Saint Luke's Regional Laboratories
Clinical Laboratory Letter

June 2012

Changes in Critical Values

A critical value is defined as an unexpected laboratory result that indicates a life threatening situation for the patient unless immediately acted upon. The policy of Saint Luke's Health System (SLHS) is to report a critical laboratory result to a licensed caregiver within 10 minutes from the time a verified critical laboratory test result becomes available. The licensed caregiver must read-back the critical results to the medical technologist to prevent telephone communication errors and then call the physician. Both laboratory and nursing must document the date and times of all phone calls.

Critical value reporting is required by CLIA, the Joint Commission and the College of American Pathologists. These regulatory agencies do not state which laboratory tests require critical value limits and notification. Individual clinical laboratories are challenged with creating a list of critical values that reflect institutional organization, clinical demand, patient population, laboratory instrumentation and staffing. Such variations have hindered the development of universal standards for critical value reporting. The medical literature contains very little outcomes-based data on critical value thresholds.

The critical value list at SLHS includes 60 different tests. It was created more than 25 years ago and has undergone very few modifications. In order to determine if our critical value list was still relevant, SLHS collaborated with 13 other well respected health system laboratories including:

- Alegent Health
- Advocate & Aurora Health Systems
- Baystate Health
- Carolinas Healthcare
- Cleveland Clinic
- Fairview Health Services
- Florida Hospital
- Henry Ford Health System
- Intermountain Healthcare
- North Shore Long Island Jewish Health
- Maine Health - NorDx
- Scripps Health
- Sutter Health

After reviewing the critical value lists from all of these entities and the most recent literature, it was decided that SLHS critical value list needed to be updated. Changes to the critical values for 11 tests have been approved by Saint Luke's Care and will take effect on August 1.

Test	Current	New
Chemistry		
Bicarbonate (CO2)	<10 >40	<10 **>45**
Calcium, Total	<6.0 >13.0	<6.0 **>14.0**
Calcium, ionized	<3.5 >6.5	<3.0 **>7.0**
Glucose, Adults	<50 >500	**<40** >500
Potassium, adult	<3.0 >6.0	**<2.7** >6.0
Sodium	<120 >155	<120 **>160**
Hematology		
Platelets	<30K >1M	**<20** >1M
Coagulation		
INR (no known OAC)	>2.0	**>5.0**
INR, on OAC	>4.0	**>5.0**
INR, cardiac OAC	>5.0	>5.0
APTT (no known anticoagulant)	>45	**>130**
APTT on heparin	>130	>130
Fibrinogen	<100	**<70**

The laboratory will no longer have separate INR or APTT critical values for patients on anticoagulants. A single critical value will be used for untreated and treated patients.

The Critical Value policy is not intended to communicate all extremely abnormal results. Too inclusive of a list or setting of suboptimal cutoffs can create numerous problems including:

- Increased phone calls
- Unnecessary burden on laboratory staff
- Physician annoyance
- Alert fatigue
- Dissatisfaction with laboratory services
- Uncertain benefit to patient care

SLHS laboratories called more than 12,000 critical value results last year. The proposed changes should reduce the number of critical notifications by approximately 4000 per year.

BAD is Officially Obsolete

Saint Luke's Regional Laboratories (SLRL) has not performed bacterial antigen testing (BAD) on body fluids since December 2001. Review of literature and internal data at the time revealed that BAD was neither sensitive nor specific and should be discontinued due to high potential for misleading results.

Mayo Medical Laboratories (MML) published a retrospective review of their own laboratory data (J. Clin. Microbiol. 2010, 48(4):1504) including 918 CSF specimens from adults and children analyzed from the years 2000-2009. BAD was found to provide no benefit beyond the Gram stain for bacterial meningitis, and MML has ceased to offer testing as well. Accordingly, BAD is no longer available through SLRL.

Whooping It Up in Kansas

The Kansas Department of Health & Environment (KDHE) has issued an alert regarding a community-wide outbreak of pertussis (AKA whooping cough) in Northeast Kansas, including Johnson County. The number of suspected cases has been increasing since April 2012, and currently greater than 100 reports have been received by KDHE.

Details regarding symptoms and diagnosis of pertussis were reviewed in detail in the March 2011 Clinical Laboratory Letter. Briefly, pertussis is a highly communicable bacterial infection caused by *Bordetella pertussis* or occasionally *B. parapertussis*. The incubation period is generally 7-10 days. Symptoms include paroxysms of coughing, often of >2 weeks duration, and inspiratory "whoop" followed by vomiting.

The diagnostic test of choice is PCR from a nasopharyngeal swab or aspirate. Only symptomatic patients should be tested, and only within the first 3 weeks of symptoms and on antibiotics for less than 5 days.

KDHE requests that healthcare providers report suspected cases of pertussis immediately by faxing a Kansas Notifiable Disease Form to 877-427-7318 or calling the Epidemiology Hotline at 877-427-7317. The form can be downloaded at:

http://www.kdheks.gov/epi/download/KANSAS_NOTIFIABLE_DISEASE_FORM.pdf

Reimbursement of Direct LDL Cholesterol

A lipid panel consists of measured total cholesterol, HDL cholesterol, and triglycerides and calculated LDL cholesterol. The latter is calculated using the Friedewald equation:

***LDL cholesterol = Total cholesterol - (HDL cholesterol + triglycerides/5*).**

This equation assumes that the amount of cholesterol in very low density lipoproteins (VLDL) can be accurately estimated by dividing triglyceride concentration by a factor of five.

Calculated LDL cholesterol levels have repeatedly been shown to be accurate when triglyceride levels are below 400 mg/dL. When triglycerides exceed this threshold, the calculation underestimates LDL cholesterol values. In this situation, LDL cholesterol can be directly measured. The National Cholesterol Education Program (NCEP) Adult Treatment Panel III recommends direct measurement of LDL cholesterol only in persons with triglyceride levels greater than 400 mg/dL.

Some insurance payers have begun denying payment for direct LDL when fasting triglyceride levels are below 400 mg/dL or undocumented. In order to challenge a denial, the laboratory must provide evidence that a patient's triglyceride level exceeds 400 mg/dL. Unfortunately, even if the challenge is successful, payers reimburse the laboratory less than the cost of the test. Thus, direct LDL cholesterol measurements have become a money loser for the health system.