Compliance and Regulatory Services

ii. Procedure: Nursing, Laboratory, Radiology, Respiratory Care, Cardiology, Pathology

iii. Supervision: Nurse Managers and Clinic Managers

iv. Implementation: Nurse Managers and Clinic Managers

2) Definitions: For purposes of this Policy, the following terms and definitions apply:

a) ***Critical Results*:** Test results that are abnormal to a degree that may indicate a life-threatening situation (also known as critical values).

b) ***Critical Laboratory Results*:** Are defined by the Department of Pathology. (See Attachment 1.)

c) ***Critical Radiology Results*:** Are determined by what the Radiologist deems necessary and are those situations in which the interpreting provider feels that immediate patient

treatment is indicated. The interpreting provider should communicate directly with the ordering provider, other healthcare provider or an appropriate representative.

d) ***Critical Respiratory Care Results*:** Critical test results from arterial blood gases (ABGs) are defined in the Blood Procurement policy.

e) ***Pediatric and Neonatal Critical Lab Test Results*:** Are listed in Point of Care testing using i-STAT Analyzer System (formerly PPB-PCS-LAB-09). (See Attachment 2.)

f) ***Provider*:** Physician, Physician Assistant or Nurse Practitioner

3) Policy Guidelines:

It is the purpose of this policy for staff involved with the call back of critical results of tests/diagnostic procedures to require the use of a "write down/document in WakeOne® and read back" procedure when exchanging critical patient information. WFBMC recognizes the importance of effective communication of the results of critical tests and critical results in patient safety.

A. Radiology critical results will be communicated per the Critical Results and Critical Tests, Radiology poliy.

B. Laboratory, Radiology and Respiratory Care personnel shall identify a critical result and shall call the appropriate department or Inpatient Unit to inform a licensed nurse, designated allied healthcare personnel or providers of the critical result.

C. After receiving a call for the reporting of a critical result, the information is "written down/documented in WakeOne™ and read back" to the communicating individual in order to verify that it was correctly recorded.

D. Critical result value(s) should be documented in the "Provider Notification" flowsheet in WakeOne™ or for places still using paper charts, on the "Critical Value Call Report Form" sticker which is then placed on an interdisciplinary Progress Note and placed in the medical record.

E. Critical results communicated in the intra-operative suite and vascular areas will be recorded in the patient care record.

F. If the recipient of the critical value call can take the appropriate patient care action, no further notification is necessary but documentation of the critical value is expected.

G. Have a second person listen to the verbal communication of critical results when possible.

H. The verbal communication must include appropriate patient identifying information.

I. Enunciate clearly and repeat more than once or as needed. Pronounce digits separately (for example, say "one six" instead of "sixteen" to avoid confusion with "sixty"). Avoid abbreviations.

J. In Inpatient areas the individual taking the critical result will notify the patient's provider within 15 minutes of receiving the result(s) and record in the "Provider Notification" flowsheet in WakeOne™ or in Downtime, the "Critical Value Call Report Form" sticker is placed on the interdisciplinary Progress Notes sheet and scanned into the patient's record. In Outpatient areas, the individual taking the critical result will notify the patient's provider within 1 hour of receiving the result(s) and record in the "Provider Notification" flowsheet in WakeOne™ or in Downtime, the "Critical Value Call Report Form" sticker placed on the Clinic Note sheet and scanned into the patient's record. **PROVIDER MUST CONFIRM RECEIPT OF CRITICAL VALUES WITHIN 15 MINUTES. SENDING A TEXT TO A PROVIDER <u>DOES NOT</u> SATISFY NOTIFICATION REQUIREMENT.**

Screenshot of Provider Notification flowsheet in WakeOne™

Provider Notification	
Reason for Communication	Critical value/result
Critical Value/Result (with read back)	
Critical Value/Result Received Time	
Critical Value/Result Caller Name	
Critical Value/Result Caller Department	
Critical Value/Result Verbal Communication to Provider (with read back)	
Critical Value/Result Provider Name	
Critical Value/Result Provider Role	
Critical Value/Result Notification Time	

Critical Value Call Report Form Sticker

CRITICAL VALUE CALL REPORT FORM

Patient Name:_____**MR#**_____

Date:_____ **Time:**_____

Critical Test Result:_____

Caller:_____**Department:**_____
(Name)

Read Back Provider :_____
(SIGNATURE OF INDIVIDUAL RECEIVING CRITICAL VALUE)

Provider Notified:_____**Time:**_____

Provider Read Back Verified :_____
(SIGNATURE OF INDIVIDUAL NOTIFIYING PROVIDER)

07-0005911 (2/05)

4) Review/Revision/Implementation

a) **Review Cycle**: This policy shall be reviewed by Clinical Compliance and Regulatory Services at least every 3 years from the effective date.

b) **Office of Record**: After authorization, the Legal Department shall house this policy in a policy database and shall be the office of record for this policy.

5) Related Policies:

Blood Procurement

Critical Results and Critical Tests, Radiology

6) Level of Evidence:

6) Governing Law or Regulations:

The 2014 Joint Commission Comprehensive Accreditation Standards Manual for Hospitals, National Patient Safety Goals (NPSG), NPSG.02.03.01

7) Attachments:

Exhibit A: Clinical Lab Values

Exhibit B: Critical Value Limits Defined for Point of Care Testing by the Clinical Laboratory in Conjunction with the Medical Directors for i-STAT User

8) Revision Dates:

4/04, 12/04, 1/05, 1/08, 10/11, 2/14, 9/17

EXHIBIT A
Critical Laboratory Values

UPDATED: 08/2016

Test	Low	High	Peds
Hematocrit (Packed Cell Volume)—Age 2 Months and older	<=18.0 %	>=60.0 %	
Hematocrit (Packed Cell Volume)—Age 14 days old to 1 Month old	<=18.0 %	> 63.0 %	
Hematocrit (Packed Cell Volume)—Age 7 days old to 13 days old	<=18.0 %	> 66.0 %	
Hematocrit (Packed Cell Volume)—Age 1 day old to 6 days old	<=18.0 %	> 67.0 %	
Hemoglobin—Age 2 Months and older	<=6.0 g/dl	>=20.0 g/dl	
Hemoglobin –Age 14 days old to 1 Month old	<=6.0 g/dl	> 20.5 g/dl	
Hemoglobin –Age 7 days old to 13 days old	<=6.0 g/dl	> 21.5 g/dl	
Hemoglobin—Age 1 day old to 6 days old	<=6.0 g/dl	> 22.5g/dl	
WBC *on admission or outpatients*		>=50.0 x 10^3	
Absolute Neutrophil Count *on admission or outpatients*	<0.5 x 10^3		
Fibrinogen	<100 mg/dl		
PTINR		>=5.0 or Not Calculated	
PTT		>=120 sec.	
Platelet Count *on Admission: outpatients*	<30,000	>1,000,000	
Urine Ketones (<12 months)			>=80.0 mg/dl
Bilirubin Total (Newborn)			>18.0 mg/dl
Calcium	<6.0 mg/dl	>13.0 mg/dl	
Ionized Calcium	<0.75 mmol/L	>1.40 mmol/L	
Glucose—Age 7 Days to Adult	<50.0 mg/dl	>600 mg/dl	>300 mg/dl
Glucose—Age 0 day to 6 days old	<45 mg/dl	>300 mg/dl	
Osmolarity	<246 mOs/kg	>334 mOs/kg	
Magnesium	<1.0 mg/dl	>6.0 mg/dl	
Phosphate	<1.0 mg/dl	>12.0 mg/dl	
Potassium—Age 1 year and older	<3.0 mmol/l	>6.0 mmol/l	
Potassium—Age 3 Months up to 1 year	<3.0 mmol/l	>6.5 mmol/l	
Potassium—Age 1 Month up to 3 Months old	<3.0 mmol/l	>7.5 mmol/l	
Potassium—Age 7 Days up to 1 Month old	<3.0 mmol/l	>7.0 mmol/l	
Potassium—Age 0 Day up to 6 Days old	<3.0 mmol/l	>6.2 mmol/l	

Test	Low	High	Peds
Carbon Dioxide	<10.0 mmol/L	>40.0 mmol/L	>40.0 mmol/L
Salicylate		>=30.0 mg/dl	>=30.0 mg/dl
Sodium	<120 mmol/L	>160 mmol/L	>160 mmol/L
Positive Blood Culture or PCR Panel	+	+	+
Positive Sterile Body Fluid Gram Stain	+	+	+
Positive Sterile sites/Body Fluid Culture for bacteria or fungus	+	+	+
Cryptococcal Ag - *First positive*	+	+	+
Positive AFB culture or smear - *First positive*	+	+	+
HSV PCR sterile body fluids	+	+	For neonates: HSV positive PCR from ANY site
Bordetella pertussis PCR—*First positive*	+	+	+
Positive Qualitative PCR in blood and sterile body fluid	+	+	+
Quantitative PCR in blood for BKV, EBV, CMV—*first positive*	+	+	+
Pneumocystis DFA-*First positive*	+	+	+
Rocky Mountain Spotted Fever(RMSF)	Titer >16	Titer >16	Titer >16
Malaria smear-*First positive*	+	+	+
Phenytoin (Dilantin)		>30.0 mcg/ml	>20.0 mcg/ml
Digoxin		>2.0 ng/ml	
Lithium		>= 2 mmol/L	
Phenobarbital		>40.0 mcg/ml	>40.0 mcg/ml
Carbamazepine		>20.0 mcg/ml	
Theophylline		>30.0 mcg/ml	
Acetominophen *(Tylenol)*		>20.0 mcg/ml	
Valproic Acid		>150 mcg/ml	>120 mcg/ml
Amikacin--*Outpatients*		>10 mcg/ml Trough >30 mcg/ml Peak	
Gentamicin: *Outpatients*		>2.5 mcg/ml Trough >10 mcg/ml Peak	

Test		Low	High	Peds
Tobramycin *Outpatients*			>2.5 mcg/ml Trough >10 mcg/ml Peak	
Vancomycin *Outpatients*			>25 mcg/ml Trough	
Peripheral Smear: *Any blasts present or any organisms including bacteria or malaria when the responsible pathologist considers it important for proper patient care*				
Arterial Blood Gases *(ED and Non-Critical Patient Care Areas Only):*	**pH**	<7.20	>7.60	
	pCO2	<25.0 mmHg	>60.0 mmHg	
	pO2	<50.0 mmHg		

Referral Laboratory Results

All referral laboratory results received in Pathology will be reviewed by a medical technologist or equivalent for the purpose of identifying those results which are designated as critical values by the referral laboratory. These values will be communicated to the appropriate caregiver, per our policy.

Anatomic Pathology

- Unexpected malignancies; all cancer diagnoses which the pathologist has reason to think are unexpected
- Significant disagreement and/or change between diagnoses which the pathologist has reason to think are unexpected
- Clinically significant, unexpected or uncommon infectious organisms, especially in immunocompromised patients; when the responsible pathologist considers it important for proper patient care; e.g. acid-fast bacteria would be reported; trichomonads in a cervicovaginal smear would not
- Tissue from a patient with endometrial tissues showing gestational changes but shows no placental or fetal tissue
- Uterine contents of expected pregnancy without villi or fetal tissue
- Body fluids positive for Toxoplasma gondii by PCR.
- Crescents in >50% of glomeruli in a kidney biopsy specimen
- Leukocytoclastic vasculitis
- Acute transplant rejection
- Unexpected tissue in a biopsy specimen suggestive of perforation

Exhibit B

Point-of-Care Testing (POCT) Critical Value Limits

Defined for Point of Care Testing by the Clinical Laboratory in Conjunction with the Medical Directors for POCT User Sites.

Revision 08/2016

Analyte	Method	Adult	Pediatric	Neonate (in NICU)	Comments
Sodium mEq/L or mmol/L	i-STAT	<120 >160	<120 >160	<120 >150	
Potassium mEq/L or mmol/L	i-STAT	<3.0 >6.0	<3.0 >6.0	<3.0 >6.0	Unexpected results >6.0 should be verified by the laboratory. Hemolysis falsely elevates results. For potassium results to be considered critical, they should also fail the normal range defined for the patient's age.
Total CO2 mEq/L or mmol/L	i-STAT	<10 >40	<10 >40	<10 >40	
Ionized Calcium mmol/L	i-STAT	<0.75 >1.40	<0.75 >1.40	<0.80 >1.40	
pH	i-STAT	<7.2 >7.6	<7.15 >7.6	<7.20 >7.45	
pCO2 mm/Hg	i-STAT	<25 >60	<30 >80	<35 >80	
pO2 mm/Hg	i-STAT	<50	<30	<30	ARTERIAL
Glucose mg/dL	i-STAT	<50 >600	<50 >300	<50 >300	
Hemoglobin g/dl	i-STAT	<=6 >=20	<=6 >=20	<=6 >=20	
Hematocrit %PCV	i-STAT	<=18 >=60	<=18 >=60	<=18 >=60	
PT/INR	i-STAT	>= 5 or value not calculated	>= 5 or value not calculated	>= 5 or value not calculated	INR values equal to or greater than 4.0, as reported by i-STAT will have a reflex venous PT/INR ordered and sent to the Clinical Laboratory for confirmatory testing.
Glucose mg/dL	Abbott Precision Xceed Pro Glucose meter	<50 >400	<50 >400	<50 >180	

criticalvaluesWFBMC091216

To whom it may concern:

I have reviewed and authorize Critical Results of Tests and Diagnostic Procedures policy.

Signature

9/11/17
Date

Dr. Russell M Howerton
Senior VP Clinical Operations – Chief Medical Officer
Wake Forest Baptist Medical Center

Signature

9-11-2017
Date

Cathleen A. Wheatley
Senior VP Clinical Operations – Chief Nurse Executive
Wake Forest Baptist Medical Center

Signature

9/6/17
Date

Dr. Gregory Pomper
Clinical Laboratory Medical Director
Wake Forest Baptist Medical Center