UR.434 Clinical Laboratory Critical Value Notification Policy

Copy of version 3.0 (approved and current)

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Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	20-May-2025	3.0	 Xiaolan Ou M.D., Ph.D.	

Signatures from prior revisions are not listed.

Prior History
UR.CP.GL.Gen.0004.0002 Updated for MediaLab use

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
3.0	Approved and Current	Major revision	13-May-2025	27-Jun-2025	Indefinite

Linked Documents

- BR.2004 Microbiology Critical Value and Courtesy Notification Policy

I. TITLE:

Clinical Laboratory Critical Value Notification Policy

II. PURPOSE:

The purpose of this document is to define a process to notify appropriate persons of laboratory values meeting the established criteria of an Alert Value for all Lab Sections within the scope of this policy.

III. SCOPE:

This policy is applicable to UR Medicine Labs at Strong Memorial Hospital (SMH), the Central Laboratory, Strong West, and other associated labs (owned or affiliated) when applicable; and when laboratory tests yield a result that meets established Standard Critical Values, also known as alert or panic values.

IV. RESPONSIBILITIES:

Approval and Signatories for this document are determined in accordance with the MediaLab Document Management Policy.

Responsibilities in regards to document management practices are outlined in the MediaLab Document Management Policy. Responsibilities specific to the process outlined in this document are listed below.

Role(s)	Responsibilities
Performing Employees	Follow policy.

V. LIMITATIONS:

For site specific values not included in this policy refer to area specific policy/procedures.

For a more comprehensive list of Microbiology critical test values, refer to Microbiology documents: Chart: BR.2004 Microbiology Critical Value and Courtesy Notification Policy and job aid BR.2008 Microbiology Critical Value and Courtesy Notification Job Aid.

Defer to Highland Hospital Critical Value Policy for Highland Hospital Location.

VI. ACRONYMS/KEY TERMS:

Acronym / Key Term	Definition
N/A	Not Applicable
Critical Value	A specific result value or level defined as significant to the health and safety of a patient. Attention is not given to differentiating which abnormal results are or are not unexpected in the context of the clinical history, the ordering physician is expected to apply context.
BR	Central Laboratory- 211 Bailey Rd
IHN	Integrated Health Network
IOH	Interlakes Laboratories
Ordering Physician	A physician with legal authority to request a laboratory test that has initiated a laboratory order.
PL	Pluta - 125 Red Creek Laboratory
SMH	Strong Memorial Hospital

SW	Strong West

VII. POLICY:

In order to assist the ordering physician in responding to certain potentially life-threatening outcomes, a group of laboratory test results that merit immediate notification has been identified. This procedure is not intended to cover all clinically serious test results or changes in test results. Therefore, it is essential that the ordering physician take responsibility for following up on all test results in a timely fashion.

Cutoff values for certain laboratory tests (list below) were determined based on the literature and experience. This list is somewhat subjective, but can be modified based on ongoing experience. Given the volume of testing performed in the clinical laboratories and lack of detailed clinical information, it is not possible to set different critical value limits based on clinical setting.

VIII. GENERAL GUIDELINES:

Critical values will be reported according to the following protocol:

A. The test result will be immediately reported. The laboratory has established a 5 minute turnaround time from verified critical result to notification. Deviations will be followed-up as needed.

B. The responsible provider, inpatient location, private office or referring laboratory including affiliate laboratories, is to be called with the results. If the provider is not available, a nurse or other designee can be given the result but should be instructed on the necessity to give this result to the provider in a timely manner.

   1. Give result(s) and request a read-back of “what was written down” and document in LIS.

   2. If the results are not given to the provider directly (nurse or designee), confirm that the recipient acknowledges the severity of the result and that it should be communicated to the provider within 15 minutes.

C. When critical results need to be called after hours or when the office is not open, an on-call provider or answering service must be available on a 24-hour basis to take responsibility for receiving the test result.

D. If an answering service is called, the urgency of the result and necessity to give this result to the responsible provider is explained, but the result is not reported and an appropriate call-back number is left. The time and person receiving the call is recorded as an internal comment in the lab information system. The responsibility for contacting the responsible provider rests with the office / answering service but the need for immediate follow-up must be communicated by reporting laboratory.

E. When the testing (reference) laboratory reports a critical value for a sample from an alternate laboratory, critical results are called to the originating laboratory. The originating lab, affiliate or otherwise, is responsible for further communications to report critical to the ordering provider or appropriate representative for clinical follow up.

F. For some tests (see list), the lab computer will be checked and if a similarly abnormal value was reported within the past two days, the repeat critical value will not be treated as an emergency and will be reported according to our standard protocol (i.e. will not be immediately called).” Exception will be given to repeated critical values within 48 hours and are preceded by a result falling within the normal range of the assay. In this case, the result will be treated as an emergency and called.
Results that are invalidated by an inadequate specimen (i.e. low glucose in contact with

RBCs over 4 hours; potassium in a hemolyzed sample) will not be reported as a critical value. These tests will be recorded with an appropriate comment in the laboratory computer.

G. Necessary Components of Calling a Critical Value:

1. Clear introduction including name, department, and laboratory (for offsite locations).
2. Reason for phone call: Critical Value.
3. Patient involved – Two identifiers (Name and DOB or MRN).
4. Ask for caregiver (doctor, nurse) of patient identified.
5. Give result(s) and request a read-back of “what was written down”.
6. Document transaction in call box, to include:
   a. First and last name of person who took the result (*if individual refuses to provide first and last name, document refusal in call box)*
   b. Test(s)
   c. Date and time, (may be automatically recorded by LIS)
   d. Verification that the read-back was performed.

Clinical Laboratory Critical Value Immediate Notification Test List

Assay	Critical Value Lower Limit	Critical Value Upper Limit	Call if similar result within 2 days?
Blood Gas			
pH (mm Hg)	7.20	7.60	Yes
pCO2 (mm Hg) *arterial only*	20	70	Yes
pO2 (mm Hg) adult *arterial only*	45	--	Yes
pO2 (mm Hg) newborn < 5 days old *arterial only*	40	91	Yes
MetHb (%)	--	30	Yes
COHb (%)	--	20	Yes
General Chemistry *(results are for **serum/plasma** unless noted)*			
Calcium (mg/dl)	6.5	13.0	Yes
Ionized calcium, uncorrected (mg/dl) *Whole Blood*	3.1	6.3	Yes
Chloride (mmol/l)	80	120	Yes
CO2 (mmol/l)	10	40	Yes
Glucose (mg/dl) newborn 0-1 days	25	325	Yes

Assay	Critical Value Lower Limit	Critical Value Upper Limit	Call if similar result within 2 days?
Glucose (mg/dl) newborn day 2-7	40	325	Yes
Glucose (mg/dl) > 7 days	50	500	Yes
Glucose (mg/dl) newborn 0-1 days *Whole Blood*	25	300	Yes
Glucose (mg/dl) newborn day 2-7 *Whole Blood*	40	300	Yes
Glucose (mg/dl) > 7 days *Whole Blood*	50	500	Yes
Glucose, *CSF* (mg/dl)	37	--	Yes
Lactate (mmol/l) *Plasma/Whole Blood*	--	3.5	Yes
Osmolality (mOsm/kg)	250	325	Yes
Mg (mEq/l)	1.0	4.8	Yes
Phosphate (mg/dl)	1.1	9.0	Yes
Potassium (mmol/l) 0-120 days	2.8	7.0	Yes
Potassium (mmol/l) > 120 days	2.8	6.2	Yes
Potassium (mmol/l) newborn 0 days – 1 year *Plasma/Whole Blood*	2.8	7.0	Yes
Potassium (mmol/l) > 1 year *Plasma/Whole Blood*	2.8	6.2	Yes
Sodium (mmol/l) *Serum/Plasma/Whole Blood*	120	160	Yes
Total Bilirubin (mg/dl) ≤ 1 week	--	15.0	Yes
Troponin T, high sensitivity (ng/L)	--	52	No
Assay	**Critical Value Lower Limit**	**Critical Value Upper Limit**	**Call if similar result within 2 days?**

Hematology			
Band Count	--	16% for 1 day old; 11% for all other ages	Yes
Hematocrit (%)	19	--	No
Malaria smear	--	Organisms +	No
Platelet count (thousand/microl)	19	--	No
Organisms seen in bld, CSF smear		any	No
WBC (thousand/microl)	--	150	No
Coagulation		Critical Value	
Heparin PF4 (HIT)	--	POS	Yes
INR	--	5.0	No
PTT	--	200	Yes
Thromboelastography (TEG) Parameters			
R Time*		>12 min	N/A
Alpha Angle		<40 degrees	N/A
Maximum Amplitude (MA)		<40 mm	N/A
Fibrinolysis (LY30)		>10%	N/A
**R Time is only TEG value considered for critical reporting when tested at the point of care in the OR. All four parameters have critical reporting values when tested in the main laboratory.*			
Toxicology			
Acetaminophen (ug/ml)	--	50	Yes
Alcohols (mg/dl)			
--Ethanol	--	300	Yes
--Methanol	--	10	Yes
--Isopropanol	--	10	Yes
--Acetone	--	20	Yes
Carbamazepine (ug/ml)	--	15	Yes
Digoxin (ng/dl)	--	2.5	Yes

Lithium (mmol/l)	--	1.50	Yes
Phenobarbital (ug/ml)	--	50	Yes
Phenytoin-Dilantin (ug/ml)	--	30	Yes
Free Phenytoin (ug/ml)	--	3.0	Yes
Salicylate (mg/dl)	--	50	Yes
Assay	**Critical Value Lower Limit**	**Critical Value Upper Limit**	**Call if similar result within 2 days?**
Theophylline (ug/ml)	--	25	Yes
Valproate (ug/ml)	--	150	Yes
Chemistry/Hematology/Blood Bank Tests with Special Critical Value Notification Criteria			
Aminoglycosides (ug/ml)	Peak/Random (Upper Limit)	Trough (Upper Limit)	
--Amikacin	≥ 65	≥ 8	Yes
--Gentamycin	≥ 35	≥ 2.1	Yes
--Tobramycin	≥ 35	≥ 2.1	Yes
--Vancomycin	≥ 80	≥ 25	Yes
Blood Bank			
Hemolytic transfusion reaction	Confirmation by lab analysis		Yes

Microbiology Tests

For a complete list of Microbiology Critical and Courtesy Calls, reference BR.2004 Microbiology Critical Value and Courtesy Notification Policy and BR.2008 Microbiology Critical Value and Courtesy Notification Job Aid.

Organism	Criteria	Call if similar result within 2 days?
Any bacteria or fungus from blood	Positive (+) smear	Yes
Any bacteria or fungus from sterile fluid or tissue (other than blood)	Initial positive (+) smear and culture	No
Confirmed bacterial resistance (unusual)	Newly confirmed patients only	
Any virus from blood, CSF or other sterile fluids/sites	Initial positive (+) culture Initial positive (+) PCR	No
Group A Streptococcus from any specimen where diagnosis is fasciitis	Initial positive (+) smear and culture	No
Herpes Simplex Virus	Positive (+) culture or PCR in term pregnant female or baby less than 6 months old	No
AFB	Initial positive (+) smear Initial positive (+) culture	1 per specimen site/day
Drug resistant M. tuberculosis	M. tuberculosis resistant to primary drugs	No
Legionella pneumophila, L. pneumophila serogroup 1 antigen	Urinary antigen and/or culture positive (+)	No
Pneumocystis	Positive (+) PCR	No
Malaria Antigen	Positive (+)	No
Rapid HIV results	Positive (+)	No
Creutzfeldt-Jakob Disease (CJD)	Positive (+) 14-3-3 Prion Protein results	No
Hepatitis B Surface Antigen	Initial positive (+)	No
Special Pathogen	Initial positive (+) from any source	No

IX. TRAINING:

Role(s)	Responsibilities
List role(s) of applicable staff	*Note which of the following are applicable: Read/review, Quiz (Knowledge Check), and/or Skills Assessment.*
Performing employees	*Read policy*

X. REFERENCES:

1. BR.2004 Microbiology Critical Value and Courtesy Notification Policy

2. BR.2008 Microbiology Critical Value and Courtesy Notification Job Aid

3. UR.538 Reference Lab Off Shift Critical Values

4. New York State Department of Health Wadsworth Center Clinical Laboratory Evaluation Program. Clinical Laboratory Standards of Practice Part 1-General Systems. January 2017: https://www.wadsworth.org/sites/default/files/WebDoc/NYSDOH_Standards_Part_1_General_Systems_01012019.pdf

5. College of American Pathologists, Cap Accreditation Program. Laboratory General Checklist.: https://www.cap.org/

XI. REVISION HISTORY:

Previous Version Number	Revised Document Version Date	Reason for Revision
UR.CP.GL.Gen.0004.0002	16 Apr 2021	Updated for MediaLab use
1.0	2Feb2024	Updated for result handoff from reference lab to originating lab and Troponin call for initial abnormal value per lab memo on 20Jan2022
2.0	13May2025	Add Whole Blood to Ionized Calcium listing