

Proc. #4840-G-220

TITLE: Clinically Critical and Infectious Disease Result Reporting

PRINCIPLE

Results suggesting a life-threatening situation that may require immediate intervention by the physician are defined as 'alert' or 'critical' values. Laboratorians may be unaware of the patient's status when such a result is generated and, therefore, unable to judge the significance of such a result. Therefore, critical/alert patient laboratory values shall be communicated by a Medical Technologist to an RN or M.D. immediately upon confirmation of the result.

For Inpatients

The following list of critical/alert test values shall be immediately telephoned, by the medical technologist, to the patient's nurse for inpatients. The RN caring for the inpatient shall be responsible for contacting the ordering, attending or resident physician as appropriate. When a critical result arises after the patient has been discharged, the Medical Technologist will be responsible for contacting the ordering Physician.

For Outpatients

The ordering Physician or RN office staff will be notified by the Medical Technologist immediately upon completion of testing for result that is critical. When the office is closed, the physician shall be paged through the answering service to call back to the laboratory for results. In the event a physician is not on duty, the physician on-call for the ordering physician shall be paged.

In the following list, both a low and a high limit are defined for tests with numerical ranges; when a result is less than the *low* value or greater than the *high* value, it will be considered an alert or critical value. For tests not reported as a numerical value, the interpretation will be reported.

The Laboratory technologist/technician shall document all calls related to critical value reporting by placing comments in result comments.

Infectious Disease Reporting

Test results involving infectious disease testing, such as HIV and Tuberculosis, are not considered critical but they must be promptly reported by the laboratory to the infectious disease department. The infectious disease staff can be paged 24/7 and will notify the physician and local health department of the findings.

Effective September 2020, laboratories subject to US regulations performing testing intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report positive and negative results to local or state health authorities in a standardized format and at a frequency specified by the Secretary of Health and Human Services to include all molecular, antigen and antibody test methods used in laboratories with all types of CLIA certificates.



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For COVID-19 test result reporting, Copley worked with a Rush team to establish an electronic laboratory reporting (ELR) interface to Illinois' National Electronic Disease Surveillance System (I-NEDS). All COVID results, Positive and Negative are reported weekly.

PERSONNEL

All Medical Technologists, Technicians, and Clinical Associates.

STEPWISE PROCEDURE

- A. Clinically Critical Value Verification
 - 1. If results fall into the critical value range:
 - a. Validate the integrity and quality of the specimen.
 - b. Validate the patient's previous test results to interpret the validity of the critical value. Repeat testing is not required if the patient's previous results back up the result currently obtained. If the results match or coincide to previous results, proceed to step B.
 - c. If it is the first testing performed or results do not match previous results, repeat the testing to verify the result.
 - d. If the critical value is verified by repeat testing but the result is still questionable and/or unlikely, an alternate specimen should be drawn and tested.
 - e. Call the patient's RN and consult regarding the validity of the result. If specimen quality is questionable, redraw the specimen.

 Also, notify other sections of the Laboratory if they have specimens from the same draw time.

 Should a repeat be required, search in the LIS for an appropriate specimen, which might have been drawn on that particular patient at approximately the same time. Validate the quality of the specimen.
 - f. If no other specimen is available, the patient shall be redrawn after the RN has been notified and verifies that a redraw is necessary.
 - g. If the patient requiring a redraw is an outpatient, the doctor shall be consulted about the necessity of a redraw.
 - h. Should the Physician determine the outpatient needs a redraw; the patient shall be contacted by the Out Patient Laboratory to arrange the return visit.
 - i. Repeat the specimen as required by individual assay policy and procedure.
- B. Clinically Critical Value Notification
 - 1. All General Lab and Microbiology critical values shall be reported by a technologist/technician as follows:
 - a. Call the RN assigned to the patient and report results. Should the RN with direct patient care responsibilities not be available, ask for the next responsible RN and report the results to him/her.



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- b. In the case of an outpatient and/or pre-surgical patient, report the critical value to the physician's office nurse or directly to the Physician.
- c. Should there not be an RN or Physician available in the physician office, require that the person taking the results request a call back to the Lab by the RN or Physician at the earliest possible time. Document this request into the computer.
- d. Request that the person taking the results repeat the patient name, medical record number, account number or date of birth and test result back to you. Two identifiers must be used.
- e. Properly identify the patient by using Name and Medical Record Number as your two (2) patient identifiers before giving result. Should a Medical Record Number not be available, Date of Birth (DOB) should be used.
- f. Confer with the nurse about clinical diagnosis.
- g. Enter the comment designated as the RBTO documentation comment in the test result field in the LIS indicating notification of the critical value.
- h. The comment states "critical result for (test name) called to (RN full name) by (tech initials) w/ RBTO at (time and date).
- i. Should a physician's office be closed, document the time the answering service was notified and when the call back is received. Include the three initials of the answering service attendee, date, time and your initials and advise the answering service that this is a critical value notification.

NOTE: It is the responsibility of the Medical Technologist to notify the physician of a critical value if a patient has been discharged from the hospital.

- 2. Reference Laboratory: Clinically Critical Value Notification
 - a. Phoned Critical Values from Reference Labs will be recorded by the receiving MT onto the phoned results form found in the drawer in LCC.
 - b. Call the results following the above critical value notification procedure.
 - c. Note on the phone form the full name of the person to whom you spoke, date, time and your initials.
 - f. This form shall be placed in LCC in the designated file for the CAs to collate with the hard copy report.
 - g. Upon arrival of the final result from the referral laboratory, attach the phoned result form to the original copy of the referral report.
 - f. If the test is in the LIS, document the notification from the referral laboratory phoned form into order note, to include full name of caller, date, time of result notification. Additionally, date, time, and the initials of the Copley care provider who was notified of the result.
- 3. Physician Notification by Nursing Staff
 - a. Nursing staff shall repeat back the patient name and results to the Laboratory technologist.
 - b. RN shall state their full name.



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- c. The RN shall do an immediate assessment of the patient prior to calling the ordering, consulting, primary care Physician and/or family practice resident with the critical value results.
- d. Nursing staff in the inpatient setting shall be responsible for disseminating critical/alert values to the physician upon completed patient assessment.
- e. The RN shall request a physician read back of results and orders. The RN shall record the time, date, and full identification and read back upon reaching the Physician with the critical value results.
- f. The RN shall coordinate resultant orders and patient care and document per nursing protocols.
- g. In certain patients who are receiving serial lab tests or imaging exams and treatment for the underlying condition is underway; the nurse does not need to call the Physician in the one hour time limit if the exam is stable or improving.

Some examples follow:

- Hemoglobin and hematocrit being tracked for blood loss while blood is being administered. Counts are improving as would be expected based on blood volume administered.
- 2. Daily chest x-rays showing resolving pneumothorax.
- 3. Creatinine for renal failure patients on dialysis.
- 4. Improving cardiac enzymes
- 5. Chemotherapy induced neutropenia
- 6. Bicarb levels

In the above cases, the nurse will receive the call, but based on improving picture and treatment underway, the nurse will not need to call the Physician within the 60-minute time frame.

Documentation will occur on the sticker placed in the Physician's order sheet regarding the rationale used for not making the contact to the physician along with the nurse signature.

Physicians are expected to review the related values/results independently when rounding.



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TEST	LOW LESS THAN	POSSIBLE EFFECT	HIGH GREATER THAN	POSSIBLE EFFECT
Blood Bank	1			1
Newborn screen Direct Coombs	Positive results called to Nursing Unit			Hemolytic disease of the newborn.
Antibody screen	Positive results called to Nursing Unit			Incompatible crossmatches/ transfusion delay
CHEMISTRY	1			,
Acetaminophen	None		150.0 ug/mL	
Ammonia	None		100 Umol/L	
Direct Bilirubin	None		2.0 mg/dL	
Total Bilirubin adult	None		30.0 mg/dL	
0 days	None		8.0 mg/dL	
2 days	None		16.0 md/dL	
3-7 days	None		18.0 mg/dL	
8 days	None		30.0 mg/dL	
BUN				
0 days-18 years	None		40 mg/dL	
>18 years	None		100 mg/dL	
Calcium-adult	6.0 mg/dL	Tetany and	12.0 mg/dL	Coma
0-10 days	7.0 mg/dL	convulsions	13.0 mg/dL	
2yrs-18yrs	6.0mg/dL		13.0 mg/dL	
CO ₂	10 mmol/L	Acidosis, alkalosis, and anoxemia	40 mmol/L	Patterns of acidosis, and anoxemia
Carbamazepine	None		15.0 ug/mL	
Digoxin	None		2.1 ng/mL	
Dilantin	None		30.0 ug/mL	
ETOH	None		0.081 g/dL	
Gentamicin Trough	None		2.0 ug/mL	
Gent Peak	None		10.0 ug/mL	
Glucose Adult	40 mg/dL		500 mg/dL	
Glucose				
(Newborn 0-3 months)	40 mg/dL	Brain Damage	500 mg/dL	Diabetic Coma
Glucose Fasting				
0-1 Day	45 mg/dL			200 mg/dL
1 day – 2 months	50 mg/dL			200 mg/dL
>2 months	40 mg/dL			500 mg/dL



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TEST	LOW LESS THAN	POSSIBLE EFFECT	HIGH GREATER THAN	POSSIBLE EFFECT
Lactic Acid	None		4.0 mg/L	
Lithium	None		1.5 mmol/L	
Magnesium	1.0 mg/dL		5.0 mg/dL	
Phosphorus	1.0 mg/dL		None	
Potassium > 2 months	3.0 mmol/L	Muscle weakness, paralysis, cardiac arrhythmias.	6.0 mmol/L	Cardio toxicity With arrhythmias
Potassium (Newborn- 0-2 Months)	3.0 mmol/L	Muscle weakness, paralysis, cardiac arrhythmias.	7.0 mmol/L	Cardio toxicity With arrhythmias
Salicylate	None		30.0 mg/dL	
Sodium				
< 12 months Adults	125 mmol/L 120 mmol/L		160 mmol/L 160 mmol/L	
Theophylline	None		20.0 ug/mL	
Tobramycin Trough	None		2.0 ug/mL	
Tobra Peak	None		20.0 ug/mL	
Tobra Random	None		12.0 ug/mL	
Valproic Acid	None		120.0 ug/mL	
Vancomycin Trough	None		25.0 ug/mL	
Vanco Random	None		50.0 ug/mL	
HEMATOLOGY				
CSF Cell Count: WBC's: 0 – 6 Months			> 10 WBC's	
Hematocrit:			> 10 WBC 3	
NICU/NSY > 3 Months	<25.0 % <20.7 %		≥ 65.0 % High NA	
Hemoglobin: NICU/NSY > 3 Months	< 7.0 g/dL < 7.0 g/dL		>21.6 g/dL High NA	
Platelet Count: 0 – 3 Months > 3 Months	<50x10 ⁹ /L <30x10 ⁹ /L		>1,200x10 ⁹ /L >1,200x10 ⁹ /L	



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TEST	LOW LESS THAN	POSSIBLE EFFECTS	HIGH GREATER THAN	POSSIBLE EFFECTS
WBC Count: 0-27 Days(NICU/NSY) 28 Days – 3 Months > 3 Months	<8.0x10 ⁹ L <2.0x10 ⁹ /L <2.0x10 ⁹ /L		>28.0x10 ⁹ /L >28.0x10 ⁹ /L >25.0x10 ⁹ /L	
Differential: % Bands: NICU/NSY	None		>15%	
Differential Abs. Neutrophils: NICU/NSY(0-3Mos)	<0.5x10 ⁹ /L		None	
Malaria Smear(Parasites)			Positive smear	
Retic Count: 0 – 14 Days	<1.0%		>10.0%	
IMMUNOLOGY				
HIV 1/2 Ag Ab Combo		Emergency Room C	harge Nurse	
Heparin Induced Antibody		Positive results called to Nursing Unit		
URINALYSIS				
Glucose		Adults- 1000 mg		
MICROBIOLOGY- CRI CAREGIVER NOTIFIC		ULTS REQUIRING IMM	1EDIATE INFECTIO	N PREVENTION AND
Positive AFB Smears		Positive cerebrospinal fluid gram stains and cultures		
Positive AFB Cultures		Bacillus anthracis		
Brucella species		Bordetella pertussis		
Corynebacterium diptheriae		Carbapenem Resistant Enterobacteriaceae (CRE)		
Haemophilus influenza - invasive		Tularemia (Francisella tularensis)		
Salmonella typhi, para		Mycobacterium tuberculosis (complex)		
Vanco Resistant Staph Species Isolates		Neisseria meningitidis or gonorrhoeae - invasive		
Yersinia pestis		Shiga-Toxin producing or E coli 0157:H7		
MICROBIOLOGY- CR	ITICAL POSITIVE RES	Streptococcus pyogeneral Pyogeneral Streptococcus pyogeneral Streptococcus pyogeneral		
Blood culture gram sta	ins	Blastomyces dermitition	dis	
Campylobacter species		ESBL/MDRO isolates		
Clostridium difficile toxin		COVID-19 positive		
Histoplasma capsulatum		MRSA		
Listeria species		Neisseria gonorrhoeae		



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Nursery Patient Positive Gram Stains	Positive Group B Strep (OB or NSY pt.)	
Nursery Patient culture growing any	Positive tissue/sterile body fluid gram stains and cultures	
potential pathogen.		
Streptococcus pyogenes (Grp A.) non-	Positive ova and parasites	
invasive		
Salmonella, Shigella or Yersinia	Pseudomonas aeruginosa in the eye	
VRE		
REFERENCE LABORATORIES	All Critical Results from a Reference Laboratory (Quest, Rush	
	Medical Center, etc. will be called to a technologist.	
	The technologist will report results in accordance with	
	Procedure No. 7180-G-220, Clinically Critical (Panic) Values	

NICU CRITICAL VALUES

Babies up to 6 months of age which are located in the NICU have separate reference ranges and critical values which have been determined by the NICU and Dietary staff.

NICU Lab Reference Ranges

*Applies to preterm and term infants admitted to the NICU up to 6 months old

Lab	Normal Reference Range	Critical Low	Critical High
Sodium	130-145 mmol/L	< 125 mmol/L	> 150 mmol/L
Potassium	3.5-6 mmol/L	< 3 mmol/L	> 7 mmol/L
Chloride	100-110 mmol/L	n/a	n/a
Calcium	8-12 mg/dL	< 6 mg/dL	> 12.5 mg/dL
Ionized Calcium	0.9-1.45 mmol/L	< 0.8 mmol/L	> 1.5 mmol/L
Magnesium	1.4-2.4 mg/dL	n/a	> 3 mg/dL
Phosphorus	5-8 mg/dL	< 4 mg/dL	> 9 mg/dL
BUN	7-20 mg/dL	n/a	> 40 mg/dL
Creatinine	0.2-1 mg/dL	n/a	> 2 mg/dL
Direct bilirubin	< 1 mg/dL	n/a	n/a
Alkaline phosphatase	<u><</u> 500 U/L	n/a	n/a
25-Hydroxy Vitamin D	20-100 ng/mL	n/a	> 125 ng/mL

REPORTING RESULTS

NOTES:

A. If specimen is hemolyzed, inform the nurse and/or doctor and add a note to the result form indicating that results may be affected due to inadequate specimen and suggest repeat, preferably by venipuncture.