

CPAL Newsletter

DECEMBER 1, 2013

VOLUME 1, NUMBER 4

*Central Pennsylvania
Alliance Laboratory*

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York, PA 17403
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The CPAL Websites

www.cpallab.com

www.cpalmolecular.com

The CPAL Members

Ephrata Community Hospital

Lancaster General Health
Lancaster General Hospital
Lancaster General Women's Hospital

Pinnacle Health
Harrisburg Hospital
Community General Hospital

Reading Health System

Summit Health
Chambersburg Hospital
Waynesboro Hospital

Wellspan Health
Gettysburg Hospital
York Hospital

What's New at CPAL?

In this Issue...

The November issue of the CPAL Newsletter includes a review on the launch of a CPAL's second test to its new FISH testing menu – ALK; a review of our newly updated version 2.0 test for HCV viral load measurement; a review of the recently introduced new HPV screening assay with simultaneous genotyping. In the CPAL Corner, there is coverage of CPAL's visit to Wellspan's York Hospital Laboratory and a new Meet the Staff entry.

Administrative Update

CPAL undergoes FDA Inspection and Affinity Group Audit of its Donor Screening Services.



On August 27th, CPAL underwent an FDA inspection of its Donor Screening testing services. The FDA inspector was on-site at CPAL for 3 days reviewing all aspects of our testing processes and documentation. The FDA inspector found CPAL's blood donor testing services to be in excellent order reporting no documentable issues and no citations.

On September 26th, representatives from Reading Hospital, Beth Frey, MT(ASCP)BB and Michelle Myers, MT(ASCP), SBB performed the annual Blood Bank Affinity Group audit of CPAL's blood donor testing services. This audit was performed to assure that all practices and processes involved with testing of blood donor products used in transfusion are reliable and accurate. The criteria used for this audit was based upon the AABB Standards for Blood Banks and Transfusion Services and FDA Guidelines.

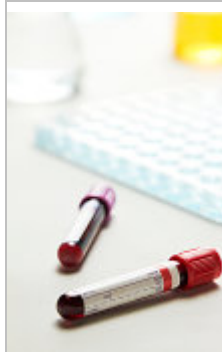
The audit covered the areas of organization, personnel, equipment, reagent suppliers, process control, documents and records, deviations and non-conformances, process improvement, and facility and personnel safety. CPAL received a very positive report on aspects of the audit. The audit team provided several operational suggestions which will be adopted.

If you would like to review the details of the BBAG Audit performed by the Reading Hospital feel free to contact CPAL's Administrative Director, Lonnie Ebersole at 717-851-1426 or by email at lebersole@cpallab.com.



Clinical Pathology Update

New Assays in Development



At CPAL, we are constantly looking for ways to improve our services to the Alliance members. Recently, we have been focusing on automating and expanding our line of autoimmune tests. Here is what is in the works:

- Celiac Disease Testing – CeliKey (tissue transglutaminase); Gliadin (deaminated)
- Connective Tissue Disease Testing – Ro (SS-A), La (SS-B), Sm, RNP, Jo-1, SCL-70
- AntiPhospholipid Syndrome – Cardiolipins, Beta 2-Glycoprotein

We are also in the final stages of bringing **Lyme G/M Western Blots** in house to improve turn-around-time for this assay and reduce cost to the members.

The CPAL Management Team

Medical Director/CEO

Peter Côté, M.D.

Administrative Director

Lonnie L. Ebersole, MS, MT(ASCP)SM

Information Systems

Cindy Cooley, MT(ASCP)

Quality Assurance

Sue Flowers, MT(ASCP)

Clinical Pathology Services

Director, Clinical Pathology

Jennifer Thebo, Ph.D., MT(ASCP)

Operations Managers

Steph Frey, MT(ASCP)

Matt Groeller, MPA, MT(ASCP)

Molecular Pathology Services

Director, Molecular Pathology

Jeffrey Wisotzkey, Ph.D., HCLD, CC

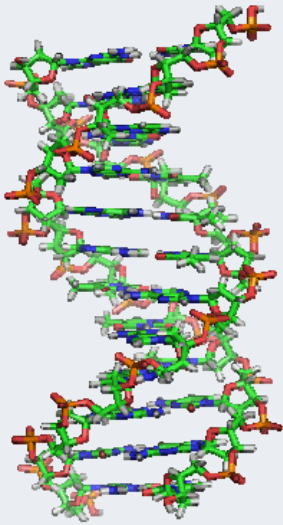
Operations Manager

Jill Johns, MT(ASCP)SH, QCYM, CCY

Total Hepatitis A Viral (HAV) Antibody Testing Platform Change

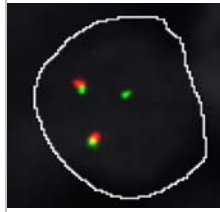


CPAL's Hepatitis A Virus (HAV) Total Antibody (IgG/IgM) test will be transitioning to a new platform. The platform change will allow the test to be more fully automated and for the test to be performed in concert with several other infectious disease markers. This move will allow us to shorten our turn-around-time for this test result.



Molecular Pathology Update

ALK Assay – Second FISH Assay LIVE at CPAL

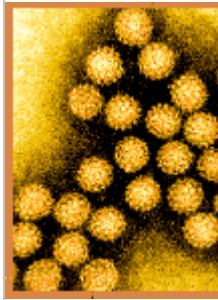


Lung cancer is the leading cause of cancer death in the United States. Non-small cell lung carcinoma (NSCLC) accounts for 75% to 80% of all lung cancers with an overall 5-year survival rate of 10% to 15%. Standard chemotherapy regimens have had marginal success in improving clinical outcomes. Targeted treatments may be used as novel molecular changes are identified.

Rearrangements of the *ALK* locus are found in a subset of lung carcinomas and their identification may guide important therapeutic decisions for the management of these tumors. The fusion of *EML4* (echinoderm microtubule-associated protein-like 4) gene with the *ALK* (anaplastic large cell lymphoma kinase) gene results from an inversion of chromosome band 2p23. The *ALK-EML4* rearrangement has been identified in 3% to 5% of NSCLC with the majority in adenocarcinoma and younger male patients who were light or nonsmokers. Recent studies have demonstrated that lung cancers harboring *ALK* rearrangements are resistant to epidermal growth factor receptor tyrosine kinase inhibitors, but may be highly sensitive to *ALK* inhibitors, like Xalkori (crizotinib). Clinical studies have demonstrated that Xalkori treatment of patients with tumors exhibiting *ALK* rearrangements can halt tumor progression or result in tumor regression. This FISH assay is a FDA-approved companion diagnostic test for Xalkori, which the FDA approved to treat certain patients with late-stage (locally advanced or metastatic), non-small cell lung cancers that harbor anaplastic lymphoma kinase (*ALK*) gene rearrangements. It can be used to identify patients who will benefit from Xalkori therapy.

For more information on CPAL FISH *ALK* Assay, please visit the CPAL Molecular Website at www.cpalmolecular.com, select the FISH tab and then *ALK*.

New HPV Screening Assay with 16/18 Genotyping introduced at CPAL

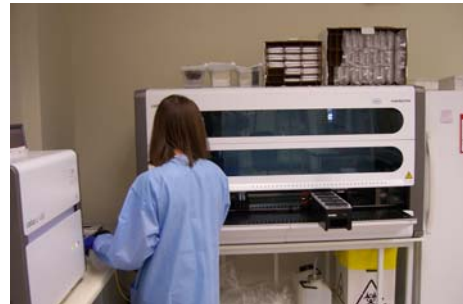


On August 19th, CPAL introduced an improved Human Papillomavirus (HPV) screening assay, the cobas[®] HPV Test (Roche Diagnostics). This information is important and useful in determining the proper course of action of the clinicians following testing.

The cobas[®] HPV Test individually identifies genotypes 16 and 18, the two highest-risk HPV genotypes responsible for more than 70 percent of cervical cancer cases, while simultaneously detecting 12 other high risk HPV genotypes (HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68). One test, in one run, from one patient sample delivers 3 results, eliminating the need for reflex testing. Only 2 ml of patient sample is required, reducing the risk of QNS. The performance of the cobas[®] HPV test is clinically validated in the landmark Athena study which shows proven equivalency in performance against the previous Hybrid Capture 2 (HC2) method in the ASC-US population.

The cobas[®] HPV Test is performed on the Roche cobas 4800 instrumentation platform, which is also used for *Chlamydia trachomatis* and *Neisseria gonorrhoea* testing, creating additional efficiencies in the laboratory workflow and reduced cost to the members.

We are pleased to offer this state of the art testing so that our client clinicians are in a better position to consider the ACS/ASCCP/ASCP cervical cancer screening recommendations in the care of their patients. For further information about CPAL's HPV testing, please see [HPV Testing](#) on the Molecular Website; www.cpalmolecular.com.

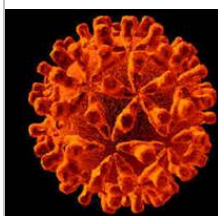


cobas 4800 Instrumentation



CPAL's Jessica Elder (standing) and Jessica Gulnac from Molecular Pathology

New, More sensitive HCV Viral Load assay LIVE October 21, 2013!!



With the launch of the *COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, v2.0* (Roche Diagnostics), the HCV Viral Load reportable range is now 15 IU/mL to 100,000,000 IU/mL.

- Quantitative results will be reported for HCV viral loads ranging from 15 IU/mL to 100,000,000 IU/mL (1.18 Log₁₀ IU/mL to 8.0 Log₁₀ IU/mL).
- Results reported as Not Detected are below the limit of detection.

The test provides clinical results which correlate closely to the *COBAS® AmpliPrep/COBAS TaqMan HCV Test*. The same level of result correlation is evident around the lower limit of quantitation of 15 IU/mL. Further, the test produces similar results to the Roche real-time PCR test utilized in two clinical trials which supported the approval of currently available direct-acting antivirals (the *COBAS® TaqMan® HCV Test v2.0 for use with High Pure System*).

Hepatitis C virus is considered to be the principal etiologic agent responsible for 90% to 95% of cases of post transfusion hepatitis. As a blood borne virus, HCV is transmitted by blood and blood products. Widespread adoption of HCV blood screening measures has markedly lowered the risk of transfusion associated hepatitis. The incidence of HCV infection is the highest in association with intravenous drug abuse and to a lesser extent with other percutaneous exposures. The global prevalence of HCV infection is estimated to be 3%; the prevalence in the USA between 1999 and 2003 was 1.6%. Following exposure, 75% to 85% of HCV infected individuals develop chronic hepatitis, with up to 20% of these chronic cases progressing to cirrhosis. In cirrhotic patients, hepatocellular carcinoma is observed in 1% to 4% of the population every year.

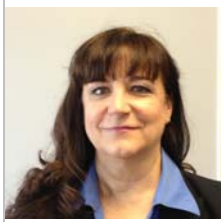
Quantitation of HCV RNA for measuring baseline viral loads and for on-treatment monitoring has been well established in demonstrating the efficacy of antiviral response to pegylated interferon plus ribavirin combination therapy. Current guidelines for the management and treatment of HCV recommended quantitative testing for HCV RNA before the start of antiviral therapy, during therapy, and generally 12 to 24 weeks following the end of treatment. Absence of detectable HCV RNA by a sensitive test, 24 weeks after the end of treatment, is the goal of treatment and indicates that a sustained virologic response (SVR) has been achieved.

For more information on the new HCV Viral Load Assay, please visit the CPAL Molecular Website at www.cpal-molecular.com, select the Molecular Microbiology tab and then HCV Viral Load.



CPAL Corner

Meet the CPAL Staff



The next employee to introduce you to is **Dr. Jennifer Thebo**. Dr. Thebo joined CPAL in June and serves as its new Director of Clinical Pathology Services covering Chemistry/Immunochemistry, Donor Screening, and Autoimmune Testing. Dr. Thebo obtained her BS in Biology from Alma College in Michigan and completed her medical technologist studies at the Butterworth Hospital School of Medical Technology in Grand Rapids, MI. She received her Master of Science degree from Western Michigan University with an emphasis in molecular biology and continued on at Western Michigan to receive her PhD. Prior to coming to CPAL, she served as the Technical Director of all the chemistry laboratories in the Sparrow Health System in Lansing, MI. She has worked for the Coulter Corporation, spent time at the Cleveland Clinic and filled several teaching posts. She also manages her own consulting firm. Dr. Thebo has numerous publications and received a number of professional awards. In her time away from CPAL, Dr. Thebo likes to dance, enjoy outside activities, and travel.

Have you been to the CPAL laboratory?

The CPAL laboratory is located just off of route 83 in York county. Easy to get to! If you have not been to CPAL or it has been a while, give us a call and arrange for a tour of the lab. We would be happy to show you around!

Contact information

When calling the laboratory, call **717-851-1416**. We will direct your call to the appropriate person. If you know the number of the person you need to speak with, feel free to call them directly. We love to hear from you!

Did You Know?

CPAL is one of only a small number of alliance-type laboratories established to serve the needs multiple non-affiliated healthcare systems?

Wise Sayings

Whatever you are, be a good one.

~Abraham Lincoln

CPAL Laboratory Employees Visit the Alliance – York Hospital



The second 'road trip' to visit the CPAL member laboratories took place on September 24th at Wellspan Health's York Hospital Laboratory. The CPAL team, lead by Cindy Cooley (LIS), included Marti Ryan (Administrative Asst.), Melissa Buckwalter (Clinical), and Jessica Gulnac (Molecular). The team took a tour of the York Laboratory Department during which they had the opportunity to meet with the laboratory staff and management.

Currently, CPAL is scheduling to visit the Summit Hospitals of Chambersburg and Waynesboro, Pinnacle Health, Reading and Gettysburg Hospitals.

Sights from the Visit



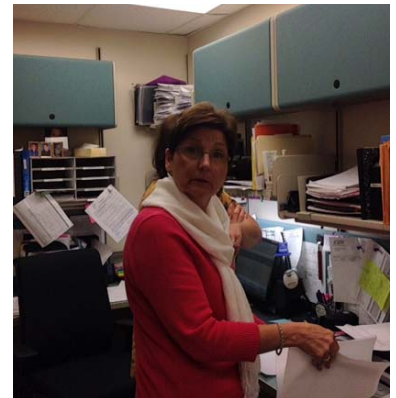
York's Diane Gaspari and CPAL's Jessica Gulnac



Tour Guide Jenny



Referrals – Brian, Lorraine, and Cheryl



Sandy Aldinger
Manager of Blood Bank Services