Quest Diagnostics

TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	5/8/2012
Department:	Core	**Due Date:**	6/1/2012

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Critical Values GEC.L40, SGAH.L45, WAH.L43 v002 **Reference Range Chart AG.F151.001** **Vancomycin SGAH.C03, WAH.C03 v002**
Description of change(s):
Revise Critical value and Reference Range (normal value) for Vancomycin Trough Update Critical Value charts to remove tests no longer performed and specify GEC blood gas values apply to 'arterial' blood Add Intact Parathyroid Hormone (iPTH) to Reference Range Chart

EMPLOYEE SIGNATURES

I have read and understand the procedure described above:

Name	Signature	Date

Employee signatures are not necessary. Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 002)

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:	

12 month (or new) management review and approval: Signature acknowledges SOP version remains in effect with NO revisions.		
Print Name	**Signature**	**Date**

Form revised 3/31/00

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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 3 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 physician or the office nurse.

   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.
   Note: Result values defined by the hospital as Critical are included in Appendix C. 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 faxed to the Client Services department and followed by a phone call to verify receipt.
   Note: Results defined as Priority 1, 2 or 3 by Quest Diagnostics are called and faxed during the hours of 7 am and 7 pm.

3. The following applies to all results as described in items 1 and 2 above:
   a) Results are called and faxed to the charge nurse, nurse caring for the patient, or a physician.

   b) Notification is documented via the LIS function Callback. Refer to the LIS procedure 'Callback' for details.

   c) All verbal reports must be read back to the reporting person. 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.

Note: Refer to Appendix D 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 Result Reporting Policy, v7.6.3, Quest Diagnostics Incorporated, Corporate Medical Standard Policy
- Adventist Hospital Client Specific Priority 3 Values

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

9. ADDENDA AND APPENDICES

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

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APPENDIX A

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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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

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APPENDIX B

Shady Grove 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
Carbamazepine			>=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		<2.9	>6.1	mmol/L
Lactic Acid			>4.0	mmol/L
Lithium			>2.1	mmol/L
Magnesium		<=1.0	>=7.0	mg/dL
Na		<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 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 C

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 D

Priority Result Reporting Policy, Definitions

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

- Priority-1 Reporting (24 hours 7 days)

  Priority-1 test results include, but not limited to, results considered "critical" according to the Clinical Laboratory Amendment of 1988 (CLIA; CFR 493.1109f) and the College of American Pathologists (CAP) Laboratory Inspection Program and so designated by the Chief Laboratory Officer or designee. Since test results cannot be fully interpreted without knowledge of the patient's current clinical condition and treatment, these Priority-1 values should be communicated promptly after they are verified and released so that the healthcare provider can determine the clinical implications and possible need for immediate attention. We will use reasonable efforts to promptly communicate these results at any hour of the day, 7 days/week.

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

  Priority-2 test results are those that may require attention prior to the receipt of routine laboratory reports. We will use reasonable efforts to promptly communicate these results the same day that results are released (up to 7pm), or if released after 7pm then promptly communicate the next morning (after 7am), 7 days/week. For facilities which are flagged by market segment as NH (nursing home) or H (hospital) in the call log, we will use reasonable efforts to promptly communicate these results at any hour of the day, 7 days/week.

- Priority-3 Reporting

  Priority-3 test results are those that may require attention before receipt of the printed report. These results apply to a limited subset of clients with no electronic means of receiving patient reports (i.e. receiving mailed or courier-delivered reports) OR who have requested Priority-3 reporting in writing during the previous 12 months.

REFERENCE RANGE CHART (Normal Values)

TEST NAME	REFERENCE RANGE	TAT
Acetaminophen (Tylenol)	Therapeutic: 10.0 – 30.0 µg/mL	Same day
Acetone, serum (Ketones)	Negative	Same day
Albumin, serum	3.4 - 5.0 g/dL (*A)	Same day
Alcohol, ethyl (blood)	<5 mg/dL	Same day
Alkaline Phosphatase	38 - 136 U/L (*A)	Same day
Ammonia	11 – 32 umol/L	Same day
Amylase, serum	25 - 115 U/L (*A)	Same day
APT (fetal Hgb)	None established	Same day
B Type Natriuretic Peptide (BNP)	0 – 100 pg/mL	Same day
Basic metabolic screen *	See individual report	Same day
Beta HCG, qual. Serum (Pregnancy Test)	Negative	Same day
Beta HCG, qual. Urine (Pregnancy Test)	Negative	Same day
Beta HCG, quant.	See individual report	Same day
Bilirubin, Cord	See individual report	Same day
Bilirubin, direct	0 – 0.3 mg/dL	Same day
Bilirubin, neonatal	See individual report	Same day
Bilirubin, total	< 1.0 mg/dL (*A)	Same day
Bleeding time	2 – 10 min.	Same day
BUN	7 – 20 mg/dL (*A)	Same day
BNP (See B Type Natriuretic Peptide)		
C – reactive protein (CRP)	< 0.9 mg/dL (*A)	Same day
Calcium, serum	8.4 – 10.6 mg/dL (*A)	Same day
Carbamazapine	Therapeutic: 4.0 - 12.0 µg/ml	Same day
Carbon dioxide (CO2)	21 – 32 mmol/L (*A)	Same day
Cardiac Profile	See individual report	Same day
CBC with or without DIFF	See individual report	Same day
Cell count, CSF	See individual report	Same day
Chloride, serum	98 – 107 mmol/L (*A)	Same day
Cholesterol, HDL	>39 mg/dL (*A)	Same day
Cholesterol, Total	120 - 200 mg/dL (*A)	Same day

NOTE: For profiles marked with an *, see the individual procedure for the tests included in the profile.

For values marked with (*A): these are the normal adult values. See the individual report for reference ranges for other age groups.

TEST NAME	REFERENCE RANGE	TAT
CKMB	0.0 - 3.6 ng/mL	Same day
Collagen ADP	71 - 118 seconds	Same day
Collagen EPI	94 - 193 seconds	Same day
Comprehensive Metabolic Panel *	See individual report	Same day
CPK	21 – 215 U/L Female 32 – 232 U/L Male	Same day
Creatinine clearance	80 – 120 ml/min/m2	1 day
Creatinine, serum	0.6 – 1.3 mg/dL (*A)	Same day
D-Dimer	≤ 0.5 ug/ml FEU	Same day
Digoxin	Therapeutic: 0.90 – 2.00 ng/mL	Same day
Dilantin (see Phenytoin)		
Drug screen *	None detected	Same day
Electrolytes *	See individual report	Same day
Eosinophil count	0.00 – 0.66 10^3/uL (*A)	Same day
Eosinophil count, fluid	No established range	Same day
Erythrocyte sedimentation rate	See individual report	Same day
Fetal Fibronectin	Negative	Same day
Fibrinogen	200 – 500 mg/dl	Same day
Fluid Cell count and Diff*	No established range	Same day
Fluid Glucose	No established range	Same day
Fluid Hematocrit (HCT)	No established range	Same day
Fluid Ph	No established range	Same day
Gamma GT	5 – 85 U/L (*A)	Same day
Gentamycin, Peak	4.0 – 8.0 µg/mL	2 – 4 hrs.
Gentamicin, Random	No established range	Same day
Gentamicin, Trough	0.3 – 2.0 µg/mL	2 – 4 hrs.
Glucose, 2 hr. pp	See individual report	Same day
Glucose, CSF	40 – 75 mg/dL	Same day
Glucose, serum	74 – 105 mg/dL (*A)	Same day
Glucose, tolerance	Physician interpretation	Same day
Guaiac, see Occult Blood		
H&H, hemoglobin & hematocrit	See individual report	Same day

NOTE: For profiles marked with an *, see the individual procedure for the tests included in the profile.

For values marked with (*A): these are the normal adult values. See the individual report for reference ranges for other age groups.

TEST NAME	REFERENCE RANGE	TAT
Hemoglobin A1c	4.8 - 6.0 %	Same day
Influenza Antigen	Negative	Same day
Intact Parathyroid Hormone (iPTH)	11.0 – 80.0 pg/mL	Same day
Iron Binding Capacity	250 – 450 µg/dL (*A)	Same day
Iron, serum	35 – 150 µg/dL (*A)	Same day
Ketones (see Acetone)		
Kleihauer Betke Test	See individual report	Same day
Lactic Acid	0.4 – 2.0 mmol/L (*A)	Same day
LDH	81 – 234 U/L Female 85 – 227 U/L Male	Same day
Lipase	63 - 286 U/L (*A)	Same day
Lithium	Therapeutic: 0.60 – 1.20 mmol/L	Same day
Liver Panel *	See individual report	Same day
Magnesium	1.8 – 2.4 mg/dL (*A)	Same day
Mono Spot	Negative	Same day
Myoglobin	10 – 92 ng/ml	Same day
Occult blood	Negative	Same day
Osmolarity, serum	280 – 295 mOsm/kg	Same day
Osmolarity, urine	500 – 800 mOsm/kg	Same day
Phenobarbital	Therapeutic: 15.0 – 40.0 µg/mL	Same day
Phenytoin	Therapeutic: 10.0 – 20.0 µg/mL	Same day
Phosphorus, serum	2.5 – 4.9 mg/dL (*A)	Same day
Platelet count	150 – 450 K/µl	Same day
Potassium, serum	3.5 – 5.1 mmol/L (*A)	Same day
Potassium, urine	12 - 62 mmol/L	Same day
Pregnancy Test (see Beta HCG)		
Protein, CSF	15 – 45 mg/dL (*A)	Same day
Protein, serum	6.4 – 8.2 g/dL (*A)	Same day
Protein, urine, 24 hour	< 149.0 mg/24 hr	1 – 2 days
Protein, urine, random	< 11.9 mg/dL	Same day
PT (prothrombin time)	12.5 – 14.8 seconds	Same day
PTT	23 - 37 sec.	Same day

NOTE: For profiles marked with an *, see the individual procedure for the tests included in the profile.

For values marked with (*A): these are the normal adult values. See the individual report for reference ranges for other age groups.

TEST NAME	REFERENCE RANGE	TAT
Renal Panel *	See individual report	Same day
Retic Count	See individual report	Same day
Rotavirus Antigen	Negative	Same day
RSV Antigen	Negative	Same day
Salicylates	Therapeutic: 2.8-20.0 mg/dL	Same day
SGOT (AST)	15 – 37 U/L (*A)	Same day
SGPT (ALT)	11 – 66 U/L (*A)	Same day
Sickle Cell Prep	Negative	Same day
Sodium, serum	135 – 145 mmol/L (*A)	Same day
Sodium, urine	20 - 110 mmol/L	Same day
Specific Gravity, Urine	1.005 – 1.030	Same day
Stool for WBC	No established range	Same day
Sweat Chloride Test	< 50 mmol/L	Same day
T4, Free	0.59 - 1.17 ng/dL	Same day
Tegretol (See Carbamazapine)		
Theophylline	Therapeutic: 10.0 – 20.0 ug/mL	Same day
Thrombin Time	15 – 20 sec.	Same day
Tobramycin Peak	4.0 – 8.0 µg/mL	Same day
Tobramycin, Random	No established range	Same day
Tobramycin Trough	0.5 – 2.0 µg/mL	Same day
Triglycerides	0 – 149 mg/dL (*A)	Same day
Troponin	0.00-0.10 ng/mL	Same day
TSH	0.34 - 4.82 µIU/mL (*A)	Same day
Uric Acid, serum	2.6 – 7.2 mg/dL (*A)	Same day
Urinalysis	See individual report	Same day
Valproic Acid (Depakote, Depakene)	50 – 100 µg/mL	Same day
Vancomycin Peak	25.0 – 40.0 µg/mL	Same day
Vancomycin, Random	No established range	Same day
Vancomycin Trough	10.0 – 20.0 µg/mL	Same day

NOTE: For profiles marked with an *, see the individual procedure for the tests included in the profile.

For values marked with (*A): these are the normal adult values. See the individual report for reference ranges for other age groups.

Technical SOP

Title	**Vancomycin by Dimension® Chemistry Analyzer**
Prepared by	Leslie Barrett Date: 6/3/2009
Owner	Jean Buss, Robert SanLuis Date: 12/28/2011

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Annual Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Vancomycin, Trough	Dimension® Chemistry Analyzer	VANT
Vancomycin, Peak		VANP
Vancomycin, Random		VANR

Synonyms/Abbreviations
VANC, VANCO

Department
Chemistry

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

The methodology for VANC is based on a homogenous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique which uses a latex particle-vancomycin conjugate (PR) and monoclonal vancomycin specific antibody (Ab). Vancomycin present in the sample competes with vancomycin on the particles for available antibody, thereby decreasing the rate of aggregation. Hence, the rate of aggregation is inversely proportional to the concentration of vancomycin in the sample. The rate of aggregation is measured using bichromatic turbidimetric readings at 340 nm and 700 nm. The concentration is determined by means of a mathematical function.[1]

Vancomycin + PR + Ab ——————> PR-Ab complex + Vancomycin-Ab
(scatters light at 340 nm)

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Vancomycin **Trough**: Collect immediately before dose (within 30 minutes).
	Vancomycin **Peak**: Collect **one hour after** the completion of infusion.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Serum
-Other Acceptable	None
Collection Container	Plain Red top tube, no additives
Volume - Optimum	1.0 mL serum
- Minimum	0.5 mL serum
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: 8 hours
	Refrigerated: (2-8°C) 2 days
	Frozen: (-20°C) 1 month
Timing Considerations	N/A

Form revised 2/02/2007

Criteria	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross Hemolysis. Reject sample and request redraw. Specimens should be free of particulate matter.
Other Considerations	Allow to clot completely prior to centrifugation.

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number	Quantity
Vancomycin Flex®	Siemens, Flex® reagent cartridge, Cat. No. DF86	80 tests/Carton

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Reagent	Vancomycin
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• The unopened reagents are stable until the expiration date printed on the label when stored at 2-8°C. • Sealed or unhydrated cartridge wells on the instrument are stable for 30 days. • Once wells 1-6 have been entered by the instrument, they are stable for 3 days. • Once the instrument has entered well 8, it is stable for 30 days.

Form revised 2/02/2007

Preparation	Reagents are supplied ready for use. No additional preparation is required.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Drug Calibrator II	Siemens Dimension®, Cat. No. DC49D

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	Drug Calibrator II
Preparation	Allow to equilibrate at room temperature (22-28°C) before use.
Storage/Stability	• Store at 2-8° C • **Unopened product**: Stable until expiration date stamped on the box. • **Opened product**: Once opened, assigned values are stable for 30 days when vials are securely capped and stored at 2–8°C between uses.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	Drug Calibrator II
Assay Range	0.0 - 50.0 µg/mL
Calibration Levels	See reagent package insert for lot specific assigned values in µg/mL
Frequency	• Every new reagent cartridge lot • Every 30 days for any one lot • When control data indicates a significant shift in assay • After the source lamp is replaced in the instrument or any other major maintenance is performed on the analyzer
Calibration Scheme	Five levels in duplicate

Assigned Coefficients	C_0 487.0 C_1 -489.8 C_2 -1.4 C_3 15.3 C_4 0.500

5.4 Calibration Procedure

Calibration/Verification Setup
1. From Operating Menu press F5:Process Control press F1: Calibration Enter Password press F2: SETUP and RUN
2. Select the test method to be calibrated. If lot number is incorrect, Press F1: Other Lot
3. Enter all information on screen
4. Press F8: QC yes/no to change to yes
5. Press F4: Assign cups If additional methods need to be calibrated, select the method.
6. Press F7: Load/run
7. Load cups into assigned position
8. Press F4: RUN

5.5 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Liquichek™ Immunoassay Plus Control Levels 1, 2, and 3	Bio-Rad Laboratories, Catalog # 360 Tri-Level

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	Liquichek™ Immunoassay Plus Control, Levels 1, 2, and 3
Preparation	• Refer to the control insert sheet for preparation, storage, and handling instructions. • Before sampling, allow the control to reach room temperature (18 to 25°C) and swirl gently to mix. Do not use a warming device. Do not use a mechanical mixing device. • Promptly replace the stopper and return to 2 to 8°C storage after each use. • If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.
Storage/Stability	• Unopened controls are stable until the expiration date when stored at -20 to -70°C. • **Thawed and Unopened**: When the control material is thawed and stored unopened at 2 to 8°C, Vancomycin will be stable for 30 days. Record date of thaw on the vial. • **Thawed and Opened**: Once the control material is thawed and opened, it will be stable for 14 days for Vancomycin when stored tightly capped at 2 to 8°C. Date vial when thawed and opened on vial. Record new expiration date on vial. • Discard the vial if there is evidence of microbial contamination or excessive turbidity. • Do not refreeze control. • Do not use after the expiration date.

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing.

Refer to the Dimension® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension® Quick Reference Guide.

6.4 Tolerance Limits

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system, into the Laboratory Information System (LIS), and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Review Patient Data

Technologist must review each result print-out for error messages. Refer to the Dimension® system manual "Error messages" section for troubleshooting. Check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

6.6 Documentation

- QC tolerance limits are programmed into the instrument and the LIS. The LIS calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Lead Technologist or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.7 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Dimension® Chemistry Analyzer

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining -20 to -70°C.
- Centrifuge

7.3 Supplies

- Calibrated pipettes and disposable tips
- Plastic serum tubes and serum cups

8. PROCEDURE

The VANC Flex® reagent cartridge Cat. No. DF86 is required to perform the VANC test. Vancomycin is performed on the Dimension® clinical chemistry system after the method is calibrated (see Reference Material in Calibration section) and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	Instrument Set-Up Protocol
1.	For instrument set up and operation: Refer to Startup and Maintenance, Siemens Dimension® procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® system. For details of the automated parameters, see below under “Test conditions.”

8.2	Specimen/Reagent Preparation
1.	Centrifuge the specimens.
2.	For sites with StreamLab (Lynx): **Qualifying** samples are loaded via the Dimension® Lynx System which automatically routes specimens to the instruments. Refer to the Dimension® Streamlab® Analytical Workcell (Lynx) System manual for instructions.
3.	Alternatively, specimens are placed in color-coded Dimension® segments for analysis by the instrument. Refer to the Sample Processing, Siemens Dimension® procedure. The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus 50 µL of dead volume. Precise container filling is not required.

8.3	Specimen Testing
1.	For QC placement and frequency, refer to the Dimension® QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension® Operators Manual
3.	The instrument reporting system contains error messages to warn the user of specific malfunctions. Results followed by such error messages should be held for follow-up. Refer to the Dimension® system manual “Error messages” section for troubleshooting.
4.	Follow protocol in Section 10.5 “Repeat criteria and resulting” for samples with results above or below the Analytical Measurement Range (AMR). Repeat critical values and document according to Critical Values procedure. Investigate any failed delta result and repeat, if necessary.

8.3	Specimen Testing
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

TEST CONDITIONS		
Sample Size:	2 µL	
Buffer Volume:	145 µL	
Antibody Volume:	80 µL	
Particle Reagent Volume:	80 µL	
Diluent Volume:	Cuvette 1: 360 µL	Cuvette 2: 162 µL
Test Temperature:	37° C	
Wavelengths:	340 nm and 700 nm	
Type of Measurement:	Turbidimetric rate	

9. CALCULATIONS

The instrument automatically calculates and prints the concentration of VANC in µg/mL

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results to one decimal point.

10.3 Units of Measure

µg/mL

10.4 Clinically Reportable Range (CRR)

0.8-150.0 µg/mL

10.5 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall within the AMR or CRR may be reported without repeat. Values that fall outside these ranges must be repeated.

IF the result is …	THEN…
< 0.8 µg/mL	Repeat the assay after assuring there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. • If repeat result agrees, report as: "<0.8 µg/mL -REP" (verified by repeat analysis). • If the average value of the repeat result and the first result > 0.8 µg/mL, report the average value.
>50.0 µg/mL	**Manual Dilution**: Using the primary tube, make the smallest dilution possible to bring the raw data within the analytical measurement range. Maximum allowable dilution: X 3 Minimum sample size to use in dilution is 50 µl. Diluent: Level 1 Drug Calibrator II or Vancomycin-free serum. **Enter the dilution factor as a whole number on the "Enter Sample Data" screen**. Reassay. Resulting readout is corrected for dilution. If replicates agree within the TEA report with remark code -REP and document per Critical Values Policy **On Board Automated Dilution**: Not Recommended due to small standard sample size.
>150.0 µg/mL	If the recommended dilution does not give results within the clinically reportable range, report as: >150.0 µg/mL-REP and document per Critical Values Policy.

Message	Code
Verified by repeat analysis	Append –REP to the result.

11. EXPECTED VALUES

11.1 Reference Ranges

Random	None established
Peak	25.0 - 40.0 µg/mL
Trough	10.0 - 20.0 µg/mL

11.2 Critical Values

Random	> 40.0 µg/mL
Peak	> 40.0 µg/mL
Trough	> 20.0 µg/mL

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Vancomycin is an antibiotic effective against most gram positive bacteria. It is especially important in the treatment of infections due to methicillin and cephalosporin resistant organisms. Current usage is generally limited to those infections in which other antibiotics are ineffective or contraindicated.
Vancomycin has several deleterious effects on bacterial metabolism. Vancomycin is eliminated from the body be excretion by the kidneys. Plasma half-life varies with the patient's age and kidney function and can be approximated from the creatinine clearance rate. Lasting effects involve auditory nerve and kidney function. Ototoxicity (hearing loss) tends to be permanent and dose-dependent. Ototoxicity is of particular concern in patients who are also given aminoglycosides. Nephrotoxicity due to vancomycin alone is uncommon and usually reversible.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.0 –50.0 µg/mL

14.2 Precision

Material	Mean µg/mL [µmol/L]	Standard Deviation (%CV)	
		Within-run	Total
Serum Pool	4.59 [3.08]	0.08 [0.05] (1.72)	0.24 [0.16] (5.31)
Plasma Pool	10.96 [7.34]	0.17[0.11] (1.52)	0.27 [0.18] (2.50)
Serum Pool	30.01 [20.1]	.30 [0.20] (1.02)	0.73 [0.49] (2.44)

14.3 Interfering Substances

Lipemia (Intralipid®) at a concentration of 600 mg/dL (6.78 mmol/L) and above tripped an error flag; therefore the magnitude of the interference could not be determined.

14.4 Clinical Sensitivity/Specificity/Predictive Values

Analytical Sensitivity:

The sensitivity of the VANC method is 0.8 µg/mL and represents the lowest concentration that can be distinguished from zero. This sensitivity is defined as the mean value (n = 20) plus two SD of the 0.0 µg/mL Drug Calibrator II.

HIL Interference:
The VANC method was evaluated for interference from hemolysis, icterus and lipemia according to CLSI/NCCLS EP7-P. Bias, defined as the difference between the control sample (does not contain interferent) and the test sample (contains interferent), is shown in the table below. Bias exceeding 10% is considered "interference".

HIL Interference			
Substance Tested	**Test concentration**	**VANC Conc. µg/mL [µmol/L]**	**Bias**[1] %
Hemoglobin (hemolysate)	1000 mg/dL [0.62mmol/L] (monomer)	3.84 [25.10]	< 10
Bilirubin (unconjugated)	80 [1368µmol/L]	37.8 [26.05]	< 10
Lipemia (Intralipid®)	200 [2.26 mmol/L]	37.9 [26.84]	< 10

[1]Analyte results should not be corrected based on this bias.

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Dimension® Clinical Chemistry System Operator's Manual
2. Dimension® Calibration/Verification procedure
3. Dimension® Cal Accept Guidelines
4. Dimension® Calibration summary
5. Sample Processing, Siemens Dimension® procedure

6. Start up and Maintenance, Siemens Dimension® procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension®
9. Laboratory Safety Manual
10. Material Safety Data Sheets (MSDS)
11. Siemens Dimension® Limits Chart
12. Quest Diagnostics Records Management Procedure
13. Dimension® Error Messages Chart
14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Hemolysis, Icteria and Lipemia; Interference from (Lab policy)
16. Repeat Testing Requirement (Lab policy)
17. Critical Values (Lab policy)
18. Therapeutic Drug Monitoring (Chemistry SOP)
19. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
20. Current package insert VANC Flex® Reagent Cartridge DF86

17. REFERENCES

1. Package Insert, Vancomycin Flex® reagent cartridge DF86, Siemens Healthcare Diagnostics Inc., 04/07/2008.
2. Package Insert, Bio-Rad Liquichek™ Immunoassay Plus Control, 08/2011.
3. Package Insert, Drug Calibrator II DC49D, Dade-Behring, 05/06/2008.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes C079.001		
000	12/28/11		Update owner	L. Barrett	J. Buss
000	12/28/11	3.2	Remove room temp range (not in the PI)	A. Chini	J. Buss
000	12/28/11	5.3	Changed statement on Sug. Cal. Level	A. Chini	J. Buss
000	12/28/11	5.5	Correct second entry of 'and' to 'or'	A. Chini	J. Buss
000	12/28/11	6.7	Add use of TEA for lot to lot runs, remove testing new calibrator lots as unknowns prior to use	L. Barrett	J. Buss
000	12/28/11	10.5	Add statements for repeat regarding TEa, AMR & CRR	L. Barrett	J. Buss
000	12/28/11	11.2	Title change to local terminology	L. Barrett	J. Buss
000	12/28/11	15	Update to standard wording	A. Chini	J. Buss
000	12/28/11	16	Update document list titles, add PI	A. Chini	J. Buss
000	12/28/11	17	Update revision dates	A. Chini	J. Buss
000	12/28/11	19	Remove package insert	L. Barrett	J. Buss

001	4/6/12	3.1	Edit trough collection instruction	L. Barrett	JBuss, RSL
001	4/6/12	11.1,11.2	Change trough values	L. Barrett	JBuss, RSL
001	4/6/12	16	Add TDM procedure	L. Barrett	JBuss, RSL

19. ADDENDA

None