TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	1/26/2018
Department:	Core, Client Services, & Processing	**Due Date:**	2/19/2018
		Implementation:	**2/19/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Critical Values SGAH.L45 v9

Description of change(s):

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.

This revised SOP will be implemented on February 19, 2018

Document your compliance with this training update by taking the quiz in the MTS system.

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**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**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: 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 bank tests on outpatients only may be called on the next business day when the physician's office opens.
3	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.

Step	Action
3 Cont	A. **ED and In-Patients** – results will be telephoned to a nurse or physician as soon as a critical result is obtained. 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. 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 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. 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.
4	If a critical or suspect result was repeated follow the steps below. 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. 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.

Step	Action
5	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.) Note: Only the first critical troponin value for each hospital encounter must be called. Subsequent critical values for troponin must be documented by appending the code TROPC to the result. This code translates to "Laboratory value indicates a critical value previously reported."
6	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 of the nurse or doctor receiving the results. The Text Code CBACK (call to and read back by) must be included in the documentation.

Reference Laboratory Results

Step	Action
1	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 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. B. Reference Lab values that are NOT on the critical value list but are either STAT or Priority 1, 2, or 2WD values are phoned to Specimen Processing and followed by a faxed report. a. Results defined as Priority 1, 2 or 2WD by Quest Diagnostics are called and faxed by the laboratory during the hours of 9 am and 7 pm. b. 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 not 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 log on the Reference Lab Results Call Log.
4	Call and fax the results to the physician, charge nurse, or nurse caring for the patient.

Step	Action
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	Document the call via the LIS function Callback. 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, QDMED704, 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
- Outpatient Critical Value Call Log (AG.F317)
- Outpatient Critical Value Log, Call to Medical Provider (AG.F320)

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 B only - specify arterial blood gas for GEC, update age ranges	L Barrett	Dr Cacciabev

Version	Date	Reason for Revision	Revised By	Approved By
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
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. ADDENDA AND APPENDICES

- Appendix A: Shady Grove and Washington Adventist Critical Values List
- Appendix B: Hospital-Defined Reference Laboratory Critical Value List
- Appendix C: Priority Result Reporting Policy Definitions
- Appendix D: Outpatient Critical Value Notification Process

APPENDIX A

Shady Grove Medical Center and Washington Adventist Hospital
Laboratory Critical Values

Test Name	Age	Critical Low	Critical High	Ref Unit
Hematology and Coagulation				
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
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		<10		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	<31	>299	mg/dL
Glucose	1 month +	<41	>499	mg/dL
K (Potassium)		<3.0	>6.1	mmol/L
Lactic Acid			>4.0	mmol/L
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			>12.0	µg/mL
Tobramycin Random			>12.0	µg/mL
Tobramycin Trough			>2.1	µg/mL
Troponin-I			>0.09	ng/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

Shady Grove Medical Center and Washington Adventist Hospital
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
Clostridium difficile	Positive *C. difficile* toxins A/B and GDH antigen

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 Adventist Hospital'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

Hospital – Defined Reference Laboratory Critical Values

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

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 may be "critical" as referenced in the Clinical Laboratory Improvement Amendments of 1988 (CLIA; CFR 493.1291(g) and the CAP Laboratory Accreditation Program. P1 results will be called 24 hours/day and 7 days/week

- Priority-2 Reporting (9am-7pm 7 days)

  P2 results may require attention prior to the receipt of routine laboratory reports but have not exceeded the P1 threshold.
  P2 results will be called during client's known office hours or between 9am–5pm if unknown, 7 days/week, the same day if released before 5pm, or the next business morning if released after 5pm.
  P2 results for NH (nursing home) and H (hospital) facilities will be called 24 hours/day and 7 days/week.

- Priority 2WD (office hours if known or 9am–5pm, weekdays)

  Prenatal genetic testing results flagged P2 and sub-classified as P2WD in the approved Priority Value Table are reported during client's regular weekday office hours. The P2WD flag does not appear on the Call Log and must be manually recognized.

- 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. For QLS sites, comments are entered in the Client Specific Message STAT Call module (menu option 7, 31, 4).
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 not required.

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 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 extension 6085
   WAH extension 5142

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.