

TRAINING UPDATE

Lab Location: GEC, SGMC & WAH
Department: All

Date Distributed: 2/19/2016
Due Date: 3/14/2016
Implementation: 3/15/2016

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Critical Values GEC.L40, SGAH.L45, WAH.L43 v6

Description of change(s):

Section 4: add definitions for suspect results and client custom values

Section 5: separate calling for IP and OP in item A;
revise item B:

- **Add result is called & documented before repeat testing**
NOTE – “If the critical value is within the AMR (straight) or the CRR (dilution) the value does **NOT** need to be repeated.”
SOP has always contained this information but it bears repeating
- **Add QV & look-back needed if repeat initiates correction**
- **Add calling hospitalist for discharged IP**

App C: update Quest definitions

NOTE: Our custom reference lab critical values are listed in Appendix B. These are the **only** reference results that **must be called 24 x 7**. All others are held for calling between 9am and 7pm (see note in section D.2 of SOP) (*SOP has contained this information since 2014*)

This revised SOP will be implemented on March 15, 2016

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

Approved draft for training (version 6)

Non-Technical SOP

Title	Critical Values	
Prepared by	Leslie Barrett	Date: 1/26/2010
Owner	Lori Loffredo	Date: 1/26/2010

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:

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.

5. PROCEDURE

A. General information

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. 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 when results of certain tests exceed critical limits important for prompt patient management.
3. 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 hours.
4. 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.

B. 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.**

1. ED and In-Patients – results will be telephoned to a nurse or physician as soon as a critical result is obtained.

2. 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.**
 - 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, then
 - Document on a Quality Variance (QV) form. Keep the QV form and fax (if a reference lab result) in Specimen Processing until notification is completed.
 - Telephone the office the next morning - or that same morning if the attempt was made after midnight - during business hours.
 - Inform the physician / office nurse of inability to provide the information prior to this notification because a direct contact was unavailable.
 - Ask for one or more telephone numbers to use in case a situation like this was to re-occur. If a new phone number is given, update the LIS in function PHYMA
 - Document the call completion in Callback and on the QV form. Forward QV form to the supervisor.
 - e) Failures to return pages are documented in the hospital occurrence reporting system.

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.
 - f) If a physician refuses to accept a critical value for a discharged inpatient, then
 - Document on a QV form and immediately notify a supervisor.
 - The supervisor must escalate the event to the Medical Director
 - The event must be documented in the hospital occurrence reporting system.
3. 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.**

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.)

Notes:

- The critical value for PTT is > 80 seconds, however, if a patient has a result between 80 seconds and 110 seconds, and that patient is on the heparin therapy list, then that result does NOT have to be called. Document in the computer that the result is consistent with the patient's history by appending the code HIS. All PTT results >110 seconds will be called.
 - 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."
- C. 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.
- D. Reference Laboratory Results
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
Note: 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 section A.2 and 3 above.
 2. 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.
Note: 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.
 3. The following applies to all results as described in items 1 and 2 above:
 - a) Document the call from the reference log on the Reference Lab Results Call Log.
 - b) Results are called and faxed to the charge nurse, nurse caring for the patient, or a physician.
 - c) Critical Value notification is documented via the LIS function Callback. Refer to the LIS procedure 'Callback' for details.
 - d) All verbal reports must be read back to the reporting person.
 - Sensitivities are not required to be read back because organism ID has already been called

- Documentation MUST included 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.
- e) The faxed report is retained in a file labeled "Ref Lab Results Called/Faxed"
- Maintain 6 months worth of files (*example: Dec, Jan, Feb, March, April, May*). Current month is always first, oldest file is last.
 - Faxes are placed in the front with newest ones at front
 - When June file is made, Dec file is shredded

Note: Refer to Appendix C for Priority Result Reporting Policy Definitions utilized by Quest Diagnostics Incorporated

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)

7. REFERENCES

CAP Laboratory General Checklist (www.cap.org).

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 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

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 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			>80	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

Form revised 3/31/00

**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
<i>Clostridium difficile</i>	Positive <i>C. difficile</i> 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
<i>Bacillus anthracis</i> , culture, nucleic acid, or antigen test	Any positive
Culture: blood, CSF, any tissue or sterile body fluid (excluding urine)	Any positive
<i>Francisella tularensis</i> , culture, nucleic acid, or antigen test	Any positive
Viral PCR for Enterovirus or HSV, Qual or Quant; CSF	Detected
<i>Yersinia pestis</i> , culture, nucleic acid, or antigen test	Any positive
<i>Ureaplasma urealyticum</i> , 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.