SUNY Downstate Medical Center -University Hospital of Brooklyn Network
Department of Pathology Policy and Procedure

Subject: Critical Values and Critical Tests

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Supporting Documents: critical values critical tests Lab-7

Approval Workgroup: QMS Workgroup

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PURPOSE

This policy and procedure establishes the timely and accurate identification and communication procedures which are required for laboratory results determined to be Critical Values so as to ensure patient safety and responsive patient care.

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POLICY

1. Timely and accurate identification and communication of Critical Values generated by the laboratory is vital to patient safety. Certain pathologic findings warrant immediate attention for beneficial patient treatment.
2. Timeliness and accuracy of reporting Critical Values are of the utmost importance. Guidelines for timeliness assist to provide responsive quality patient care. Accuracy of communication is confirmed using the approved read back method.
3. The Department of Pathology monitors compliance with the Critical Value Policy.

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DEFINITIONS

1. Critical Values: are those results that may require immediate clinical intervention to avoid patient morbidity or mortality.
2. Read Back: procedure in which reported information is written down and "Read Back" by the recipient of the laboratory results to confirm the accuracy of verbal communications.
3. Timeliness: measurement of the period of time between the time a critical value is available, post analysis and the time the clinician is notified of the result.
4. Critical Test : Critical tests are defined as tests or procedures that must be conducted and reported quickly to determine the course of care. Critical tests require rapid processing, performance and communication of results even if the results are within normal limits. This differs from critical values which are abnormal values that indicate a possible life threatening situation.

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RESPONSIBILITIES

1. Lab Staff: identifies critical values based on review of the list of departmental Critical Values, timely reports them to a responsible health care provider and documents the activity.
2. Supervisor or designee: tracks compliance with the Critical Values Policy. Performs audits and prepares reports for presentation at Performance Improvement Committee meetings.
3. Medical Director/Medical Board: reviews and approves laboratory values determined to be Critical Values.

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PROCEDURES

A. Generally

1. The laboratory develops the critical value result list in consultation with the Laboratory's Directors, Pathologists and the SUNY Downstate Medical Center University Hospital of Brooklyn Network medical staff.
2. The laboratory technical staff is required to be familiar with the tests and results categorized as critical values on the Critical Value list.

3. The laboratory tests and results qualifying for the Critical Value list is reviewed and approved annually and as needed, whenever changes in the ranges of particular tests change or when new tests are introduced warranting an addition, modification or deletion to the critical value list.
4. Critical values generated from testing by the laboratory's reference laboratories will be treated in the same manner as those generated by the laboratories of the institution in regard to the protocol for notification of the clinician and documentation of the notification.

B. Communication of Critical Values

1. Critical values are noted by the technical staff:
    a. Results are flagged by the laboratory information system during the result review and reporting processes to alert the technical staff performing the tests that a critical value exists.
    b. The laboratory technical staff review test results against the Table of Critical Values.

2. If a test result is identified as a critical value, the technical staff member must verify the result prior to the reporting of the result to the physician/designee by
    a. Verifying the patient identification;
    b. Checking the integrity of the sample, i.e. the presence of a clot or hemolysis;
    c. Following laboratory section policy as to analyte specific requirements concerning repeat analysis, fresh sample aliquoting, second specimen requests, dilution and/or checks of calculation(s), where appropriate.

3. Once a result is verified the technical staff member must notify the ordering physician, service assigned physician, physician extender or a nurse designee of the critical value.
    a. Critical values may only be reported to licensed health care providers.

4. The technical staff member must report the critical value to the physician/designee either in person or by telephone.

5. Reporting of Critical Values to Satellite Facilities:

    a. During the hours of normal operation, Monday through Friday the respective satellite facility of specimen origination should be called.

    b. During non-operational hours a critical value result should be reported using the after hour's instructions noted below for the appropriate satellite facility.

MIDWOOD SATELLITE: SUITE AF

During Office Hours:	M, T, W, F 9:00 a.m. – 5:00 p.m. Th 12:00 noon – 8:00 p.m.	Call the Satellite at 718-270-8920 or 8921
After Office Hours:	During the Week -	Page the Ordering Physician through the UHB Page Operator

Weekends:
Friday at 5:00 p.m. thru Monday 9:00 a.m.
Page the on-call Physician for the Midwood Satellite facility

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FHS SATELLITE:	***SUITE 0***		
During Office Hours:	M, T, Th	9:00 a.m. - 8:00 p.m.	Page the Ordering Physician through the UHB Page Operator
	W, F	9:00 a.m. - 5:00 p.m.	
	S	9:00 a.m. - 1:00 p.m.	
After Office Hours - -or— If No Response	Page the Family Practice Resident on-call		

1. The laboratory technical staff should record the following in the laboratory information system/laboratory report to memorialize the notification:
   - √ Name and title of the physician/designee who was given the result;
   - √ Date and time of the call/notification in 24 hour military time format;
   - √ Identity of the reported test/s and result/s;
   - √ Performance of the "read-back" procedure.
   - √ Initials of the laboratory technologist who made the call/notification;

2. Reporting of Cytopathology critical values and diagnoses.
   a. Critical values or diagnoses should be reported to authorized provider by attending pathologist signing out the critical diagnosis.
   b. Notification may be by telephone or pager.
   c. Contact should be documented in Cytopathology report.

C. Communication of Critical Test Results

1. All results for laboratory tests categorized as 'Critical Tests' must be reported to the Clinician following the same protocol as for Laboratory Critical Values.
2. Reporting a critical value during the day shift
   a. Contact the ED or clinic or nursing station where the patient is located.
   b. If unsuccessful within 15 minutes, page the requesting physician noted in the patient's laboratory record
   c. If unsuccessful or there is no answer within 15 minutes, call the Infection Control Officer or designee and give the result.(ext. 1940)

3. Reporting critical values during off- hours (evenings, nights, weekends)1.
   a. Contact the ED, clinic, or nursing station where the patient is located
   b. If unsuccessful within 15 minutes, page the ordering physician noted in the

patient's laboratory record

c. If there is no answer within 15 minutes, call the page operator to determine the Fellow-on-call or the physician covering the service for paging.
d. If there is no answer within 15 minutes, page the nursing supervisor who will assist in locating the appropriate healthcare provider

4. Reporting critical values for discharged patients
    a. Contact the ED, clinic, or nursing station where patient is located.
    b. Business hours - If laboratory is informed that patient has been discharged, Infection Control Officer/ designee will be informed of results
    c. Off hours – evenings/ nights/weekends - If laboratory is informed that patient has been discharged, the lab will notify the Nursing Supervisor who will enter the information on the AOD log. On the next business day, the Infection Control officer/designee who receives the information from the AOD log will notify the appropriate healthcare provider.

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4. Documentation of all attempts of contact should be made in the comments section of the patient's electronic laboratory record/LIS.

E. Timeliness of Reporting

1. All Critical values must be timely called to a responsible health care provider.
    a. All critical values must be reported to the health care provider within 15 minutes of result availability.

F. Read-Back Procedure

1. The laboratory technical staff member will telephone the clinical care unit, identify him/herself, report the Critical Value and request a verbal "read-back" or repeat back of the patient name, test(s) and results that are provided to the physician/designee to ensure that the result was communicated properly.
2. The report recipient must write down the result and perform a "Read Back' of the results by verbally repeating the results back to the reporter in order to receive a confirmation of accuracy from the individual giving the test result.
3. The report recipient will fill out the "Write-Down / Read Back" label and place the label in the Progress Notes of the medical record.

G. Review and Audit

1. The Supervisor or designee will regularly review laboratory results generated by their section regularly to ensure appropriate follow-through, documentation and compliance with this Critical Value Policy and Procedure.
2. On a selected day or days each month data will be collected from the Laboratory

Information System to review the timeliness of calling an inpatient critical value.

a. The data collected will be presented at the Departmental Performance Improvement Committee Meeting and the Executive Performance Improvement Committee (EPIC).
b. The data collected will be used to monitor compliance with the JCAHO National Patient Safety Goal: Improving the Effectiveness of Communication Among Caregivers.
c. Responsible services will be informed of outliers and required to institute corrective actions.

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ATTACHMENTS

1. Laboratory Critical Value Lists
2. Audit Sheet: Timeliness of Calling an Inpatient Critical Value

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REFERENCES

1. CAP Laboratory Accreditation Program July 2013
2. NYSDOH Laboratory Standards July 2011
3. JC National Patient Safety goals: Improving the Effectiveness of Communication Among Caregivers
4. Institutional Policy: Timeliness of Critical Test Results; PTSAF-14
5. Institutional Policy: Documentation of Verbal Telephone Orders, PTSAF-9

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TABLE OF LABORATORY CRITICAL VALUES

	ANALYTE	RESULT
Blood Bank	Cord specimens	Positive direct antiglobulin (direct coombs)
	Routine specimens	Positive direct AND indirect antiglobulin (direct AND indirect coombs)
	Obstacles regarding procurement of compatible blood/blood components for transfusion	
	Maternal titers of significant red cell antibodies during pregnancy	
	Results of a life threatening transfusion reaction workup	
	Failure to call for Rh immune globulin for eligible patient, within 72 hours following known or possible exposure to Rh positive red cells	
	Cardio thoracic patients who have a cold agglutinin	
	Reference laboratory results of significant red cell antibodies or autoimmune status	

	ANALYTE	UNITS	Less than	Greater than	Exception
Hematology	Cell count, CSF, neonate	k/uL	---	0.05	
	Hematocrit	%	15	60	
	Hematocrit, neonate	%	36	68	
	Hemoglobin	g/dL	5.0	20.0	Specimens with

	Hemoglobin, neonate	g/dL	10.0	23.0	critical values reported with previous 48 hrs- report as "Known Patient"
	Platelets	k/µL	30	900	
	Platelets, neonate	k/uL	100	400	
	WBC	k/µL	2.0	35.0	
	WBC, neonate 0-24 hrs	k/uL	9.0	34.0	
	WBC, neonate 1-7 days	k/uL	5.0	34.0	
	WBC, CSF	cells/cu mm	---	0.01	
	New findings of blasts, bacteria or sickle cells in peripheral blood				
	Presence of blood parasites (malaria, babesia, microfilaria)				
	Presence of malignant cells or microorganisms in CSF or other body fluids				
Coagulation	APTT	secs	---	70	"Known Patient
	D-Dimer	mg/mL	0.05	---	
	Fibrinogen	mg/dL	100	---	
	INR			6.0	
Urinalysis	Positive Ketones and 3+ Glucose				
	Presence of bacterial, cellular, fatty, granular or RBC casts				
	Reducing substances, infants		Any positive		

☞**Note: Hematology, Coagulation and Urinalysis alert values reported on specimens within the previous 48 hours may be reported as "Known Patient".**

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TABLE OF LABORATORY CRITICAL VALUES

	ANALYTE	UNITS	Less than	Greater than	Exception
Chemistry Blood Gas	pH, arterial		7.20	7.60	
	pCO2,arterial	mm/Hg	20	60	
	pO2, arterial;	mm/Hg	50	---	
Chemistry Routine	Amylase	U/L	---	500	
	Bilirubin, neonate	mg/dL	---	15.0	
	BUN	mg/dL	---	100.0	Pre-dialysis
	Calcium, ionized	mmol/L	0.8	1.8	
	Calcium	mg/dL	7.0	12.0	
	Calcium, neonate	mg/dL	6.0	12.0	
	CO2 (bicarbonate)	mmol/L	10	36	
	Chloride	mmol/L	70	120	
	Creatinine	mg/mL	---	10.0	Pre-dialysis
	Creatinine, neonate	mg/mL	---	1.5	

	Creatine kinase	U/L	---	400	
	Glucose, adult	mg/dL	40	450	
	Glucose, CSF	mg/dL	35	---	
	Lactic acid	mmol/L	---	3.0	
	Lead	ug/dL	---	15	
	Magnesium	mmol/L	1.0	5.0	
	Magnesium, neonate	mmol/L	1.0	2.9	
	Microprotein, CSF, neonate	mg/dL	15	150	
	Phosphorus	mg/dL	1.0	8.0	
	Potassium	mg/dL	3.0	6.0	
	Sodium	mmol/L	120	155	
	Sodium, neonate	mmol/L	125	145	
	Troponin	ng/mL	---	0.4	
Chemistry Therapeutic Drugs	Amikacin	ug/mL	---	35	
	Cyclosporine	ng/mL	---	500	
	Digoxin	ng/mL	---	2.5	
	Gentamicin, peak	mcg/mL	---	12.0	
	Lithium	mmol/L	---	1.6	
	Phenobarbital	mcg/mL	---	55.0	
	Phenytoin	mcg/mL	---	30.0	
	Procainamide & NAPA	mcg/mL	---	30.0	
	Salicylate	mg/dL	---	40.0	
	Tacrolimus FK506	mg/mL	---	30.0	
	Theophylline	mcg/mL	---	25.0	
	Tobramycin	mcg/mL	---	12.0	
	Valproic Acid	mcg/mL	---	150.0	
	Vancomycin	mcg/mL	---	50.0	

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TABLE OF LABORATORY CRITICAL VALUES

	Isolate	Result	
Microbiology	**Alert Values**		
	Rapid Antigen		
	Bacterial Antigen, CSF (Group B strep, H. Flu B, pneumococcus, meningococcus)	Positive	
	Clostridium Difficile Toxin A	Positive	
	Cryptococcus Antigen	Positive	
	Influenza A & B	Positive	
	Latex antigen	Positive	

	(Group B strep, H. Flu B, pneumococcus, meningococcus)			
	Culture/Smear			
	Blood Culture		Preliminary Positive	
	CSF smear/culture		Preliminary positive	
	Donor organ transplant culture		Positive	
	Throat culture, pediatrics		Group A Strep	
	Stool culture		Positive enteric pathogens	
	Findings of			
	Bordatella Pertussis		Positive	
	Cryptococcus neoformans		Positive	
	Cornyebacterium Diphtheria		Positive	
	Dimorphic fungi (Histoplasma, coccidiodes, blastomyces, paracoccidiodes)		Positive	
	Influenza		Positive	
	Neisseria gonorrhea		Positive	
Immunology				
	Expedited Maternal HIV Ab/Ag		Preliminary Positive	
	Expedited Newborn HIV-1 antibody		Preliminary Positive	
	Expedited Needlestick HIV-1		Preliminary Positive	

	Finding
Cytology	**Critical Values**
	Bacteria or fungi in CSF cytology in immunocompromised or immunocompetent patients
	Fungi in FNA of immunocompromised patients
	Herpes in PAP smears of near term pregnant patients
	Pneumocystis, fungi or viral cytopathic changes in bronchoalveolar lavage (BAL), bronchial washing or brushing specimens in immunocompromised or immunocompetent patients
	Significant disagreement between immediate interpretation and final FNA diagnosis
	Unexpected malignancy

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TABLE OF LABORATORY CRITICAL TESTS

Microbiology			
	Mycobacterium Tuberculosis, AFB, Mycobacterium species	Positive smear and/or culture	
Cytology	Immediate specimen adequacy assessment on deep organ FNA		