CCLS Connection

"Your partner in health care ... together we make a difference"

September 2013
Volume 9, Issue 5

Inside this issue:

Cindy Johnson

CentraCare Laboratory Services (CCLS) is proud to announce that Cindy Johnson, Director of Laboratory Operations, has been elected to the American Society for Clinical Laboratory Science (ASCLS) National Board of Directors. In her role as Secretary/Treasurer for ASCLS, Cindy will be able to fulfill her passion of shaping the future of the professional organization. Cindy stepped down as Chair of the ASCLS Government Affairs Committee (GAC) in order to carry out her new role. She stated, *"While I am excited to have been elected to this position, it does not diminish my passion for governmental, legislative and regulatory issues that impact the laboratory profession. I feel strongly about staying informed about health care issues that impact this profession as well as educating the public about them."*

Mission Statement

As part of **CentraCare Health,** we are a team of dedicated health care professionals whose mission is to provide quality service, expert consultation and comprehensive medical laboratory information to Central Minnesota.

CentraCare Laboratory Services

Washington Decisions Impacting Clinical Laboratories

Submitted by: Cindy Johnson, Director of Laboratory Operations

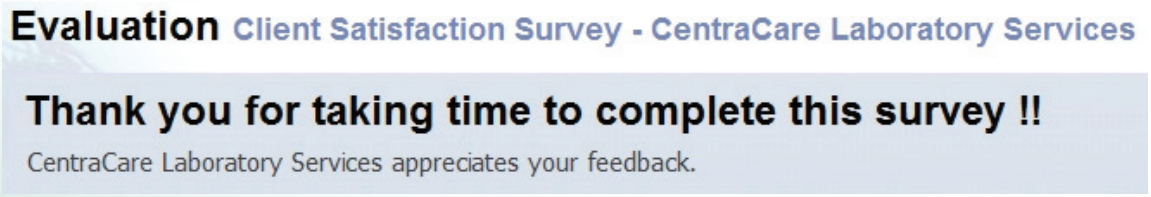
The pressing issues for the clinical laboratory are the Centers for Medicare & Medicaid Services (CMS) proposals impacting the Clinical Laboratory Fee Schedule (CLFS).

On July 19, 2013, a proposed rule to revamp the CLFS by CMS was published in the Federal Register. CMS is proposing a process under its existing authorities in 1833(h)(2)(A)(ii) that would allow for the systematic examination of payment amounts. This examination would seek to identify codes that had undergone "technological changes" affecting the price of the test. CMS cites the increased use of point of care testing, genetic and genomic testing, and laboratory developed tests as rationale for developing this process. Under its proposal, CMS would review all CLFS codes during a five-year period, beginning with the oldest codes, reviewing a portion of the total codes each year and making appropriate adjustments. After the initial review of the codes, CMS will allow the public to nominate codes for review; however, these codes must have been on the CLFS for at least five years. Public nominations must include sufficient rationale describing the technological changes and how those changes affect payment and delivery.

In addition to its proposal to modernize the rate-setting process under the CLFS, CMS proposed in the CY2014 Hospital Outpatient Prospective Payment System (OPPS) Notice of Proposed Rulemaking to bundle clinical laboratory payments into the OPPS payments.

Another component to the proposed rule is an update to payment policies and payment rates for services furnished under the Medicare Physician Fee Schedule (PFS). Effective Jan. 1, 2014, CMS proposes reductions in the technical component (TC) of 40 pathology codes it described as misvalued. These reductions would be significant, as much as 80 percent. For physicians, the cuts included in the proposed 2014 PFS rule primarily impact technical component payment and global payment for pathology services performed on non-hospital patients.

The Clinical Laboratory Coalition (CLC), which includes several laboratory professional organizations, will be discussing these CMS proposals and the impact on the clinical laboratories throughout the next few weeks. Public comments were due to CMS by Sept. 6, and the final rule, which would become effective Jan.1, 2014, is expected in November.



Coming Soon: Customer Satisfaction Survey

In an effort to improve our clinical and service quality CCLS will soon be launching an electronic survey for its customers. The survey will be brief and cover topics such as quality, safety, service and value. This online survey will come to your email inbox to be distributed to as many colleagues as you see fit for input. Watch for the survey to arrive in the next few weeks and thank you in advance for your participation. We look forward to improvements we can achieve with your feedback.

Dr. Miron Joins Pathology Team

Submitted by: Pamela Rakke, Anatomic Pathology Specialist

Dr. Joel Miron

We are pleased to announce the addition of Dr. Joel Miron to St. Cloud Pathologists, PA. He will join Drs. Stephen Bologna, Joseph Schoenecker, Brian Kay, Bradley Curtis, Marc Dvoracek and Matthew Zieske in providing pathology services to CentraCare Health entities and area clinics.

Dr. Miron, a native of Brookings, S.D., spent his undergraduate years at Luther College in Decorah, Iowa and received his medical degree at Sanford School of Medicine at the University of South Dakota. He completed his residency in anatomic and clinical pathology at the University of Iowa Hospitals and Clinics where he also served as the Chief Resident in the Department of Pathology. Dr. Miron remained at the University of Iowa Hospitals and Clinics to complete his surgical pathology fellowship. Dr. Miron's wife, Aimee, loves to be involved in theater in any capacity. They have two children, Adelaide (7) and Henry (3) and a Great Pyrenees dog. Dr. Miron's interests are varied. Among them are professional football (particularly the Miami Dolphins), amateur soccer, theater and reading science fiction and history.

CCLS is very excited about the knowledge and expertise Dr. Miron brings to our laboratory services. Please join us in welcoming Dr. Joel Miron to St. Cloud Pathologists, PA.

CentraCare Health Unveils a New Web Site

The new, improved centracare.com becomes live on Sept. 17. Focused on our patients and visitors, centracare.com is now more dynamic and user friendly. With this new site comes a new location for CentraCare Laboratory Services and its available tools. Look for Laboratory Services in the alphabetical listing under the Services tab.

Expanding the Urine Toxicology Panel

Submitted by: Erin Telfair, Clinical Laboratory Scientist

CentraCare Laboratory Services at St. Cloud Hospital implemented a 13 drug screen for urine on the MEDTOX PROFILE®-V MEDTOXScan® Drugs of Abuse Test System Aug. 26. This expanded drug panel standardizes urine drug screening within CentraCare Health laboratories.

The PROFILE®-V MEDTOXScan® Test Device is a one-step immunochromatographic test for the rapid, qualitative detection of one or more of the following in human urine: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, THC (Cannabinoids) and Tricyclic Antidepressants or their metabolites. The added six drug classes will address the changing needs in pharmacotherapy monitoring, especially with controlled substances.

The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System detects drug classes at the following cutoff concentrations:

AMP Amphetamine (d-Amphetamine)	500 ng/mL	OPI Opiates (Morphine)	100 ng/mL
BAR Barbiturates (Butalbital)	200 ng/mL		
BZO Benzodiazepines (Nordiazepam)	150 ng/mL	OXY Oxycodone (Oxycodone)	100 ng/mL
BUP Buprenorphine (Buprenorphine)	10 ng/mL	PCP Phencyclidine (Phencyclidine)	25 ng/mL
COC Cocaine (Benzoylecgonine)	150 ng/mL	PPX Propoxyphene (Norpropoxyphene)	300 ng/mL
MAMP Methamphetamine (d-Methamphetamine)	500 ng/mL	THC Cannabinoids (11-nor-9-carboxy-$\triangle^9$-THC)	50 ng/mL
MTD Methadone (Methadone)	200 ng/mL	TCA Tricyclic Antidepressants (Desipramine)	300 ng/mL

From package insert

There is no change to sample requirements or the turn-around time of test results.

However, the sample stability for refrigerated (2 to 8°C) specimens is only 48 hours.

Urine may be frozen at minus 20°C or colder for storage and future testing if needed.

CCLS to Expand Molecular Testing Capability

Submitted by: Jerry Crissman, Microbiology Technical Specialist

In 2009, septicemia was associated with more than 800,000 hospitalizations in the United States and was the most expensive cause of hospitalization. Septicemia occurs when a pathogenic microorganism, usually a bacterium or a fungus, enters the bloodstream and causes an inflammatory immune response. Because bloodstream infections and septicemia are pervasive problems associated with high mortality rates, timely delivery of appropriate treatment is essential.

Bloodstream infections with gram-positive bacteria often are complicated by antimicrobial resistance. The inability to rapidly identify resistant strains of pathogenic bacteria has led to antimicrobial use that is often ineffectual, wasteful, or bears risk of proliferating resistant strains. Rapid identification of both organism and resistance is essential to implementing efficient and appropriate therapy.

Gram-positive bacteria also are a common source of contamination during blood draws. Contaminant species are frequently responsible for false-positive blood cultures that lead to inappropriate antimicrobial use. Patients with contaminated blood culture bottles often are presumptively treated for bloodstream infections for several days until the organism can be identified as a contaminant using conventional biochemical methods. Due to the large burden of infections and contaminants due to gram-positive bacteria, rapid identification of bacteria isolated from blood cultures is a primary health care concern.

CentraCare Laboratory Services will soon introduce the Verigene Gram-Positive Blood Culture (BC-GP) Test. This test is a multiplexed, automated nucleic acid test for the identification of genus, species, and genetic resistance determinants for a broad panel of the most common gram-positive blood culture isolates. While conventional microbiological methods may require two to four days to produce bacterial identification and resistance results, the Verigene BC-GP test provides results within two and a half hours of blood culture positivity. The Verigene System's unique instrumentation allows for true random access test processing, enabling 24/7 on-demand testing directly from positive blood culture bottles with less than five minutes of user hands-on time per test.

This breakthrough technology helps our hospital improve patient care and lowers costs by providing time-critical information, allowing earlier detection of disease and more targeted treatment. For example: Traditional methods for the identification of MRSA/MSSA from positive blood cultures require almost 2 days before final resolution. Because methicillin-resistant Staphylococcus aureus (MRSA) causes at least half of all Staphylococcal bacteremias, patients are empirically started on vancomycin therapy. However, vancomycin is far less effective for methicillin-susceptible Staphylococcus aureus (MSSA) than penicillins such as nafcillin or first generation cephalosporins. Pathogen identification paired with the detection of resistance markers enables clinician to make informed treatment decisions faster. The efficacy of switching to appropriate anti-MSSA agents can been seen with lower relapse rates, shorter duration of bacteremia, decreased length of stay, and lower hospitalization costs.
The Verigene BC-GP Test is performed directly on blood culture bottles identified as positive by a continuous monitoring blood culture system and which contain

(continued on page 6)

(continued from page 5)

CCLS to Expand Molecular Testing Capability

Submitted by: Jerry Crissman, Microbiology Technical Specialist

gram-positive bacteria. The Verigene BC-GP Test is indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial bloodstream infections; however, it is not to be used to monitor these infections. Sub-culturing of positive blood cultures is necessary to recover organisms for susceptibility testing, identify organisms not detected by the Verigene BC-GP Test, differentiate mixed growth, associated antimicrobial resistance marker genes to a specific organism, or for epidemiological typing.

For more information about this testing addition, please contact Jerry Crissman, Microbiology Technical Specialist, at 320-251-2700 ext. 57361.

Additional Resources:

- Elixhauser A, Friedman B, Stranges E. 2011. Septicemia in US Hospitals, 2009. HCUP Statistical Brief #122. Agency for Healthcare Research and Quality.
- Sahm DF et al, 1997. Rapid Characterization Schemes for Surveillance Isolates of Vancomycin-Resistant Enterococci. JCM 8:2026-2030.
- Von Eiff C, Herrmann M, Peters G. 1995. Antimicrobial susceptibilities of Stomatococcus mucilaginosus and of Micrococcus spp. Antimicrob Ag Chemo. 39:268-270.
- Wojewoda, Christina M, Sercia, Linda, Tuohy, Marion J., Wilson, Deborah A., Procop, Gary W., Hall, Geraldine S., Richter, Sandra S. Cleveland Clinic, Cleveland, OH. Identification of Gram Positive Bacteria and Detection of Resistance Determinants from Blood Cultures Using a Microarray-Based Assay.
- Buchan BW, Mackey T, Cahak C, Couillard H, Jannetto PJ, and Ledeboer NA. Department of Pathology, Medical College of Wisconsin, Milwaukee, WI, Dynacare Laboratories, Milwaukee, WI. Rapid Detection of Gram-Positive Bacteria and Resistance Determinants Directly from Positive Blood Cultures using the Microarray-Based Sample-to-Result Verigene BC-GP Assay.

CCLS CONNECTION
Editor: Jeremy Angell

Contributors:
Jeremy Angell
Jerry Crissman
Cindy Johnson
Pamela Rakke
Erin Telfair

CentraCare Laboratory Services - River Campus
1406 Sixth Ave. North
St. Cloud, MN 56303
(320) 255-5999

CentraCare Laboratory Services - River Campus Clinic Collection Site
1200 Sixth Ave. North
St. Cloud, MN 56303
(320) 240-2211

CentraCare Laboratory Services - Health Plaza
1900 CentraCare Circle
St. Cloud, MN 56303
(320) 229-4903

CCLS CONNECTION DISTRIBUTION LIST

If you know someone who would like to be added to our distribution list, or if you would like to be removed from the list, please let us know.
E-mail us at:
cclabser@centracare.com