TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	4/17/2015
Department:	All Staff	**Due Date:**	5/3/2015
		Implementation:	**5/4/2015**

DESCRIPTION OF PROCEDURE

Name of procedure:

Critical Values GEC.L40, SGAH.L45, WAH.L43 v4

Description of change(s):

Section 9: standardize K+ **low value as <3.0** for all sites,
combine App A&B and re-title,
re-number subsequent appendices

The technical SOPs listed below are also being revised:

- V-LYTE Integrated Multisensor (Na+ / K+ / Cl-) by Dimension Vista® System
- QuikLYTE Na+ / K+ / Cl- by Dimension® Xpand Chemistry Analyzer

The change has already been implemented in LIS and DI

The SOP will be implemented on May 4, 2015

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

Approved draft for training at all sites (version 4)

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**
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.

Priority 1, 2, or 3 Values – Quest Diagnostics terms to describe results for specific laboratory tests.

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. The Laboratory Technologists or Client Service personnel will 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. **Notification is expected to be completed within one hour for inpatients and within two hours for outpatients**.
   3. 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 <u>on outpatients only</u> 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 have 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) should be repeated before it is reported (see step 4 below).

   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.
      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 the 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, the initial result is called, resulted in the computer and the call documented.

   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 the repeated result will be called, entered in the computer, and the call documented.

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. 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 above.

2. Reference Lab values that are NOT on the critical value list but are either STAT or Priority 1, 2, or 3 values are phoned to Specimen Processing and followed by a faxed report.
Note: Results defined as Priority 1, 2 or 3 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

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6. RELATED DOCUMENTS

- Critical Values-Accepting Results in LIS, LIS procedure
- Callback, LIS procedure
- Priority Result 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

9. ADDENDA AND APPENDICES

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

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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				
Bleeding Time			>15	mins
Fibrinogen		<100	>800	mg/dL
Hgb	>= 30 days	<=6.0	>=20.0	g/dL
Hgb	0 – 29 days	<=6.0	>=24.0	g/dL
INR			>=4.0	None
Platelet Count		<=30	>=900	K/uL
PTT			>80	Secs
WBC		<=2.0	>=30.0	K/uL
Chemistry, Immunochemistry and Toxicology				
Acetaminophen			>=50	ug/mL
Alcohol			>400	mg/dL
Ammonia			>=200	umol/L
Bilirubin, Total			>=18.0	mg/dL
Calcium		<6.0	>13.0	mg/dL
Carbamazapine			>=15.0	ug/mL
Chloride		<75	>125	mmol/L
CO_2		<10		mmol/L
Digoxin			>=2.00	ng/mL
Gentamicin, Peak			>=12.0	ug/mL
Gentamicin, Random			>=12.0	ug/mL
Gentamicin, Trough			>=2.0	ug/mL
Glucose	0 – 30 days	<=30	>=300	mg/dL
Glucose	1 month +	<=40	>=500	mg/dL
K (Potassium)		<3.0	>6.1	mmol/L
Lactic Acid			>4.0	mmol/L
Lithium			>2.1	mmol/L
Magnesium		<=1.0	>=7.0	mg/dL
Na (Sodium)		<120	>160	mmol/L
Phenobarbital			>=50.0	ug/mL
Phenytoin			>=30.0	ug/mL
Phosphorus		<=1.0		mg/dL
Salicylate			>30.0	mg/dL
Theophylline			>=20.0	ug/mL
Tobramycin Peak			>12.0	ug/mL
Tobramycin Random			>12.0	ug/mL
Tobramycin Trough			>=2.0	ug/mL
Troponin-I			>=0.6	ng/mL
Valproic Acid			>175.0	ug/mL
Vancomycin Peak			>40.0	ug/mL
Vancomycin Random			>40.0	ug/mL
Vancomycin Trough			>20.0	ug/mL

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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	

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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 %

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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)

  These results are reported 24 hours/day and 7 days/week and include, but are not limited to, results considered "critical" according to the Clinical Laboratory Amendments of 1988 (CLIA; CFR 493.1109f) and the CAP Laboratory Accreditation Program. Because test results cannot be fully interpreted without knowledge of the patient's clinical condition and treatment, reasonable effort must be made to promptly communicate Priority-1 values after verification and release, allowing the provider to determine the clinical implications and possible need for immediate attention.

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

  These results are reported 9 am to 7 pm, 7 days/week and include those that may require attention prior to the receipt of routine laboratory reports. We use reasonable efforts to promptly communicate these results the same day that results are released (up to 7pm), or if released after 7pm then the next morning (after 9 am), 7 days/week. For NH (nursing home) or H (hospital) facilities flagged in the call log, reasonable efforts are used to communicate these results at any hour every day.

- Priority-3 Reporting

  These results may require attention before receipt of a printed report; they apply to clients with no electronic means of receiving patient reports (e.g., receiving mailed or courier-delivered reports) OR who have requested Priority-3 reporting in writing.