Title: Laboratory - Critical Values and Notification of diagnoses of infectious diseases of particular significance - Guideline

University of Missouri Health System	**Document Owner:** Rachel Mullins	**Last Approved Date:** 08/21/2017
	Content Expert: Rachel Mullins	

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I. Policy Statement

a. Critical results and notification of diagnoses of infectious diseases or conditions of particular significance are reported to the responsible caregiver. The critical result or notification of diagnoses of infectious diseases of particular significance will be read back and the results verified with the responsible caregiver. These results are defined and reviewed for currency by Pathology's Laboratory Director. The Executive Committee of the Medical Staff (ECOMS) approves the critical values. A listing of these critical results will be maintained within Pathology.

b. To ensure that critical/significant values are reported to the responsible caregiver and that the appropriate action in reporting and confirming receipt of the critical/significant result is taken.

c. Scope**:** This procedure applies to the testing personnel at MU Health Care (MUHC). This applies to results received by the laboratory from outside reference laboratories.

II. Definitions

a. Critical results are results that, if left untreated, could be imminently life threatening or place the patient at serious risk.

b. Significant results are diagnoses of infectious diseases or conditions of particular significance which may possibly require immediate action.

III. Process/Content

a. **Procedure**

i. The responsible clinician on record will be called/paged within one (1) hour from the time of obtaining all critical significant results.

ii. After communicating the new diagnosis or critical value to the responsible caregiver; ask them to read back the diagnosis or critical value as per the Reporting Critical Values policy.

iii. Critical values have been established as listed below for the following laboratory tests.

iv. Upon the detection of a critical value in Chemistry, Coagulation, or Hematology, conduct investigation regarding the following:

1. Verify there are no errors regarding specimen integrity or labeling

a. Correct patient was drawn

b. Tube was labeled with correct patient name
c. Possible contaminations due to errors in venipuncture process
d. Optimal tube fill
e. Clot check (Coagulation and Hematology testing)

2. Verify there are no clerical errors. Verify that all manual entry tests have been recorded accurately.
3. Verify there are no clinical errors.
    a. Review instrument results for any abnormal assay flags
    b. For hematology assays perform slide review to verify results or refer to Result Reporting-Hematology
4. In the event you have verified the above and the result is not consistent with patient's previous result or clinical status; repeat analysis and call caregiver.

b. **ANATOMIC/SURGICAL PATHOLOGY**

We have determined that certain surgical pathology diagnoses may be considered particularly significant or unexpected. Examples of these include malignancy in unsuspected samples, absence of chorionic villi with clinically expected villi (potential ectopic pregnancy), a change of frozen section diagnosis after review of permanent sections, or the presence of significant infectious organisms. We always call a diagnosis of a new malignancy.

c. **CHEMISTRY**

i. **Critical Results:**

TEST	LOW	HIGH
ACETAMINOPHEN @ 4 hr		> 150 mcg/mL
ACETAMINOPHEN @ 8 hr		> 100 mcg/mL
ACETAMINOPHEN @12 hr		> 50 mcg/mL
ALCOHOL		> 300 mg/dL
AMIKACIN		> 35 mcg/mL
AMYLASE		> 300 U/L
AMMONIA		>120 umol/L
Betahydroxybutyrate		>0.29 mmol/L
BUN		≥80.0mg/dL
CALCIUM	<6 mg/dL	> 13 mg/dL
CALCIUM (<1 mo)	<7 mg/dL	>11 mg/dL
CARBAMAZEPINE		> 12 mcg/mL
CO2	<10 mmol/L	>45 mmol/L
CK		>500 U/L
DIGOXIN		> 2.4 ng/mL
Direct Bilirubin (<1 mo.)		>1.5 mg/dL
FREE PHENYTOIN		>3.0 mcg/mL
GENTAMICIN Peak		≥ 20 mcg/mL

TEST	LOW	HIGH
GENTAMICIN Trough		≥ 2 mcg/mL
GLUCOSE	<40 mg/dL	> 400 mg/dL
GLUCOSE (<1 mo)	<40 mg/dL	> 300 mg/dL
CSF GLUCOSE	<40 mg/dL	
IONIZED Calcium	<0.95 mmol/L	> 1.45 mmol/L
IONIZED MAGNESIUM	<0.31 mmol/L	> 1.51 mmol/L
LACTIC ACID		≥4.0 mmol/L
LITHIUM		> 2.0 mmol/L
MAGNESIUM	<1.0 mg/dL	
PHENOBARB		> 50 mcg/mL
PHOSPHATE	<1.0 mg/dL	
POTASSIUM	<2.5 mmol/L	> 6.5 mmol/L
POTASSIUM (<1 mo)	<3.0 mmol/L	> 6.5 mmol/L
CSF PROTEIN (0 to 1 yr)		>300 mg/dL
CSF PROTEIN (1yr to adult)		>150 mg/dL
SALICYLATE		>27.0 mg/dL
SODIUM	<125 mmol/L	>170 mmol/L
T. BILIRUBIN 0-24 hrs		> 8.0 mg/dL
T. BILIRUBIN 24-48 hrs		> 11.0 mg/dL
T. BILIRUBIN 48-72 hrs		> 13.0 mg/dL
T. BILIRUBIN 72hrs - Adult		> 15.0 mg/dL
24 Hr. Urine Total Protein		≥5000 mg/24hour
TCA		> 500 ng/mL
THEOPHYLLINE		> 20 mcg/mL
TOBRAMYCIN Trough		>2.0 mcg/mL
TOBRAMYCIN		> 20.0 mcg/mL
VALPROIC ACID		> 150 mcg/mL
VANCOMYCIN		>50 mcg/mL

Note:
Critical BUN values (≥80.0 mg/dL) on patients with end stage renal disease will not be called. Critical values will be noted end stage renal disease (ESRD).

Critical creatine kinase values (CK>500 U/L) on patients will be called to licensed care provider one time per admission. Subsequent critical values will be noted as “previously elevated CK”.

ii. **Significant Results:**

1. Positive Influenza results must be called to the nurse if the patient is in the hospital.

2. Positive RSV results on patients less than 18 years of age must be called to the nurse if the patient is in the hospital.

d. **COAGULATION**

i. **Critical Results:**

Parameter	Critical Value
INR	>4.0
Activated Partial Thromboplastin Time (APTT)	>150 seconds
Fibrinogen	<90 mg/dL

ER Patients only: D-Dimer > 0.5

e. **CYTOLOGY**

i. **Significant Results**

1. Results of all positive cases for cytology are called to the physician at the time of sign out by the medical transcriptionist and documented in CoPath.
2. Physicians are notified of all positive cases through the cancer diagnosis system in PowerChart. The physician must acknowledge receipt of the diagnosis through Power Chart.
3. Results of PCP/GMS stains are called to the physician at the time of signout and that notification is also documented in CoPath.

f. **HEMATOLOGY**

i. Critical Results:

Parameter	Low value	High value
ANC (any age)	<0.5 X 10^9/L	none
WBC (0-18 years old)	<2 X 10^9/L	>50 X 10^9/L
WBC (18 and greater years old)	<1 X 10^9/L	>80 X 10^9/L
Hemoglobin (8 weeks and Up)	<6 g/dl	>21 g/dl
Hemoglobin (0-8 weeks)	<7 g/dl	>24 g/dl
Hematocrit (any age)	<21%	>65%
Hematocrit (0-24 hours)	<42%	>65%
Platelets (any age)	<20 X 10^9/L	>1,000 X 10^9/L

g. **MICROBIOLOGY**

i. **Critical Values**

1. Growth from blood, CSF, and joint fluid cultures.
2. Positive Gram stains from CSF, brain, dural, epidural, or spinal specimens.
3. Positive Gram stains or growth from blood products (transfusion reactions). Notify Blood Bank immediately at 882-1297.
4. Growth from cell-saver cultures.

ii. **Significant Results:**

1. Positive Influenza results must be called to the nurse.

2. Positive RSV results on patients less than 18 years of age must be called to the nurse.
3. Fungus or significant pathogens growing from eye cultures.
4. Initial isolation or observation of organisms having importance for control of nosocomial infections, such as *Salmonella*, *Shigella*, *Campylobacter*, *E. coli* O157:H7, *Mycobacterium tuberculosis*, or Vancomycin-resistant *Staphylococcus aureus* (VRSA).
5. Unusual pathogenic organisms such as *Acanthamoeba*, *E. histolytica*, systemic fungi and rarely isolated bacteria such as *Francisella tularensis*, *Legionella*, *Brucella*, or *Listeria*.
6. Positive Acid-fast smears from any specimen.
7. Positive Shiga toxin results from the Biofire GI Panel
8. Postive Norovirus results from the Biofire GI Panel on patients in the hospital.
9. Positive *Clostridium difficile* results.
10. In addition, fax the following results to the Infection Control (IC) Department:
    a. Positive Acid-fast smears.
    b. Any culture growing *M*. *tuberculosis* as identified by the State Public Health Laboratory.
    c. Any postive *Salmonella*, *Shigella*, *Campylobacter*, or *E. coli* O157:H7 results.
    d. Positive *Legionella* cultures.
    e. Positive Dialysis water cultures (≥ 30 CFU/mL).

h. **MOLECULAR PATHOLOGY**

i. Significant Results:

1. Positive Ehrlichia by PCR
2. Positive HSV PCR on CSF
3. Newly positive BK virus by PCR
4. Newly positive CMV by PCR
5. Positive JAK2 mutation by PCR
6. Positive BRAF mutation by PCR
7. Positive EGFR mutation by PCR
8. Positive KRAS mutation by PCR

i. **OUTPATIENT CLINICS**

i. **Significant Results:**

1. Positive Influenza results must be called to the nurse.
2. Positive RSV results on patients less than 18 years of age must be called to the nurse.

j. **REFERENCE LAB RESULTS**

i. UH and WCH processing staff will alert the patient caregiver of all critical result upon notification by the reference laboratory.

ii. Reference laboratories may provide notification by phone, fax, or interface.

1. Interfaced results may post prior to notification but the critical must still be called to verify receipt.

k. **SPECIAL CHEMISTRY**
   i. **Significant Results:**
      1. Positive sweat chloride results.
      2. Reactive quantiferon gold test results.

l. **TOXICOLOGY**
   i. **Significant Results:**
      1. Lead > 5.0 mcg/dL
      2. Methanol > 10 mg/dL
      3. Isopropanol > 10 mg/dL
      4. Ethylene Glycol > 10 mg/dL

m. **TRANSFUSION MEDICINE SERVICES**
   Positive ABSC for patient in OR or that have an immediate need for transfusion
   WCH Patients only: Positive Fetal Screen

n. **URINALYSIS**
   i. **Critical Results:**
      1. Crystals - Cystine, Leucine, Tyrosine – any amount after verification by Pathologist or if a pathologist is not available another technologist trained in Urinalysis may confirm.
      2. Positive Reducing Substances - any amount in children ≤ 2 years old
      3. Urine Glucose >1000 mg/dL and Ketones > 80 mg/dL

IV. Attachments

a. Patient Care - Critical Results - Policy
b. Laboratory - Reporting Critical Values - Guideline

V. References, Regulatory References, Related Documents, or Links

a. Not applicable