


<p>New Vision Medical Laboratories</p> <p>St.Ritas Medical Center Lima, Ohio</p> <p>Policy and Procedure Manual</p>		<p>Policy Number: nvml.101</p> <p>Initiation Date: November 1, 1979 Revised Date: August 1, 2023</p>
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SUBJECT: Critical Values

POLICY: The laboratory will identify test results that have critical values and will notify within 30 minutes the physician or other clinical personnel responsible for patient care when validated critical values are obtained.

PROCEDURE:

A. Critical value results will be validated prior to reporting according to standard operating procedures for each test and by the general procedure outlined below.

1. Compare the critical value with prior results and correlation with other clinical data and clinical condition. Report value if results are consistent with findings.
2. If a previous value is not available and/or results are not consistent with findings proceed as described below, reporting the result at the point when the value has been validated.

Note: The nursing unit and/or physician must be notified that there will be a delay for verification and re-testing. Values obtained in initial testing can be given verbally to the physician with the reminder that the result is preliminary and must be confirmed.

- a. Examine the specimen for patient identification, fibrin, clots, hemolysis, and correct sample type.
- b. Verify that the correct patient has been collected.
- c. Re-run the test using a fresh aliquot from the primary tube sample if examination indicates there is no problem with specimen integrity or identification.
- d. Immediately alert all involved testing areas if a re-draw is requested.
- e. Request a stat redraw of all specimens (if possible) and document the reason needed and any special requirements in the re-collect function. Notify the patient care area of the situation and the need for re-draw.
- f. Run the new specimen to re-validate any critical value obtained.

B. The physician or other clinical personnel responsible for patient care must be notified immediately (within 30 minutes) of all critical values.

1. For testing performed in the laboratory, the technologist or customer service staff will call the appropriate location, identify the patient using two patient identifiers (patient's name and account number for inpatients; patient's name and date of birth for outpatients), the test name(s), and the critical result(s) to physician, clinical person, or designee, and indicate that the result exceeds critical limits.
 - a. Have the person that is accepting the critical value, read back the two patient identifiers, the test name(s), and the critical value(s). Obtain the name (first and last) of the person to whom the result was given.
 - b. Document the call in the LIS (In SCC, the "Call" function is used.) including the person's name, the time of the call, and "RBO" as verification of "read back obtained." If the person refuses to read back the result, document the

- refusal with the person's name and "RBR" to indicate "read back refused."
- c. Exception reports will be monitored periodically to verify that all critical values have been called to an appropriate person. If there is no documentation of the call, the critical value must be called by the person monitoring the exception report.
2. For *Emergency or Urgent care* patients at the ambulatory care centers (PE-PCACC, DE-DACC, UC-ESUC, WU-WSUC, 60-LON, CE-CON, OHIOS, CCWCO- CCWCO), printed copies of the reports can be given directly to the attending physician in lieu of calling the critical value. This direct delivery of the critical report must be documented in the LIS as in B.1.c. above. (ie. "Printed report given to Dr. Smith.") When blood is received at NVML after the urgent care closes, and testing produces a critical result, the critical value will be called to PCACC's emergency department at 419-226-4400 for documentation and follow up. This is for Emergency patients only. Outpatients from the urgent cares (DA-DACC, PO-PCACC, EO- ESUC, WO-WSUC) will still need critical values called to the ordering physician.
 3. For testing performed at a reference laboratory, the physician or other clinical personnel responsible for patient care will be notified immediately of all results flagged as critical by the reference laboratory as in step B.1.a-c above. Reference laboratories are given a laboratory contact phone number only. Critical values are therefore called directly to laboratory staff.
 4. For POCT testing such as POC Glucose, the testing personnel will follow the physician's orders and established Nursing Service protocol for physician notification and patient treatment. Appropriate comment codes can be appended in the analyzer to document actions taken.
 5. For *Direct to Consumer Lab* patients, the laboratory technologist will immediately telephone the critical result to the ordering patient using the phone numbers provided on the D2C order (try emergency number if you cannot reach the patient at their designated number). * See Direct to Consumer Test requi
 - a. Advise the patient to seek medical attention as soon as possible (either their primary care provider or Emergency Department) using the scripting below:
 - i. "This is (insert your name) from New Vision Medical Laboratory with information about your recent lab test. Your (insert test) result is (insert result). Your result is abnormal to the extent that we advise seeking medical attention ASAP."
 - ii. Don't give any other advice or opinions.
 - b. Only give result to the patient or the person provided on the order. **DO NOT** leave a result on an answering machine/voicemail. Use the scripting below if prompted to leave a message:
 - i. "This is (insert your name) from New Vision Medical Laboratory with information about your recent lab test. Please call me back at (insert your lab phone number) as soon as possible." - Document the call in the LIS

c. If the patient doesn't return your call within 30 minutes:

i. Call the patient back

ii. If still no answer, call every 1 hour for 3 hours,

iii. If no response after 3 hours (total of 3 attempted calls), contact the patient's local EMS/police. Use the scripting below:

Call Sheriff office of County Pines in

a. "This is (insert your name) from New Vision Medical Laboratory. I have critical lab results for (insert patient name) and have been unable to reach them by phone. I'm requesting a well check. This patient needs to seek medical attention."

b. Give the dispatcher the patient's address

c. Document the EMS/police call in the LIS .

d. The following results must be called for a Direct to Consumer critical lab result.

Test Name	Low	High
Glucose	≤40 mg/dl	≥500 mg/dl
Sodium	≤120 meq/L	≥160 meq/L
Potassium	≤2.7 meq/L	≥6.0 meq/L
Hemoglobin	≤ 7.0 g/dl	
Platelet	≤30,000/mm ³	≥ 1,000,000

*Applies to *
Non-direct
to Consumer
Patients.*

6. Certain identified consistent long term patient critical values may not be called after the initial notification.
7. Certain surgical pathology may be considered particularly significant or unexpected. Such findings are communicated to the physician by the pathologist. Documentation of that communication will be included in the pathology report dictated by the pathologist.
8. If an outpatient's physician or other clinical personnel responsible for patient care is unavailable after 60 minutes, call the Pathologist for disposition

Quantitative Critical Values

Revised: Oct 2021

Test Name	Low	High	Note:
Anti-Xa (UNFRA)		≥1.0 U/ml	
APTT		> 120 seconds	
Arterial	pH	<7.2	>7.6
	pCO2	<20 mm Hg	>70 mm Hg
	pO2	<40 mm Hg	760 mm Hg
Bilirubin		≥14.0 mg/dl	Neonate 0-28 days
Calcium	≤6.0 mg/dl	≥13.0 mg/dl	
		≥11.5 mg/dl	
*CO2	≤10 meq/L	≥40 meq/L	
*Creatinine		≥3.0 mg/dl	N/A for dialysis patients
Fibrinogen	< 80 mg/dl		
*Glucose	≤40 mg/dl	≥500 mg/dl	
*Hematocrit	≤ 21.0%	> 60.0%	
	≤ 33.0%	> 55.0% venous	Neonate (0-28 days)
		> 70.0% capillary	Neonate (0-28 days)
*Hemoglobin	≤ 7.0 g/dl		
	≤ 11.0 g/dl		Neonate (0-28 days)
Ionized Calcium	≤0.77 mmol/L	≥1.59 mmol/L	
Magnesium	≤0.5 mg/dl	≥5.0 mg/dl	
Phosphorous		≥ 12 mg/dl	Outpatient dialysis
*Platelets	≤30,000/mm ³	≥ 1,000,000	
Prothrombin Time (INR)		INR of 5.0	
	INR <1.0	INR > 5.0	
Potassium	≤2.7 meq/L	≥6.0 meq/L	Outpatient dialysis
		≥ 7.0 meq/L	
Sodium	≤120 meq/L	≥160 meq/L	
*WBC	≤1,000/mm ³	>30,000/mm ³	Non-OB patient
	<6,000	>35,000/mm ³	0-1 Day

***The laboratory calls critical values the first time the limit is exceeded. Whenever a value falls outside the critical range and then becomes critical again, a new call is made**

Qualitative Critical Values

Revised: August 2023

Urine Glucose	Glucose 1000 along with positive Ketone	SRMC, PCACC, & DACC
AFB Culture	Positive	
AFB Smear	Positive	
Blood Culture	Positive	
Bone Marrow Culture	Positive	
GC Culture	Positive	OB patient
GC Smear	Positive	OB patient
Gram Stain	Positive	Sterile Body Fluid
India Ink Prep	Positive	
Isolates of: Salmonella, Shigella, Campylobacter, E. coli 0157:H7 VRSA/VRSE VISA/WISE	All isolates	
Biofire Film Array CSF panel: Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitides Streptococcus agalactiae Streptococcus pneumoniae Cytomegalovirus Enterovirus Herpes simplex virus 1 Herpes simplex virus 2 Human herpes virus 6 Human parechovirus Varicella zoster virus Cryptococcus neofomans/gatti GI panel: Campylobactor Salmonella Vibrio Yersinia E.Coli 0157: H7 Shigella	Detected	All CSF samples that give "Detected" values are to be called to the unit or office. GI panel on the Biofire results giving a "DETECTED" for tests indicated are to be called as critical values on all INPATIENT testing for SRMC.
Spinal Fluid Culture	Positive	
Spinal Fluid Gram Stain	Positive	
Transfusion Reaction	Hemolytic Transfusion Reaction	


Drug Level Critical Values

Revised: March 2023

Test Name		Value
Acetaminophen		> 150 mcg/ml
Carbamazepine		15 mcg/ml
Digoxin		> 3.0 ng/ml
Gentamicin	Peak	> 10 mcg/ml
	Trough	> 2 mcg/ml
Lithium		> 1.5 meq/L
Phenobarbital		> 60 mcg/ml
Phenytoin		> 30 mcg/ml
Salicylate		≥ 30 mcg/ml
Valproic Acid		> 200 mcg/ml
Vancomycin	Peak	> 40 mcg/ml
	Trough	> 20 mcg/ml

POLICY APPROVAL:


 _____ Date 8-31-23
 Dr. Amber Patton



 _____ Date 8/21/23
 Dr. Mathew Kuhn


 _____ Date 8/21/23
 Dr Elsa Malcolm


 _____ Date 8/24/23
 Dr. Scott Wendroth


 _____ Date 8/21/23
 Dr. Shelley Odronic


 _____ Date 8-21-23
 Dr. Patrick Feasel


 _____ Date 8/14/23
 Dan Myers, - Executive Director New Vision Medical Laboratory


 _____ Date 8/14/23
 Jennifer Schroeder / Operations Manager NVML Lima

These forms can be found in epic under Patient Chart, media tab, order or Jen's file box outside her office.



Direct to Consumer Test Request Form

PLEASE PRINT INFORMATION: *All information must be filled in.*

Name: _____

Gender: _____

Address: _____

Phone Number: _____

City/State/Zip: _____

County _____

Date of Birth: _____

SSN: _____

Emergency Phone Number: _____

MARK THE TESTS YOU WANT COMPLETED:

*(Indicates testing requires fasting, 8 hours for glucose, 12 hours for triglycerides for most accurate results)

Blood Typing (ABO & RH) - \$10.00 _____

*Lipid Panel - \$30.00 _____

CBC/Diff - \$15.00 _____

PSA Screen - \$35.00 _____

*Comprehensive Metabolic Panel (CMP) - \$25.00 _____

TSH - \$35.00 _____

*Glucose - \$10.00 _____

*A1C - \$20.00 _____

*Basic Metabolic Panel (BMP) - \$20.00 _____

Urinalysis - \$15.00 _____

Vitamin D,25 Hydroxy - \$40.00 _____

HIV 1 & 2 with Confirmation - \$60.00 _____

*Men's Health (Lipid Panel, PSA, Testosterone, CBC, BMP) - \$120.00 _____

*Women's Health (Lipid Panel, Vit D, TSH, CBC, BMP) - \$120.00 _____

Anemia Panel (Iron, TIBC, Ferritin, H&H) - \$75.00 _____

TOTAL AMOUNT DUE: \$ _____

Patient Signature: _____
(if under 18, guardian signature)

Date: _____

Employee Signature: _____

Date: _____



Testing you can **TRUST**

When it comes to your health, Stay ahead of the game

DIRECT TO CONSUMER TESTING



Types of tests

These are some examples of the types of tests you can order on your own to monitor your health.

CBC/Diff — provides numbers of red and white cells, which are used to help diagnose and monitor many different conditions, like infections and anemia.

BMP — is a basic test to check the status of kidney electrolytes and glucose.

CMP — is a comprehensive test for kidney and liver function, electrolytes and glucose.

Glucose — determines your blood glucose levels and screens for diabetes.

A1C — is used to monitor type 1 and type 2 diabetes.

Lipid panel — checks for heart disease, cholesterol, LDL, HDL.

PSA screening — checks for prostate cancer risk.

TSH — evaluates your thyroid.

Urinalysis — screens for kidney disease and urinary tract infections.

Vitamin D — tests for bone weakness and calcium deficiencies.

Blood typing — finds your blood type (A,B,AB or O) and if your Rh is positive or negative.

Anemia Panel — Iron, TIBC, Ferritin, H&H.

HIV — for screening and diagnosis of HIV infection.

Direct to Consumer Fact Sheet

New Vision Medical Laboratory strongly recommends you consult with your provider for proper interpretation of test results. If you do not have a provider, please go to [mercy.com/find a doctor](https://www.mercy.com/find-a-doctor).

*****Copies of lab results will not be forwarded to any physician. Laboratory personnel will not answer questions regarding how to interpret test results**.***

Payment must be received the day of services. Direct access pricing cannot be requested after the date of service.

No split orders – All testing on a physician order must be billed in the same manner, either all is billed to insurance or all is paid direct to consumer. If a patient has two orders and would like one to be direct access and the other billed to insurance there must be two separate encounters, one for each order.

Credit card payments can only be taken for direct to consumer testing. No other bill payment options are available.

When it comes to your health, **Stay ahead of the game**

DIRECT TO CONSUMER TESTING



DIRECT TO CONSUMER STAFF INSTRUCTIONS

1. Have patient fill out Direct to Consumer Test Request Form completely – choosing which testing they would like completed. (No information may be omitted.)
2. Calculate and write in the total amount due.
3. The patient and employee must sign and date the test request form.
4. Patient will complete and sign the Direct to Consumer Testing Consent form. (No information may be omitted)
5. Register and place patient on the Market Street Dar to obtain a billing number.
6. Order the testing in Softlab – ***Make sure all patient contact information is complete and accurate in Softlab.***

Ward = NVDRL

Dr = WRLDR

7. Complete the payment process using Experian Health's online portal <https://onesource.passporthealth.com> – (use the billing number obtained from Epic registration)
8. Make copies of the following documents and ***scan into the registration in Epic.***
 - Direct to Consumer Test Request Form
 - Direct to Consumer Testing Consent Form
 - Credit Card receipt
10. Give copies of the above paperwork along with the Direct to Consumer Lab Testing Fact sheet to the patient.
11. Send original paperwork packet to core lab - Attn: Jen
12. Once testing is complete. Results will be printed and mailed to the address provided on the Test request form.



DIRECT TO CONSUMER TESTING CONSENT FORM

By voluntarily participating in this testing, I recognize and accept all risks associated with the Direct to Consumer program. I understand the results of the blood tests do not constitute a complete medical examination or diagnosis. For diagnosis of a medical problem, I must see a provider for a complete medical examination.

I understand that a physician's order is not required for this testing today. I also understand that it is my responsibility to pay in full for this testing at the time of service.

Direct to Consumer Testing is not reimbursed by any health insurance company or by Medicare, Medicaid or any other city, state, or federal programs. You may not submit a request for payment or reimbursement of the charges from Direct to Consumer Testing to any health insurance company or to Medicare, Medicaid, or any other city, state, or federal program. New Vision Medical Laboratory will not bill your insurance company for this service.

I hereby release New Vision Medical Laboratory, the medical staff, and any other organization involved in this testing, and their agents from all liabilities, medical claims, or expenses that may arise from my participation or any injury sustained during this testing.

I understand it is my responsibility to share test results with my provider.

When testing is completed a copy of your tests will be mailed to you. Infrequently, results of tests are sufficiently abnormal or critical that New Vision Medical Laboratory may need to contact you immediately so you can make a decision on seeking medical care. **New Vision Medical Laboratory strongly recommends you consult with your provider for proper interpretation of test results.** If you do not have a provider, please go to mercy.com/find a doctor.

If you have any questions regarding our services, please call 419 226-9021.

I have read this form and understand its contents. I understand the results will be released to me and New Vision Medical Laboratory will maintain the confidentiality of the test results.

If receiving HIV testing, results will be reported to the State Department of Health as required by law.

I also allow New Vision Medical Laboratory to contact me at a later date regarding this testing.

New Vision Medical Laboratory can leave a message on my voicemail. YES NO

ALL DATA LISTED BELOW IS REQUIRED IN ORDER TO PERFORM TESTING.

X _____
PATIENT SIGNATURE (if under 18, guardian signature) Date

PLEASE PRINT PATIENT INFORMATION:

Name: _____

Address: _____

City/State/Zip: _____

Date of birth: _____ Gender: _____

Phone number: _____

Emergency phone number: _____

Social Security Number: _____

(By providing your ssn, you are giving permission to allow your results to go back to MyChart and your electronic medical record)