

TRAINING UPDATE

Lab Location: All Sites **Date Implemented:** 3/19/24
Department: All Technical Staff **Due Date:** 4/15/24

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Critical Values

Description of change(s):

Effective April 15, 2024, when calling critical values, lab staff will begin documenting the AHC employee ID of the person notified instead of the name. Name will only be used when an AHC employee ID is not available (as in the case where critical values are called to a physician's office).

The critical value will be documented using the following:

- AHC employee ID of the person notified
- Date of notification
- Time of notification
- Tech code of lab staff member that called the critical value

Example of how this will look:

Order physician:	TEST,PHYSICIAN 6					
Basic Metabolic Profile						
NA	L	130	[135-145]	mmol/L	(893-A) {s}	
K		4.7	[3.5-5.1]	mmol/L	(893-A) {s}	
CL		101	[98-107]	mmol/L	(893-A) {s}	
CO2	C	<10	[21-32]	mmol/L	(893-A) {s}	
		Called to and read back by: 1234567 03142024 1434 4082				
Glucose		101	[74-105]	mg/dL	(893-A) {s}	
BUN		12	[7-20]	mg/dL	(893-A) {s}	

Adventist HealthCare
 Site: All Laboratories

Title: Critical Values

Non-Technical SOP

Title	Critical Values	
Prepared by	Leslie Barrett	Date: 1/26/2010
Owner	Robert SanLuis	Date: 7/12/2017

Laboratory Approval		
Print Name and Title	Signature	Date
<i>Refer to the electronic signature page for approval and approval dates.</i>		
Local Issue Date:		Local Effective Date:

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1. **PURPOSE**
 To describe the process to screen results, identify critical values, notify clinical personnel and/or a physician and document the notification.

2. **SCOPE**
 This procedure applies to all Laboratory staff.

3. **RESPONSIBILITY**
 Laboratory testing personnel must demonstrate competency in identifying critical values and notification process during new employee orientation and again whenever changes are made to the critical value list.

 The medical director reviews the values for appropriateness and then submits to the each hospital's Medical Executive Committee for approval. If any changes are made to the current list the medical director makes the responsible staff aware of all changes and requires competency.

4. DEFINITIONS

Critical Value – potentially life-threatening result for a specific laboratory test.

Suspect Results – results that are suspected to be not representative of in-vivo physiology such as aberrant electrolyte values, values incompatible with life or values from dilution of an IV line.

Priority 1, 2, or 2WD Values – Quest Diagnostics terms to describe results for specific laboratory tests.

Client Custom Values – Quest Diagnostics term for Hospital defined reference laboratory critical values

STAT Value from Reference Lab – any result for a Reference laboratory test that the hospital laboratory requested to be called

TEa – Total Allowable Error; TEa is the amount of error that can be tolerated without invalidating the medical usefulness of the analytical result.

AMR - The Analytical Measurement Range is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process

CRR - The Clinically Reportable Range is the range of analyte values that a method can report as a quantitative result, allowing for specimen dilution, concentration, or other pretreatment used to extend the direct analytical measurement range.

The establishment of the CRR is a medical judgment made by the Laboratory director, and is based in part on the assay technology.

Outpatient – a patient serviced by the Lab Outpatient drawing area, usually registered to SLAB or WLAB

5. PROCEDURE**In-House Testing**

Step	Action
1	Approved critical values are contained within this policy, posted throughout the department and linked to the appropriate tests within the Laboratory Information System.
2	Critical values will be called as follows: <ul style="list-style-type: none"> A. Upon obtaining a Critical value for an inpatient the Laboratory Technologists will immediately call critical values to the charge nurse, nurse caring for the patient, or a physician (within 1 hour). B. Upon identification of a critical value on an outpatient, the Technologist or Client Services personnel will notify the appropriate Licensed Practitioner or on call designee caring for the patient within two (2) hours. C. All critical results must be called on all inpatients and outpatients 24 hours per day, 7 days per week except for Blood Bank on outpatients (See Appendix A for Blood Bank critical values). Critical results for blood

Step	Action
	<p>bank tests on outpatients only may be called on the next business day when the physician's office opens.</p>
<p>3</p>	<p>The Laboratory will screen all results for critical values. Each critical result should be reviewed carefully prior to release. If the critical value is within the AMR (straight) or the CRR (dilution) the value does NOT need to be repeated. Any critical value that is suspect (e.g. high sodium with a normal chloride or a low RBC with a normal Hct & MCV) must be called with the result given to the caregiver AND the technologist is required to state "result is suspect and WILL BE REPEATED" (see step 4 below). The initial result must be accepted in the LIS and the call documented electronically.</p> <p>A. ED and In-Patients – results will be telephoned to a nurse or physician as soon as a critical result is obtained.</p> <p>B. Out Patients and Discharged In-Patients – results will be telephoned to the ordering physician or the office nurse. If the admitting physician for a discharged inpatient was a hospitalist, the result is called to the on-call hospitalist. Note: The internal lab notification process for OP critical values is outlined in Appendix D.</p> <ol style="list-style-type: none"> a. If the physician office is closed, contact is initiated via the answering service or pager. b. If a response is not received within one hour, a second attempt must be made c. All attempts must be documented in Callback d. If no response is received after two (2) attempts, notify the pathologist on call and document the incident on a PI/Variance form. e. Failures to return pages are documented in the hospital occurrence reporting system. f. Note: Provided the initial notification attempt occurred the time limits specified in section A.2 above, these events are classified as compliant with the policy. g. If a physician refuses to accept a critical value for a discharged inpatient, then <ol style="list-style-type: none"> i. Document on a QV form and immediately notify a supervisor. ii. The supervisor must escalate the event to the Medical Director iii. The event must be documented in the hospital occurrence reporting system. <p>C. Expired Patients - Call and confirm with the nursing/medical staff that the patient has expired. Document in the LIS by adding the code PEXP and free-text the date, time, and name of the staff member.</p>

Step	Action
4	<p>If a critical or suspect result was repeated follow the steps below.</p> <p>A. If there is no clinical significant difference (both results are within the TEa limit for that analyte) between the initial and the repeat results, no further action is required (the initial result was already accepted and the call documented). If the initial result was verbally reported as “the value is xxx, it is suspect and WILL BE REPEATED”, call a second time and confirm the initial result.</p> <p>B. If there is a clinically significant difference between the initial result and the repeated result (the difference between the two results is greater than the TEa limit for that analyte), the test should be run a third time. If the last two results match, then a corrected report must be issued. The repeated result will be called, entered in the computer, and the call documented. A quality variance (QV) form must be completed and a look-back performed.</p>
5	<p>All verbal results must be read back to the reporting person. (The person receiving the results, by repeating back the patient name, test name, test results, to the laboratory personnel, will verify the results.)</p> <p>Note: Troponin critical values vary based on whether the result is an initial test or a subsequent one. Subsequent critical values are determined by delta criteria rules. Refer to appendix A for details. If the subsequent critical value does NOT qualify to be called, document this by appending the code TROPc to the result. This code translates to “Laboratory value indicates a critical value previously reported.”</p>
6	<p>All Critical Value calls MUST be documented in the Laboratory Information System (LIS). The documentation MUST include the date and time of the telephone call, and the first and last name, or AHC employee ID, of the nurse or doctor receiving the results. The Text Code CBACK (call to and read back by) must be included in the documentation.</p>

Reference Laboratory Priority Results

Step	Action
1	<p>Client custom critical values from the reference laboratory are treated in the same manner as critical values from the hospital laboratory. These are phoned to Specimen Processing and followed by a faxed report</p> <p>A. Result values defined by the hospital as Critical are included in Appendix B. These must be called and documented within the time limits specified in above.</p> <p>B. Reference Lab values that are NOT on the critical value list but are either Priority 1, 2, or 2WD values are phoned to Specimen Processing and followed by a faxed report.</p> <p>a. Results defined as Priority 1, 2 or 2WD by Quest Diagnostics are called 7 am – 7 pm.</p> <p>b. The laboratory will call Priority results for inpatients ASAP upon receipt.</p>

Step	Action
	c. Refer to Appendix C for Priority Result Reporting Policy. Definitions utilized by Quest Diagnostics Incorporated
2	Antibiotic Sensitivities - Laboratory staff will only notify the provider/nursing unit that sensitivities have been updated. Actual sensitivity results will <u>not</u> be verbally reported. A. For inpatients, the provider/nursing unit will be instructed to view sensitivity results in Cerner. B. For outpatients, results will be faxed to the physician's office.
3	Document the call from the reference lab on the Reference Lab Results Call Log and document the call details on the faxed reference lab result and fax to SGMC OPL for entry into Call back (FAX# 240-826-5411). Retain fax and call original documentation.
4	Call and fax the results to the physician, charge nurse, or nurse caring for the patient as appropriate. Results available in Cerner do not need to be faxed.
5	All verbal reports must be read back to the reporting person. Note: Documentation for sensitivity results will only include notification that sensitivities are available; no actual results will be verbally reported.
6	SGMC OPL will document the call via the LIS function Callback during hours of operation. Refer to the Callback procedure for details. Documentation MUST include the date and time of the telephone call, the first and last name of the nurse or doctor receiving the results and the comment code CBACK.
7	The faxed report is retained in a file labeled "Ref Lab Results Called/Faxed." A. Maintain 6 months of files (example: Dec, Jan, Feb, March, April, May). Current month is always first, oldest file is last. B. Faxes are placed in the front with newest ones at front. C. When June file is made, Dec file is shredded

6. **RELATED DOCUMENTS**

- Critical Values - Accepting Results in LIS, LIS procedure
- Callback, LIS procedure
- PRIORITY, STAT and CALL Test Reporting Policy, QDMOQ704, Quest Diagnostics Incorporated, Corporate Medical Standard Policy
- Adventist Hospital Client Specific Priority 3 Values
- Reference Lab Results Call Log (AG.F278)
- Data Innovations Instrument Manager, Laboratory policy
- Laboratory Service Expectations, Laboratory policy
- Critical Value Call Log (AG.F580)

7. **REFERENCES**

CAP Laboratory General Checklist (www.cap.org).
Critical Values in Coagulation – Am J Clin Pathol 2011;136:836-841

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L007.010		
000	7/8/11	Section 5: Item B – Add process for expired patient, PTT critical value revised and troponin note added. Section 9: Appendices A - C revised (add C diff; revise PTT, Mg, Tobra peak and random; add GEC blood gas)	R SanLuis R Master	Dr Cacciabeve
001	4/6/12	Section 5: Item B.5 – Clarify first critical value applies to each hospital encounter Section 9: Appendices A & B revised (change Vanc trough; remove amikacin & DADS) Appendix C only - specify arterial blood gas for GEC, update age ranges	L Barrett	Dr Cacciabeve
002	3/21/14	Section 5: Item B.2 – Specify after hours reporting and refusal to accept results on discharged patients. Item D – Change process; ref lab to phone, then fax reports; add log, add filing and retention; add read back not required for sensitivity Section 6: add call log Section 9: App D updated to match corporate changes for Priority 2 Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett L Loffredo	Dr Cacciabeve
3	4/13/15	Section 9: standardize K+ low value as <3.0 for all sites, combine App A&B and re-title, re-number subsequent appendices	L Barrett	Dr Cacciabeve
4	7/22/15	Section 9: App A revised (delete bleeding time, update units for WBC & Plt, revise troponin, correct Cl, replace ≥ and ≤ signs with > and < and edit values accordingly)	L Barrett	Dr Cacciabeve
5	2/1/16	Section 4: add suspect results and client custom values Section 5: separate calling for IP and OP in item A, revise item B to state result is called & documented before repeat testing, add QV & look-back needed if repeat initiates correction and add calling hospitalist for discharged IP App C: update Quest definitions	R SanLuis L Loffredo L Barrett	Dr Cacciabeve
6	4/5/17	Update owner Header: add other sites Section 4: add Outpatient Section 5: add reference to App D, remove PTT note Section 6: add DI and Service Expectation SOPs, add logs Section 9: add OP process as App D App A: revise PTT value from >80 to >110	L Barrett R SanLuis	Dr Cacciabeve
7	7/12/17	App A: correct PTT value to >100	L Barrett	Dr Cacciabeve

Version	Date	Reason for Revision	Revised By	Approved By
8	1/19/18	Updated format of procedure. Section 5: Added staff will notify pathologist if they cannot reach a provider to report a critical value within 2 hours. Deleted requirement to call sensitivities; lab staff will only notify that a sensitivity is available.	S Codina	Dr Cacciabeve
9	6/1/18	Section 5: Updated troponin subsequent testing App A: Added troponin delta criteria	L Barrett R SanLuis	Dr Cacciabeve
10	3/25/20	Header & App A: Changed WAH to WOMC App A: Removed GDH antigen for C diff App B: Added SARS COV2	L Barrett	Dr Cacciabeve
11	11/12/20	App A: Added SARS CoV-2, amikacin, anti-Xa; revised troponin for new method	L Barrett	Dr Cacciabeve
12	4/1/21	App B: Added TB culture, deleted SARS COV-2	L Barrett	Dr Cacciabeve
13	11/3/21	Header: Deleted site names, added All Labs Section 6: Updated call logs App A: Retired, added FWMC ED for SARS COV-2 Footer: Updated prefix to AHC	L Barrett	Dr Cacciabeve
14	9/28/22	Section 5: Updated priority value resulting, calling and documentation steps 1, 3, & 6. Section 9: Updated Appendix B, added E Appendix A: Updated glucose and K+ low critical value and Lactic acid call criteria Appendix B: Updated to Standard and Custom priority values Appendix C: Updated Priority 2 and # 4 and 6. Appendix D: Updated # 1 Appendix E. added this	R SanLuis	Dr Cacciabeve
15	3/15/24	Section 5, step 6, "In House Testing", added "or AHC employee ID".	D Collier	Dr Cacciabeve

9.

ADDENDA AND APPENDICES

- Appendix A: Laboratory Critical Values List
- Appendix B: Reference Laboratory Priority Value List
- Appendix C: Priority Result Reporting Policy Definitions
- Appendix D: Outpatient Critical Value Notification Process
- Appendix E: Job Aid – Who to call for discharged and outpatients.

APPENDIX A

Laboratory Critical Values

Test Name	Age	Critical Low	Critical High	Ref Unit
Hematology and Coagulation				
Anti-Xa			>2.0	IU/mL
Fibrinogen		<100	>800	mg/dL
Hgb	>= 30 days	<6.1	>19.9	g/dL
Hgb	0 – 29 days	<6.1	>23.9	g/dL
INR			>3.9	None
Platelet Count		<31	>899	x10(3)/mcL
PTT			>100	Secs
WBC		<2.1	>29.9	x10(3)/mcL
Chemistry, Immunochemistry and Toxicology				
Acetaminophen			>49.9	µg/mL
Alcohol			>400	mg/dL
Amikacin Peak			>30.0	µg/mL
Amikacin Random			>30.0	µg/mL
Amikacin Trough			>8.0	µg/mL
Ammonia			>199	µmol/L
Bilirubin, Total			>17.9	mg/dL
Calcium		<6.0	>13.0	mg/dL
Carbamazapine			>14.9	µg/mL
Chloride		<75	>126	mmol/L
CO ₂				mmol/L
Digoxin			>1.99	ng/mL
Gentamicin Peak			>11.9	µg/mL
Gentamicin Random			>11.9	µg/mL
Gentamicin Trough			>1.9	µg/mL
Glucose	0 – 30 days	<35	>299	mg/dL
Glucose	1 month +	<51	>600	mg/dL
K (Potassium)		<2.9	>6.1	mmol/L
Lactic Acid			>2.0*Sepsis >4.0*	mmol/L
*Only increasing values will be called				
Lithium			>2.10	mmol/L
Magnesium		<1.1	>6.9	mg/dL
Na (Sodium)		<120	>160	mmol/L
Phenobarbital			>49.9	µg/mL
Phenytoin			>29.9	µg/mL
Phosphorus		<1.1		mg/dL
Salicylate			>30.0	mg/dL
Theophylline			>19.9	µg/mL
Tobramycin, Peak or Random			>12.0	µg/mL
Tobramycin Trough			>2.1	µg/mL
Troponin-I (initial test)			>100	pg/mL
Valproic Acid			>175.0	µg/mL
Vancomycin Peak			>40.0	µg/mL
Vancomycin Random			>40.0	µg/mL
Vancomycin Trough			>20.0	µg/mL

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Troponin-I Subsequent Test Delta Criteria

Prior Critical Value	Delta Threshold	Example
101 - 500 pg/mL	Value doubles	Prior value of 101, next value must be 202 or greater
501 – 1,000 pg/mL	Increase of 250	Prior value of 600, next value must be 850 or greater
1,001 pg/mL or more	Increase of 1000	Prior value of 2,000, next value must be 3000 or greater

Laboratory Critical Values

Microbiology	
Culture/Test	Result
Blood Culture	Gram stain on first positive bottle in set, unless gram morphology differs in second bottle
Cerebral Spinal Fluid	Positive gram stain
Fluids (sterile body fluids other than urine)	Positive gram stain
Malaria	Positive preliminary report
<i>Clostridium difficile</i>	Positive <i>C. difficile</i> toxins A/B
SARS CoV-2 (for infectious disease purposes)	Detected (in-patients and FWMC ED & WOMC ED only)

Blood Bank	
Blood not available (due to either antibodies or no stock of compatible blood)	
Positive antibody screen if it will take more than 2 hours from the time of identification to provide compatible blood products.	
Suspected hemolytic transfusion reaction	
Positive DAT (direct antiglobulin test) on Transfusion Reaction investigation if the pre-transfusion DAT was negative or the DAT is demonstrating a stronger positive result than the pre-transfusion specimen.	
Positive DAT (direct antiglobulin test) for neonate	

Shady Grove Medical Center's Emergency Center at Germantown Critical Values

Test Name	Age	Critical Low	Critical High	Ref Unit
Arterial Blood Gas				
PCO ₂ (arterial)	>17 yrs	<19.0	>67.0	mmHg
PCO ₂ (arterial)	31 days – 17 yrs	<21.0	>66.0	mmHg
PO ₂ (arterial)	> 18 yrs	<43		mmHg
PO ₂ (arterial)	31 days – 17 yrs	<45	>124	mmHg
PO ₂ (arterial)	0 – 30 days	<37	>92	mmHg
pH (arterial)	all	<7.21	>7.59	

APPENDIX B - REFERENCE LABORATORY PRIORITY VALUES**Standard Priority Values**

Test	Result	Priority
Cryptococcus antigen, serum or CSF	Positive	2
AFB smear	Any positive	2
TB culture	Any positive	2
<i>Bacillus anthracis</i> , culture, nucleic acid, or antigen test	Any positive	1
Culture: blood, CSF, any tissue or sterile body fluid (excluding urine)	Any positive	1
<i>Francisella tularensis</i> , culture, nucleic acid,	Any positive	1
Viral PCR for Enterovirus or HSV, Qual or Quant; CSF	Detected	1
<i>Yersinia pestis</i> , culture, nucleic acid,	Any positive	1
<i>Ureaplasma urealyticum</i> , culture, respiratory	Positive in < 1 year old patient	2
Heparin – Induced Platelet Antibody	Positive	2
Serotonin Release Assay (%)	≥20 %	2

Custom Priority Values - (Microbiology)

Organism Code	Priority 2 - Organism
1	Acinetobacter anitratus
363	Acinetobacter anitratus/haemolyticus
329	Acinetobacter baumannii
925	Acinetobacter baumannii complex
1234	Acinetobacter baumannii complex, carbapenem resistant
364	Acinetobacter baumannii/haemolyticus
32	Acinetobacter species
1204	Candida auris
1213	Citrobacter freundii complex, CRE
1211	Enterobacter aerogenes, CRE
1210	Enterobacter cloacae complex, CRE
702	Enterococcus avium (VRE)
701	Enterococcus faecalis (VRE)
700	Enterococcus faecium (VRE)
705	Enterococcus raffinosus (VRE)
665	Enterococcus species (Vancomycin-resistant)
874	Escherichia coli (ESBL positive - urine ID)
873	Escherichia coli (ESBL)
935	Escherichia coli (urine ID), KPC/CRE
931	Escherichia coli, KPC/CRE
876	Klebsiella oxytoca (ESBL positive - urine ID)
875	Klebsiella oxytoca (ESBL)
937	Klebsiella oxytoca (urine ID), KPC/CRE
933	Klebsiella oxytoca, KPC/CRE
878	Klebsiella pneumoniae (ESBL positive - urine ID)

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877	Klebsiella pneumoniae (ESBL)
936	Klebsiella pneumoniae (urine ID), KPC/CRE
932	Klebsiella pneumoniae, KPC/CRE
880	Proteus mirabilis (ESBL positive - urine ID)
879	Proteus mirabilis (ESBL)
938	Proteus mirabilis (urine ID), KPC/CRE
934	Proteus mirabilis, KPC/CRE
1214	Salmonella species, CRE
1215	Serratia marcescens, CRE
311	Staphylococcus aureus (MRSA)
901	Staphylococcus aureus (VISA)
867	Staphylococcus aureus (VRSA)
311U	Staphylococcus aureus MRSA (urine ID)
900	Vancomycin resistant S. aureus (VRSA)

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APPENDIX C**Priority Result Reporting Policy, Definitions**

Quest Diagnostics Incorporated, Corporate Medical Standard Policy uses the following definitions:

- Priority-1 Reporting (24 hours 7 days) - P1 results are called as critical values.
- Priority-2 Reporting (7am-7pm 7 days)
 - P2 results for inpatients are called ASAP upon receipt.
 - P2 results for outpatients will be called during client's known office hours or between 9am-4pm if unknown, 7 days/week.

- Client Custom Priority Value Reporting

A client may request custom Priority Value thresholds or procedure for notification for all of their patients to allow for

- Tighter reporting criteria (more phone calls)
- More liberal reporting criteria (fewer or no phone calls)
- Alternative hours for reporting (e.g., no weekend calls)

The request must be in writing, approved by the Medical Director and remains in effect until revoked or changed in writing from the client.

The following process and forms may be localized with lab address, contact names, return fax number and attention to, etc.

1. Provide the following applicable form to a client or group that expresses interest in customizing Priority Result Reporting for their patients:
Solo/group request for custom priority result reporting
2. The Medical Director or Chief of Staff of a group practice or hospital medical staff may approve customized Priority Values for the entire group or hospital. The Form makes it clear that it is their responsibility to advise the other practice members. The Medical Director/Advisor of a corporation that is using Blueprint for Wellness may use this Form.
3. Completed form is returned to the Medical Director, or designee, to review.
 - a. If incomplete, return forms to sales representative or the client
 - b. If not approved, client must be informed
 - c. If approved, proceed to next step
4. Authorized personnel enter approved client specific values into the local database.
Call documentation may be requested as needed.
5. Customer Solutions will scan the original signed and approved request and retain per Record Retention Schedule after client account is deactivated.
6. Periodic renewal is required. Custom organisms listed in Appendix B.

APPENDIX D

Outpatient Critical Value Notification Process

A. Technical staff

1. This process is followed for any outpatient critical value that is reported while the outpatient service desk at **SGMC is open**. Refer to the policy Laboratory Service Expectations for hours.
2. Call the Client Service desk and document the call on the Outpatient Critical Value Call Log.
SGMC 240-826-6085
3. Document the date and time of call, accession number, patient name, and test. Also record your tech code and person who received the information. It is not necessary to provide the actual test result.
4. When the outpatient service desk is closed, call the result to the medical provider and document in the LIS or Data Innovations. See Related Documents for appropriate procedures.

B. Client Service personnel

1. When a call is received, document the call on the Outpatient Critical Value Log, Call to Medical Provider form.
2. Record the following information
 - a. date and time of call
 - b. name of the person calling
 - c. accession number
 - d. patient name
 - e. test
 - f. who the result is called to
3. Utilize the patient name, accession number and test to find the result(s) in the LIS.
4. Call the result to the medical provider and document in Callback. Refer to the LIS procedure Callback for details.

Appendix E: Job Aid – Who to call for discharged and outpatients.

1. SGMC & WOMC “who” the staff call.
 - a. Discharged patient that was previously admitted to the hospital—
 - i. Call the hospitalist on duty for most.
 - ii. Call OB on call for L&D and Mother baby patients.
 - iii. Call the pediatrician on call for pediatric patients.
 - iv. Call the intensivist on duty if the patient was discharged directly from the ED.
 - b. Discharged patient that was discharged directly from ED (was never admitted to the floor)—Notify the ED charge or physician on duty.
2. Priority 2 Results for outpatients will be called during office hours.

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