CRITICAL VALUE POLICY

SCOPE
This policy is applicable to all laboratories within Marshfield Labs Laboratory Service Line.

PURPOSE
Critical values may imply a life-threatening situation for the patient and must be brought to the immediate attention of the physician and/or the patient care staff responsible for the patient. Prompt notification of potentially life threatening test results is important to ensure appropriate care is administered. Critical (panic) values are established for a normal population, though in some instances may not be considered "critical" when related to particular disease states. Interpretation of test results and determining if a result is critical to a particular disease state is the responsibility of the requesting physician. The purpose of this policy is to provide employees with the list of test values identified by the Laboratory Medical Director(s) and/or Section Heads as potentially life-threatening.

POLICY STATEMENT
- All critical values are promptly reported to the ordering provider or designee following section site/site specific notification procedures. Approved designees include:
  - Designee listed in the Emergency Information tab.
  - Nurse responsible for the patient
  - Provider's Medical Assistant (M.A.) or Health Service Coordinator
  - Nurse in the same department or unit
  - Health Unit Coordinator (HUC) on same unit, only if RN is not available.
  - Technologist in the laboratory from which the specimen was referred (Outreach only)
- Notification must include the following:
  - Patient's full name
  - Medical record number (or accession number)
  - Date and time of specimen collection
  - Test name
  - Patient test result and reference range.
  - Any additional pertinent information (i.e. hemolysis, lipemia, etc.)
- Notification and verification of read back must be electronically documented in the lab or Transfusion Service information system(s). Read back documentation must include the identity (first and last name) of the person called.
- Critical results from tests which have not been ordered (e.g. platelet count on a hemoglobin test, parasite/fungal organisms on a body fluid smear prepared for a different test, etc.) are subject to the same notification and documentation.
- Refer to Attachment I for Critical Value List:

Chemistry	MolecularPathology
Coagulation	Microbiology
Cytogenetics	Pathology
Cytology	TherapeuticDrugs
Hematology	Transfusion Service

POLICY

Attachment I

Critical Value List

Chemistry	Critical Low	Critical High	Units
Ammonia (< 1 yr.)	-----	>110	umol/L
Bicarbonate	< 10.0	> 40.0	mmol/L
Bilirubin, Neonatal Total	-----	> 15.0	mg/dL
Blood Gases			
pH	< 7.20	> 7.60	mm Hg
PCO_2	< 20.0	> 70.0	mm Hg
PO_2 – Arterial (ABG)			
≤ 1 day	< 35.0	-------	mm Hg
> 1 day	< 40.0	-------	mm Hg
PO_2 – Capillary (CBG)			
≤ 1 day	<35.0	-------	mm Hg
> 1 day	<40.0	-------	mm Hg
BUN	-------	>100	mg/dL
Calcium, Total	< 6.5	> 13.0	mg/dL
Calcium, Ionized	< 3.0	> 6.3	mg/dL
Carbon Monoxide	-------	> 20.0	%
Creatinine	-------	>10.0	mg/dL
Ethanol	-------	> 300	mg/dL
Ethylene Glycol	Positive		
Glucose			
< 1 yr.	< 30	> 325	mg/dL
≥ 1 yr.	< 40	> 450	mg/dL

Chemistry	Critical Low	Critical High	Units
HIV rapid serology testing, employee exposure	Positive		
Magnesium	< 1.0	>5.0	mg/dL
Phosphorus	< 1.0	-----	mg/dL
Potassium			
< 1 mo.	< 2.5	> 6.9	mmol/L
≥ 1 mo.	< 2.5	> 6.0	mmol/L
Sodium	< 120	> 160	mmol/L
Volatile (methanol and isopropanol)	Positive		
Troponin I	See Note below.		

Coagulation	Critical Low	Critical High	Units
Activated Partial Thromboplastin Time (APTT)	------	> 100.0	seconds
Fibrinogen	< 50	----	mg/dL
Heparin, Unfractionated or Low Molecular Wt	≤ 0.10	> 1.50	anti-Xa IU/mL
INR	----	> 6.0	
Platelet Function Test	-----	≥ 300	seconds

Hematology	Critical Low	Critical High	Units
Hematocrit			
≤ 1 mo.	< 20	> 78	%
> 1 mo.	< 20	> 60	%
Hemoglobin			
≤ 1 mo.	< 7	> 27	g/dL
> 1 mo.	< 7	> 20	g/dL

Platelet Count	< 30.0	> 1000.0	x 10^3/uL
WBC	< 1.0	> 35.0	x 10^3/uL
Blood parasites (Babesia, Anaplasma, Ehrlichia, Malaria sp)	Positive smears		
Hematology: Marshfield Clinic Adult Oncology Critical Results between 1630-0700, Weekends, Holidays, and Patients Drawn at other Centers for Lab Only.			
Hemoglobin	< 7	-----	g/dL
Platelet	< 20	-----	x 10^3/uL
WBC	< 0.5	-----	x 10^3/uL

Therapeutic Drugs	**Critical Low**	**Critical High**	**Units**
Acetaminophen	-----	≥50	ug/mL
Carbamazepine	-----	> 15.0	ug/mL
Cyclosporine (Transplant patients)	-----	> 700	ng/L
Digoxin	-----	≥ 3.0	ng/mL
Gentamicin	-----	> 10.0	ug/mL
Lamotrigine	-----	≥ 20	ug/mL
Lidocaine	-----	> 7.0	ug/mL
Lithium	-----	> 2.0	mmol/L
Oxcarbazepine Metabolite	-----	≥ 40.0	ug/mL
Phenobarbital	-----	> 55.0	ug/mL
Phenytoin	-----	> 30.0	ug/mL
Phenytoin, Free	-----	> 3.0	ug/mL
Salicylate	-----	> 50.0	mg/dL
Tacrolimus	-----	>25	ng/mL

Therapeutic Drugs	Critical Low	Critical High	Units
Theophylline			
<6 mos.	-----	> 15.0	ug/mL
≥ 6 mos.		> 25.0	ug/mL
Tobramycin	-----	> 10.0	ug/mL
Vancomycin	-----	> 30.0	ug/mL
Valproic Acid	-----	> 150	ug/mL
Zonisamide	-----	≥ 60.0	ug/mL

Transfusion Service	Results	Units
DAT (cord blood or neonatal sample)	Positive	
Bacterial detection in a previously transfused blood product	Positive	
Transfusion reaction workup	Evidence of immune mediated hemolysis	
Emergency-released RBC unit that was issued and transfused prior to completion of testing	Evidence of incompatibility	

Cytogenetics
All 15;17 chromosome translocations, trisomy 13 and trisomy 18 results.

Microbiology: Notification is not required if there was a previous positive within 72h of the collection time	Results
AFB stain	Positive
AFB culture, if direct AFB stain was negative	Positive
Blood culture	Positive
CSF Gram stain (Note: All positives are called)	Positive

Microbiology: Notification is not required if there was a previous positive within 72h of the collection time	Results
CSF bacterial culture, if direct Gram stain was negative, or if Gram stain does not correlate with culture result	Positive
Internal eye fluid Gram stain (i.e. vitreous, aqueous) Note: All positives are called	Positive
Internal eye fluid bacterial culture, if direct Gram stain was negative, or if Gram stain does not correlate with culture result	Positive
M. tuberculosis nucleic acid amplification (results from a reference lab)	Positive
Blastomyces, Histoplasma, Coccidioides & Paracoccidioides isolated in culture	Positive
Blastomyces, Histoplasma, Coccidioides, Paracoccidioides or Pneumocystis found on microscopy (e.g. Silver, Gram, or Fungal)	Positive
HHS/USDA Select Agents (Including but not limited to *Bacillus anthracis, Brucella spp., Burkholderia mallei, Burkholderia pseudomallei, Francisella tularensis, & Yersinia pestis.)*	Positive
Any other result/organism that is suspected to be significant, based upon circumstances	Positive

Molecular Pathology	Results
Herpes Simplex Virus, Lyme, Enterovirus and Varicella Zoster Virus by PCR on CSF (spinal fluid)	Positive
Anaplasma/Ehrlichia/Babesia by PCR for Hospital and Emergency Department patients.	Positive

Pathology
Significant or unexpected surgical pathology.

Cytology
All abnormal GYN Cytology results that are reported as: • High grade squamous intraepithelial lesions (HSIL), • Atypical endocervical cells favor neoplasia, • Atypical endometrial cells favor neoplasia, • Atypical glandular cells favor neoplasia, • Atypical squamous cells cannot exclude high grade squamous intraepithelial lesion (ASC-H), • Malignant cases, • Results deemed significant or unexpected

All abnormal Non-GYN Cytology results that are reported as:

- Blastomyces, Coccidioides Immitis, Coccidioidomycosis, Cryptococcus, or Histoplasmosis (Reported to provider or designee and Lab Communicable Disease),
- Pneumocystis Jiroveci (Carinii) (Reported to provider or designee only),
- Malignant cases,
- Results deemed significant or unexpected

NOTE:
Nationally, there is no consensus on whether elevated troponin ought to be called to the ordering clinician as a critical value. It is widely acknowledged that laboratory results requiring critical value callback take longer to appear in the medical record. As Marshfield Clinic was an early adopter of electronic medical records, it is not surprising that reporting efficiency has taken precedence over person-to-person contact for elevated troponin levels. In other words, when myocardial injury or infarction is suspected, the ordering provider is awaiting the troponin value, and patients are generally not released before a result is reported. This is in contrast to critical values such as low platelet count or potassium level (placement of a CBC or electrolyte order does not mean that a clinician is expecting a medically emergent result, so the critical value policy ensures information is received in a timely manner). The laboratory has optimized assay workflow for rapid reporting of troponins.

At the request of an inquiring clinician, the policy was re-reviewed in February 2015 with laboratory professionals and practicing physicians, including clinicians in leadership roles Clinic-wide (Institution for Quality, Innovation and Safety and Board of Directors). The consensus opinion is that in standard of care medical practice, providers ordering a troponin in the outpatient setting, based on concern for myocardial injury, and should monitor patients in the clinic until a result is available. As such, the laboratory's role in optimizing patient care is to strive for highest accuracy and turn-around time, and to be available to answer clinician questions about the troponin assay and results, rather than interfering with the efficiency of the current reporting process.

Submitted: Dr.Sitwala 2.20.15