

Critical Results/Values Policy

Purpose

This document outlines the criteria for immediate notification of the licensed caregiver responsible for the care of a patient when critical results/values of specified test results are exceeded.

Scope

This policy covers the criteria and process in calling Critical Tests/Values to a licensed caregiver. This policy does not cover the Critical Test; see *Critical Test Policy* (QM 5.8.8.101).

Definitions

Critical Results/Values: it is defined as those test results that indicate that the patient is in imminent danger of death, significant morbidity, or serious adverse consequences, which would require medical intervention of an urgent nature, or which require immediate attention or action by the provider.

Critical Result/Value Measurement Parameter: is defined as the elapsed time from when the critical (abnormally high or low) result was first known to the time it is reported to the licensed responsible caregiver.

Licensed Caregiver: means any licensed caregivers who will be able to respond to the critical results to provide the needed care to the patient in a timely manner. This includes the Physician (MD), Certified Nurse Anesthetist (CRNA), Perfusionist, Nurse Practitioner (NP), Physician Assistant (PA), the Registered Nurse (RN), or Licensed Vocational Nurse (LVN).

Read-Back: is a process that could be accomplished by following the steps below:

1. The laboratory staff calls the critical test result to the licensed caregiver.
2. The laboratory staff solicits “read back” of the critical test result from the licensed caregiver, including patient name and medical record number (MRN).
3. The laboratory staff acknowledges that the licensed caregiver received the critical test results correctly, including patient name and medical record number (MRN).

Repeat-Back: is a process wherein the licensed caregiver is repeating back as the critical result is being written down.

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Critical Results/Values Policy, Continued

Policy

The SCPMG/KFH Laboratory Systems requires that all critical results/values to be called verbally to a licensed caregiver responsible for the care of the patient.

The laboratory staff solicits and documents “read-back” process whenever communicating critical results/values verbally.

Repeat-back is only allowed in certain situations such as a code, emergency situations, or in the OR, where a formal Read-back is not feasible.

List of defined Laboratory Critical Test Results/Values is maintained and periodically reviewed by the SCPMG Laboratory Operations (OPC), Quality Subcommittee (QSC), and in consult with other clinical specialty groups to establish appropriate aspect of patient care.

Note:

See attachment or click on the link below for the complete list of Critical Test Results/Values.

<http://kpnet.kp.org:81/california/scpmg/labnet/testmenu/documents/Regional-Critical-Values.pdf>

There is no defined critical result/value in Anatomic Pathology and Transfusion Services.

There is no requirement to repeat critical result/value. However, it is required to verify specimen integrity, e.g., hemolysis, lipemia, icterus, etc. before releasing the critical result/value.

Provisions

- Timeliness of Notification
- Reporting and Documentation
- Data Analysis and Monitoring

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Critical Results/Values Policy, Continued

Timeliness of Notification

Critical Results/Values

Inpatient Notification:

Notify the licensed caregiver within 15 minutes from the time the final laboratory critical result/value is verified.

Timeliness of Notification (continued)

Outpatient Notification:

Notify the licensed caregiver within 60 minutes from the time the final laboratory critical result/value is verified.

Note:

For any outpatient after-hours notification, refer to the area after-hours notification policy.

Reporting and Documentation

Laboratory staff immediately notifies the patient's licensed caregiver responsible for the patient's care, as appropriate, whenever a critical result/value for a specified laboratory result is obtained.

Note:

If requested, faxing of critical results/values is allowed **only after** verbal notification and read-back have occurred and documented.

The laboratory staff documents the critical result/value call in the Laboratory Information System. This documentation includes, laboratory staff's name, date and time of call, full name of the recipient, and "read-back" of the critical test result.

If unable to notify the licensed caregiver within the specified timeframes, or if the licensed caregiver refuses to receive the critical result/value, notify a Laboratory Supervisor, Laboratory Manager, Laboratory Director, a Pathologist, or area Nursing Administrators, as applicable; or follow the established laboratory notification/escalation process.

Document all actions taken by all parties in the notification process using the Unusual Occurrence Report (UOR), and forward the UOR to the area Risk Management.

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Critical Results/Values Policy, Continued

Data Analysis and Monitoring

Each area medical center laboratory periodically (at least monthly) collects and analyzes data, improves, and monitors the timeliness of calling critical results/values.

Data collected for monitoring may include a representation on a sampling of critical results/values.

This data, including data regarding any delay or refusal of the critical call by the licensed caregiver, will be presented to the area Quality/Patient Safety Committee or Medical Executive Committee, as applicable, and quarterly to the Laboratory Quality Subcommittee (QSC).

Non-Controlled Documents

The following non-controlled documents support this policy.

- TJC Comprehensive Accreditation Manual

Controlled Document(s)

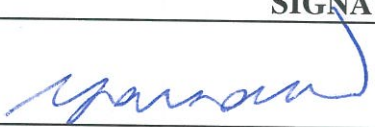

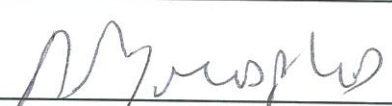
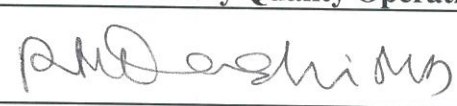
The following controlled documents support this policy.

Attachment	
Document Number	Document Name
N/A	SCPMG Laboratory Systems List of Critical Results/Values

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Critical Results/Values Policy, Continued

Reviewed and approved by:

SIGNATURE	DATE
	9-23-10
Louie Farnacio Quality Systems Leader	
	9/23/2010
Fred Ung Quality and Compliance Director	
	9/23/10
Darryl Palmer-Toy, MD, PhD Chair – Laboratory Quality Operations	
	11-3-10
Ramesh Doshi, MD Chair - Laboratory Operations	

Reviewed and approved by (For Medical Center Area Approval Only):

SIGNATURE	DATE
Name: _____ Laboratory Manager	
Name: _____ Laboratory Director	

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Critical Results/Values Policy, Continued

HISTORY PAGE

Change type: New, major, minor	Changes made to SOP - describe	Signature responsible person/date	Laboratory Director review/date	QSL/Labora tory Mgr. review/date	Date change implemented
New		Lmf/4-28-9			9/23/10
Major	Anatomic Path definition of critical result/value	Lf/4-29-10			9/23/10
Major	Lactic Acid added	Lf/8-09-10			9/23/10
Major	Transfusion Service definition of critical result	Lf/9-21-10			9/23/10
Major	Repeat testing requirement for critical result/value	Lf/9-23-10			9/23/10

Critical Results/Values Policy, Continued

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Fred Ung Quality and Compliance Director	
Darryl Palmer-Toy, MD, PhD Chair – Laboratory Quality Operations	
Ramesh Doshi, MD Chair - Laboratory Operations	

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Major	Repeat testing requirement for critical result/value	Lf/9-23-10			

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updated 9/8/2010 QSC critical values regional 09/2010 rev5

Chemistry

Pediatric*

Analyte	Unit	Low Value	High Value	Effective Date	Date Revised and Approved	Literature Reference	Approvals
Bilirubin Neonatal	mg/dL		0 Days > 8 1 Days > 11.4 2 Days > 13.6 3 Days > 14.5 4 Days > 15.0 > 4 Days > 18.0	12/10/2002	4/13/2009	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee Approved by Regional Chiefs of Pediatric/ Dr. Wald 12/01
Glucose Neonatal	mg/dL	<45	>200	10/3/1997	9/9/2009	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Potassium Neonatal	mEq/L	<3.0	>6.4	2/13/2003	10/7/2005	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Gentamycin	ug/mL		>12	2/27/2002	2/27/2002	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Urine Ketones if Glucose > 1000 mg/dL (0-18yr)		All	All	2/28/2007	2/28/2007		Approved by SCPMG Laboratory Operations Committee

* Adult critical Values apply except where noted

Hematology

Pediatric*

Analyte	Unit	Low Value	High Value	Effective Date	Date Revised and Approved	Literature Reference	Approvals
Hematocrit Neonatal	%	<30	>71	9/14/2007	9/14/2007	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Hemoglobin Neonatal	g/dL	<9.5	>22.3	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Absolute Neutrophil	Per cumm	<500		10/3/1997	12/10/2003 and 1/28/2004		Approved by Quality sub-committee Approved by SCPMG Laboratory Operations Committee
Peripheral Blood Smear	N/A	Blasts present	Blasts present	10/1/2007	10/1/2007		Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee

* Adult critical Values apply except where noted

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Chemistry

Adult

Analyte	Unit	Low Value	High Value	Effective Date	Date Revised and Approved	Literature Reference	Approvals
Calcium	mg/dL	<6.6	>12.9	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
CO2	mEq/L	<11	>40	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Glucose	mg/dL	<46	>484	11/23/2004	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Lactic Acid	mg/dl		>20	7/16/2010	7/16/2010		Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Magnesium	mEq/L	<0.8	>4.0	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Potassium	mEq/L	<2.8	>6.2	10/3/1997	9/28/2005	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Sodium	mEq/L	<120	>158	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Troponin	ng/ml		>0.5	11/17/2009	11/17/2009		Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee

Coagulation

Adult & Pediatric

Analyte	Unit	Low Value	High Value	Effective Date	Date Revised and Approved	Literature Reference	Approvals
Fibrinogen	mg/dL	<100		11/12/2001	3/12/2009	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
PT - Prothrombin Time	INR		>5.0	9/25/2003	9/25/2003	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Heparin Anti-Xa	IU/mL		(Unfrac Heparin) ≥ 0.8, (LMWH) > 1.3	8/15/2005	10/28/2009		Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Heparin (low molecular weight)	IU/mL		(12 hour dosing): anti-Xa > 1.3 (24 hour dosing) anti-Xa > 2.1	4/17/2007	4/17/2007		Approved by SCPMG Laboratory Operations

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Fondaprinex (Arixtra)	mcg/mL		≥ 1.30	8/28/2007	8/28/2007		Approved by SCPMG Laboratory Operations
PTT - Heparin Therapy	secs		>140	9/29/2004	9/29/2004	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
PTT - Non Medicated	secs		>68	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee

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Genetics

Adult & Pediatric

Analyte	Unit	Low Value	High Value	Effective Date	Date Revised and Approved	Literature Reference	Approvals
Prenatal cytogenetic studies	N/A	abnormal	abnormal	11/1/2008	10/22/2008		Approved by SCPMG Laboratory Operations Committee
Newborn cytogenetic studies	N/A	abnormal	abnormal	11/1/2008	10/22/2008		Approved by SCPMG Laboratory Operations Committee
STAT cytogenetic & sex determination studies	N/A	abnormal	abnormal	11/1/2008	10/22/2008		Approved by SCPMG Laboratory Operations Committee
Genetic Critical Value Notification by phone, fax, e-mail or hardcopy is at the discretion of the Laboratory Director							

Hematology

Adult

Analyte	Unit	Low Value	High Value	Effective Date	Date Revised and Approved	Literature Reference	Approvals
Hematocrit	%	<18	>61	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Hemoglobin	g/dL	<6.6	>19.9	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Absolute Neutrophils	Per cumm	<500		10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Quality Sub-Committee Approved by SCPMG Laboratory Operations Committee
Platelets	Per cumm	<37,000	>910,000	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
WBC Total	Per cumm	<2,000	>37,000	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Peripheral Blood Smear	N/A	Blasts present	Blasts present	10/1/2007	10/1/2007		Approved by Quality Sub-Committee Approved by SCPMG Laboratory Operations Committee

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Microbiology

Adult

Analyte	Unit	Low Value	High Value	Effective Date	Date Revised and Approved	Literature Reference	Approvals
Positive Blood Cultures			If Present	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Positive Gram Stain from CSF and other sterile body fluids			If Present	10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Positive Blood Parasites			If Present	7/31/2006	7/31/2006	CAP Accreditation Requirements, Microbiology Checklist, April 2005, MIC 52280	Approved by SCPMG Laboratory Operations Committee

Therapeutic Drugs

Adult

Analyte	Unit	Low Value	High Value	Effective Date	Date Revised and Approved	Literature Reference	Approvals
5 - Flucytosine (5FC)	mcg/mL		> 100	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Acetaminophen	mcg/mL		> 150	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Amikacin	mcg/mL		Trough > 5.0 Peak > 25.0	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Amitriptyline	ng/mL		≥ 500	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Chlordiazepoxide (Librium)	ng/mL		Chlordiazepoxide: > 4000; Norchlordiazepox: > 1000	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Clorazepate (Tranxene)	ng/mL		> 3000	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Desipramine	ng/mL		≥ 500	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Diazepam (Valium)	ng/mL		> 3000 (Diazepam + Desmethyldiazepam)	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Digoxin	ng/mL		> 2.0	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations

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Doxepine	ng/mL		≥ 500	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
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Ethosuximide (Zarontin)	mcg/mL		> 100	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Fondaparinux (Arixtra)	mcg/mL		≥ 1.30	8/28/2007	8/28/2007		Approved by SCPMG Laboratory Operations
Gentamicin	mcg/mL		Trough > 2.0 Peak > 8.0 Neonatal: > 12.0	2/27/2002	2/27/2002	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Gentamicin, routine	mcg/mL		> 8	10/3/1997	10/3/1997 Reviewed 2/27/2002.	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee 3/02
Heparin (low molecular weight)	IU/mL		(12 hour dosing): anti-Xa > 1.3 (24 hour dosing) anti-Xa > 2.1	4/17/2007	4/17/2007		Approved by SCPMG Laboratory Operations
Heparin (unfractionated)	IU/mL		anti-Xa > 0.8	8/15/2005	8/15/2005		Approved by SCPMG Laboratory Operations
Imipramine	ng/mL		≥ 500	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Lead	mcg/dL		≥ 45	4/9/2007	4/9/2007		Approved by SCPMG Laboratory Operations
Lithium	meq/L		> 1.5	10/3/2007	10/3/2007		Approved by SCPMG Laboratory Operations
Methotrexate	micromole/L		Call all Reports Potentially toxic with leucovorin rescue are at 24 hrs: > 5.0 at 48 hrs: > 1.0 at 72 hrs: > 0.1	10/3/2007	10/3/2007		Approved by SCPMG Laboratory Operations
Nortriptyline	ng/mL		≥ 500	10/3/2007	10/3/2007		Approved by SCPMG Laboratory Operations
Phenobarbital	mcg/mL		> 50	6/10/2002	3/27/2002	Regional Chiefs of Neurology	Approved by SCPMG Laboratory Operations Committee 3/02. Approved by Regional Chiefs of Neurology, Approved by Chiefs of Primary Care
Phenytoin (Dilantin)	mcg/mL		> 25	6/10/2002	3/27/2002	Regional Chiefs of Neurology	Approved by SCPMG Laboratory Operations Committee 3/02. Approved by Regional Chiefs of Neurology, Approved by Chiefs of Primary Care

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Phenytoin, Free	mcg/mL		> 3.0	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
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Primidone (Mysoline)	mcg/mL		> 12.0	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Salicylate	mg/dL		Children (<14y): > 15.0; Adult: > 35.0	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Tegretol (carbamazepine)	mcg/mL		> 15	6/10/2002	3/27/2002	Regional Chiefs of Neurology	Approved by SCPMG Laboratory Operations Committee 3/02, Approved by Regional Chiefs of Neurology, Approved by Chiefs of Primary Care
Theophylline	mcg/mL		> 20	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Therapeutic Drugs		1 unit above therapeutic range, unless otherwise defined.		10/3/1997	10/3/1997	Kost, G. J., 1990. Critical Limits for Urgent Clinician Notification at US Medical Centers JAMA 263(5): 704 -	Approved by Chiefs of Primary Care Approved by SCPMG Laboratory Operations Committee
Thiocyanate	mg/dL		> 2.5	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Tobramycin	mcg/mL		Trough: > 2.0; Peak: > 10.0	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Trazodone	ng/mL		> 5000	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Trimethoprim (Bactrim) & Sulfamethoxazole	mcg/mL		TMP: > 10.0; SMOX: > 200	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Valproic Acid (Depakene)	mcg/mL		> 170	6/10/2002	6/10/2002	Regional Chiefs of Neurology	Approved by SCPMG Laboratory Operations Committee 3/02, Approved by Regional Chiefs of Neurology, Approved by Chiefs of Primary Care
Vancomycin	mcg/mL		Trough ≥ 50	9/25/2006	9/25/2006	Regional Reference Laboratories and Infectious Disease Committee (RLID)	Approved by SCPMG Laboratory Operations
Volatiles, Blood Alcohol	mg/dL		Ethanol: > 200 Methanol: > 20 Acetone: > 50 Isopropanol: > 50	10/3/1997	10/3/1997		Approved by SCPMG Laboratory Operations
Warfarin (Coumadin)			INR > 5	9/23/2003	9/23/2003		Approved by SCPMG Laboratory Operations

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Point of Care

Analyte	Unit	Low Value	High Value	Effective Date	Date Revised and Approved	Literature Reference	Approvals
Glucose	mg/dL	> 1 month < 55 Neonatal: < 45	> 400 neonatal: >200	1/25/2009			Approved by SCPMG Laboratory Operations