

## C-REACTIVE PROTEIN AND ERYTHROCYTE SEDIMENTATION RATE

Both C-reactive protein (CRP) and the erythrocyte sedimentation rate (ESR) have been in use for several decades. Methods of analysis of both have improved greatly over the last 10 years in particular and their clinical utility has become better defined. Over the last two years CRP has become a prognostic tool in patients with atherosclerotic coronary artery disease.

As laboratory tests, ESR and CRP are measures of inflammation. CRP is the earliest of the acute phase reactants to increase in response to inflammation, but it fluctuates considerably in chronic illness. ESR is a physical phenomenon that depends upon the presence of a number of proteins classified as acute phase reactants. Collectively, these are less subject to day-to-day variation in chronic illness.

In the primary assessment of acute inflammatory diseases, ESR and CRP should not be ordered together. While either can be used to assess disease activity, CRP

will typically correlate more closely with manifestations of the disease than will ESR. One notable exception is systemic lupus erythematosus (SLE), where ESR correlates more closely with disease activity. CRP does have a role in evaluation of patients with SLE: it can signal concurrent bacterial infection or other secondary inflammatory disorders.

ESR is believed to be a more consistent measure of disease activity in chronic inflammatory disorders, although rigorous evaluation of available data indicate that there may be exceptions (e.g. ankylosing spondylitis). ♦

Avera Laboratory Network *Lab News* is published every other month to provide the latest updates on services from labs of the Avera Laboratory Network.

*Editors:* Lori Murray  
*Reporters:* Michelle Sedlacek  
Tonya Klingaman  
Rebecca Aman

Questions may be directed to your Avera Laboratory Network representative or contact Lori Murray at (800) 657-8095, [lori.murray@avera.org](mailto:lori.murray@avera.org)

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## For The Grill...

Summer is upon us and the grills are hot. Whether you do a lot of cooking or not, when it comes to grilling, it seems we all are looking for ways to “spice” up the things we cook. Sauces and marinades are ways to add flavor to foods, but knowing how to use them makes all the difference.

**Sauces**—rich and thick, savory or sweet, add delicious flavors to almost any grilled fare. Use a premium sauce of your choice and capture real homemade taste. Serve warmed sauce on the side for added zest. Here’s how to protect the rich, deep color and spicy flavor of barbecue sauce, especially tomato and molasses based ones that can burn if applied too early.

### For grilled steaks and chops:

Baste with sauce after meat has been turned for the last time. About the last 3 minutes of grilling.

### For grilled chicken:

Baste with sauce the last 10 minutes of grilling. Turn once.

### For hot dogs and sausage:

Baste with sauce the last 5 or 6 minutes, turning often

### For barbecued meats:

(cooked by indirect heat) baste the last hour of cooking.

*Basting sauces made from seasoned oils and butters may be brushed on throughout the grilling adventure*

**Dry Rubs** are combinations of seasonings and spices rubbed onto meat before grilling. Basic rubs often include coarsely ground pepper, paprika and garlic powder. Some include mustard, brown sugar, dried jalapeno or cayenne pepper. Crushed herbs, such as sage, basil, thyme and oregano are also good choices.

**Marinades** add flavor, but they also help tenderize less tender cuts of meat. Basic marinades include an acidic ingredient, such as wine, vinegar, soy sauce or lemon juice, combined with herb, seasonings and oil. Always marinate in the refrigerator, turning meat occasionally. Reserve some of the marinade before adding the meat to use as a baste while the meat is cooking. ♦



## EDITORS NOTES:

Please pay particularly close attention to the article below regarding Competitive Billing and the CPI freeze. This is a major issue facing us, and it is imperative that all facilities and staff are knowledgeable of potential impacts. We are facing a potentially major crisis that could cripple laboratories, patient care, and our economy. It is crucial that you get involved and are in contact with your state representatives. If you have questions in regard to contacting these government officials, please contact ALN for assistance. ♦

- Lori Murray

## PROPOSED MEDICARE LEGISLATION...

### on Prescription Drug Coverage Has Major Potential to Impact Negatively on Clinical Laboratory Reimbursement

Proposed legislation coming from the House of Representatives [House Committee on Ways and Means] called the “House Republican Principles to Strengthen Medicare with Prescription Drug Coverage” has potential, devastating impact for clinical laboratories. The provisions relating to the clinical laboratory include:

- Extension of the freeze on CPI updates for clinical laboratory services for a minimum of 3 years and is tied to;
- Implementation of a competitive bidding system

Information from the American Society for Clinical Laboratory Science:

### QUALITY AND ACCESS FOR LABORATORY SERVICES THREATENED BY THE CONTINUED FREEZE OF A CPI UPDATE AND IMPLEMENTATION OF COMPETITIVE BIDDING

(continued on page 2...)

(Proposed Medicare Legislation continued from page 1...)

The clinical laboratory fee schedule Consumer Price Index (CPI) update has been repeatedly frozen or limited by Congress over the past 10 years. Moreover, over the past 17 years reimbursement for laboratory services has been cut significantly. The Balanced Budget Act (BBA) of 1997 totally eliminated a CPI increase for clinical diagnostic laboratory tests from 1998 through 2002. This reduction was a continuation of a lengthy series of reductions the industry has experienced since 1984.

As a result of these cuts, laboratories have suffered real reductions in their reimbursement levels. These reductions to the clinical laboratory fee schedule have occurred while at the same time the cost of business continued (and continues) to grow due to new federal regulations, increasingly burdensome red tape requirements imposed by Medicare contractors, personnel shortages, safety regulations, and keeping pace with new technology.

Adding insult to injury, the Centers for Medicare and Medicaid Services (CMS) has been considering competitive bidding for the procurement of Medicare Part B laboratory services for over fifteen years. The methodology for this would be complicated and difficult for all parties because laboratory testing is a service, not a commodity. Laboratories are also a service and can vary greatly depending on the provider, making this effort far more difficult to implement, than a competitive bidding program for health care equipment or supplies, which are usually standard and interchangeable.

Competitive bidding provides incentives for laboratories to knowingly submit bids under their actual costs in order to “meet or beat” the competition to obtain Medicare business. When revenues are less than costs, a laboratory cannot maintain the resources necessary to provide timely results that are accurate and reliable. As

## WAIVED LABS TARGET FOR CMS INSPECTION THIS YEAR

Concerns about the quality of waived testing has prompted the Centers for Medicare and Medicaid Services (CMS) to inspect 2 percent of waived laboratories annually, starting this year. CMS made this announcement April 1 in a letter to state Medicaid directors. The decision was impacted by poor performance by Certificate of Waiver (COW) laboratories in two CMS pilot studies involving 10 states, the agency said. There has been a significant increase in the number and types of tests that are waived, and the number of laboratories with no oversight. Laboratories

that occurs, Medicare beneficiaries will suffer the consequences of poor quality.

Competitive bidding for laboratory services will destroy most hospital and smaller private laboratories around the nation who will not be able to provide services at the “winning price” since these laboratories do not realize the economies of scale of large commercial ventures. This is to the detriment of our patients (delayed results; no control over quality), our economy (testing going out of state/region), and our providers (no direct contact between provider and testing personnel/pathologist for discussion of test results).

CMS data shows that payments with the Medicare Part B fee schedule for outpatient laboratory tests declined from \$3.8 billion in 1992 to \$3.6 billion in 1998. During the same period total annual Medicare spending grew from \$141 billion to \$231 billion. At this point, laboratory services represent only 1.6 percent of overall Medicare Part B expenditures.

Competitive bidding would move the Medicare Program toward a more complex and expensive payment methodology rather than toward a more rational, simple system. The IOM Report concluded that competitive bidding would likely result in multiple fee schedules across the country and possibly even within separate bidding areas.

Competitive bidding violates Medicare’s basic premise that a beneficiary should have access to “any willing provider”. Coupling this process with a continuation of the freeze of the CPI update will cripple laboratories as they struggle with personnel shortages and bioterrorism preparedness in communities throughout the nation. It is important that our voice be heard in Washington on this issue. Please contact your state representatives and bring this issue to their attention. ♦

targeted for inspections will be notified in advance, first by letter and then by telephone, to confirm on-site visits, and the visits will focus on the education of testing personnel to ensure quality. CMS says inspectors will provide assistance to laboratories if quality problems are found, to help them achieve desired results. CMS also stated that at this time there will be no charge for the visits. The College of American Pathologists has noted concern about Food and Drug Administration regulatory proposals to expand the number of waived tests exempt from quality control and proficiency testing. CAP maintains that no test is without risk to patients and believes that all laboratory testing should be subject to quality improvement measures. ♦

Reference: Statline April 2002

(Case Study continued from page 4...)

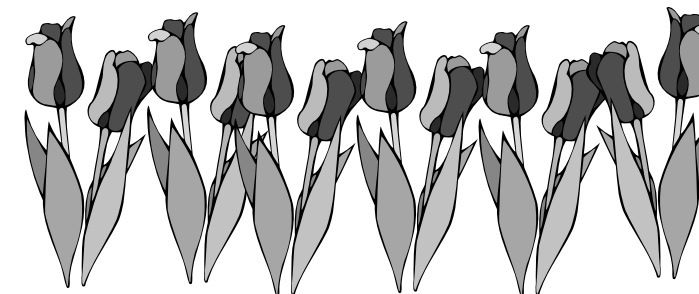
### Laboratory Findings in DKA

Glucose	>300 mg/dl
pH	<7.3
Bicarbonate	>15 mmol/L
Sodium	initially may be normal, then decreased
Potassium	initially elevated (moved from cells to serum) then decreased as excreted in urine
BUN	initially may be increased (prerenal azotemia)
Serum osmolality	>330 mOsmol
Anion gap	>18
Amylase	may be elevated
Urine	positive glucose, ketone
WBC	may be high secondary to hemoconcentration, >30,000 suggests bacterial infection

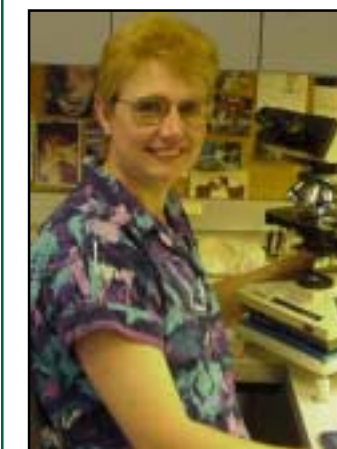
### Treatment

- 1) rapid fluid volume replacement (to remedy dehydration, replace electrolytes, and dilute glucose)
- 2) correction of hyperglycemia and hyperketonemia (provide insulin to allow glucose to be used for energy and halt ketogenesis)
- 3) prevention of hypokalemia during treatment (potassium decreases due to rehydration and reentry into cells)
- 4) identify and treat any suspected underlying bacterial infection

DKA is a serious complication that may result in death. In fact, DKA causes 16% of diabetes-related fatalities. In children less than 10 years of age, DKA accounts for up to 70% of fatalities. It is very important for diabetics to recognize the early warning signs of diabetic ketoacidosis to initiate prompt intervention and avoid serious complications or even death. ♦



## CLIENT SERVICE SPOTLIGHT



**Sandra Davis** is an employee of Avera St. Luke’s. She has worked there since 1989. Sandy completed her Bachelors degree at NDSU in Animal Science and later completed her Cytotechnology Certification at UND. She has been ASCP certified for 24 years.

Sandy and her husband, Dale, have a son Christopher, 17, and a daughter Leah, 14. They also have a white German Shepherd named Coty, 3 cats and 2 horses. Sandy enjoys spending time outdoors riding horses, gardening, doing yard work. She also enjoys cooking, canning and helping her neighbors with cattle.

Sandy is an integral part of the laboratory services at Avera St. Luke’s. She has been instrumental in implementing and promoting the AutoCyte thin later PAP technology. Sandy says that the “crew” she works with is more like family. This makes her job even better. ♦

## TIDBITS:

In a Nov. 30, 2001 program memo (A-01-135), CMS incorrectly indicated that clinical diagnostic lab tests for SNF residents could only be billed by the company that actually performed the test. However CMS clarifies in the new memo [April 8 program memorandum (AB-02-043)] that lab tests actually do fall under consolidated billing. “SNFs must make arrangements under Part A and may make arrangements under Part B whereby the SNF bills the intermediary and receives payment from the program [and] the SNF pays the lab” whatever they’d agreed to, the memo says. The beneficiary can’t be charged by the lab at all. For more information on the April 8 program memorandum (AB-02-043), go to [www.hcfa.gov/pubforms/transmit/AB02043.pdf](http://www.hcfa.gov/pubforms/transmit/AB02043.pdf). To access the November 2001 memo, go to [www.hcfa.gov/pubforms/transmit/A01135.pdf](http://www.hcfa.gov/pubforms/transmit/A01135.pdf). ♦

## CASE STUDY

A 14 year-old girl was brought to the emergency department by her parents. She was very weak and semi-comatose. She showed no signs of trauma or seizure and had no significant medical history. Physical exam was non-remarkable except for quick, gasping respirations and weak, rapid pulse. Lab results were as follows:

		Reference Range
Na	128 mmol/L	135-145 mmol/L
K	5.8 mmol/L	3.5-5.2 mmol/L
BUN	35 mg/dl	5-25 mg/dl
Cl	87 mmol/L	95-105 mmol/L
HCO <sub>3</sub>	8 mmol/L	20-30 mmol/L
Glucose	510 mg/dl	70-160 mg/dl
Osmolality	385 mOsmol	285-310 mOsmol
Anion gap	58mmol/L	<17 mmol
pH	7.24	7.35-7.45
Urine glucose	>1000	negative
Urine ketones	4+	negative

Her diagnosis was Type I diabetes complicated by diabetic ketoacidosis. She was admitted to the pediatric intensive care unit and treated for hyperglycemia and hyperketonemia. It is estimated that 10-20% of patients with new onset Type I diabetes will manifest DKA as their initial presentation.

Diabetic ketoacidosis (DKA) is an acute complication caused by an absolute or relative lack of insulin. An absolute lack occurs when insulin is not taken regularly or, as in this case, there is no knowledge of the need for insulin. A

relative lack of insulin is caused by physical stress such as surgery, trauma, MI, infections, or stroke. Infection is the most frequent cause of DKA with pneumonia and UTI being the most common. Under physical stress the body requires more insulin than is usually administered daily and levels become deficient. DKA is almost always associated with Type I diabetes, however it can occasionally be present with Type II diabetes under severe stress or poor compliance with diet and treatment. DKA is a result of a cascade of several factors which arise from the lack of insulin. First, hyperglycemia occurs, followed by glucosuria, then ketosis, and finally a state of ketoacidosis exists.

### Signs and Symptoms of DKA

frequent urination	abdominal pain
excessive thirst	difficult, rapid breathing
dehydration	decreased consciousness, coma
headache	stupor
nausea	decreased blood pressure
vomiting	fruity breath odor

Glucose is an osmotically active molecule that will affect the kidneys and serum in a similar manner. When levels reach 300 mg/dl or higher, glucose will initially pull intracellular water (with potassium following)

from the cells in an attempt to dilute the blood sugar. Eventually extracellular dehydration occurs as water is lost through urination. The kidneys are unable to reabsorb all the glucose and it will "spill" into the urine. As the glucose level rises in the urine, it will pull water and electrolytes along. The osmotic action of elevated glucose levels causes the symptoms of thirst, frequent urination, and dehydration.

As carbohydrate metabolism is interrupted, the body must resort to lipid oxidation as a secondary fuel source. The by-products of lipid metabolism are ketones: acetone, acetoacetic acid, and beta-hydroxybutyric acid which are very strong organic acids. The ketones cause the pH of the blood to become more acidic than the tissues. Ketoacids are released into the urine as non-reabsorbable anions of sodium and potassium salts which causes further loss of electrolytes.

The body will attempt to compensate for the acidity through the bicarbonate-carbonic acid buffer system and by respiratory regulation. The ketoacids are buffered by bicarbonate and then excreted in the urine. The loss of the measured anion, bicarbonate, causes the anion gap to increase. The lungs will attempt to correct the metabolic acidosis by blowing off accumulated acid through Kussmaul respiration. Kussmaul respiration is the deep, rapid breathing with frequent sighing patients with DKA experience.

*(continued on page 5...)*

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