CPAL Newsletter

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Central Pennsylvania Alliance Laboratory

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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?

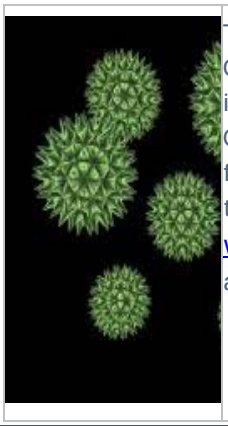
In this issue, you will find information to new testing added to CPAL's Molecular Pathology menu, an update on our automated IFA platform for performing ANA and native DNA testing, EBV and ToRCH panel testing, a review of specimens that can be submitted for the detection of Chlamydia and Neisseria gonorrhoeae, as well additions to the CPAL Corner.

Molecular Pathology Update

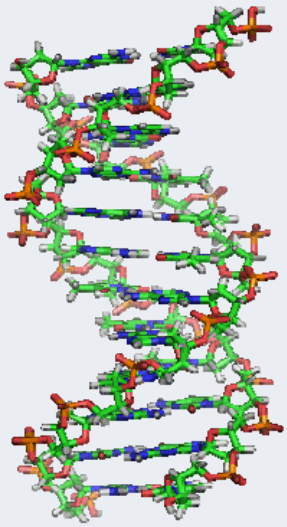
Bordetella pertussis/parapertussis PCR

CPAL has developed Real Time PCR assays for the sensitive detection and differentiation of Bordetella pertussis and Bordetella parapertussis DNA in nasopharyngeal swabs (NPS) and nasal aspirates (saline). The test is a real-time polymerase chain reaction (PCR) amplification and detection system that utilizes a bi-functional fluorescent probe-primer for the detection and differentiation of Bordetella pertussis and Bordetella parapertussis. The assay provides two results; Bordetella pertussis (Bp) is identified in the specimen by targeting IS481 while Bordetella parapertussis (Bpp) is identified in the specimen by targeting IS1001. This test should be used only in patients in whom there is a suspicion of Bordetella-related illness and should never be used for screening asymptomatic individuals. NP swabs are the preferred specimen for Bordetella PCR testing by CPAL and are available from the laboratory – call 717-851-1416. For more information on this assay, please visit the CPAL Molecular Website at www.cpalmolecular.com, select the Molecular Microbiology tab and click on Bordetella pertussis/parapertussis PCR.

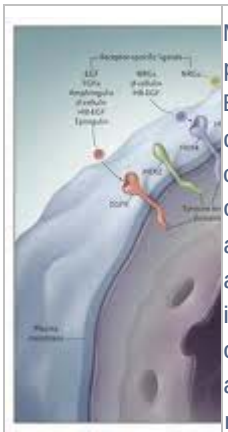
Varicella-Zoster (VZV) PCR



The Varicella Zoster Virus (VZV) real time PCR assay available at CPAL is a sensitive and specific assay used for the detection of VZV in swabs specimens, CSF and bronchial wash specimens. Swab Collection Kits for VZV by PCR as performed by CPAL are available from the laboratory – call 717-851-1416. For more information on this assay, please visit the CPAL Molecular Website at www.cpalmolecular.com, select the Molecular Microbiology tab and click on VZV Real-Time PCR.



EGFR (Epidermal Growth Factor Receptor) Mutational Analysis



Mutation analysis of the EGFR gene (exons 18-21) is now performed at CPAL. Using Scorpions and ARMS technologies, the EGFR real time PCR assay is highly sensitive (typically able to detect mutations present in samples at a level of 1-5%) and is capable of detection of 29 somatic mutations in the EGFR oncogene. If a deletion or insertion mutation is detected by the PCR assay, the sample is further subjected to DNA sequence analysis and the specific characterization of the mutation is reported. The identification of EGFR as an oncogene has led to the development of anticancer therapeutics directed against EGFR including gefitinib and erlotinib for lung cancer and cetuximab for colon cancer. For more information on this assay, please visit the CPAL Molecular Website at www.cpalmolecular.com, select the Molecular Oncology tab and click on EGFR Mutational Analysis.

KRAS Mutational Analysis (*Companion Diagnostic*)

CPAL is now performing all KRAS testing using the therascreen® KRAS RGQ PCR Kit. The therascreen® KRAS RGQ PCR Kit (QIAgen) is ***an FDA*** approved, in vitro, assay intended to aid in the identification of colorectal cancer patients for treatment with Erbitux® (cetuximab) based on a KRAS "no mutation detected" test result. Oncogenic mutation of the KRAS gene leads to a constitutively activated protein which is commonly found in many carcinomas, including 30-50% of colorectal carcinomas and 15-30% of lung non-small cell adenocarcinoma. Several studies have indicated that the presence of mutant KRAS in colorectal tumors correlates with a poor prognosis and is associated with a lack of response to EGFR tyrosine kinase inhibitors. For more information on this assay, please visit the CPAL Molecular Website at www.cpalmolecular.com, select the Molecular Oncology tab and click on KRAS Mutational Analysis-FDA.

Specimens for Chlamydia/N. gonorrhoeae Testing by CPAL

CPAL was one of the first laboratories in the nation to adopt the current Roche cobas 4800 CT/NG Test. In early May of 2012, after extensive validation of the assay in our laboratory, we began offering testing for both CT and NG on:

1) Endocervical swab specimens

2) Male and female urine samples

3) Cytology samples collected in PreservCyt media (pre-quot)

4) **Clinician-Instructed, Self-Collected Vaginal swabs**

Swab collection kits, including those for Clinician-Instructed/Self-Collected samples, are available from CPAL.

For more information on this assay, please visit the CPAL Molecular Website at www.cpalmolecular.com, select the Molecular Microbiology tab and click on CT/NG PCR Testing

New Assays in Development

New assays are constantly in development at CPAL. Here is a list of some of the new assays we are currently working on…

HER2 FISH, ALK FISH, CLL FISH, BCR/ABL Real Time Quantitative PCR

CPAL's LabNexus Molecular Portal Operational

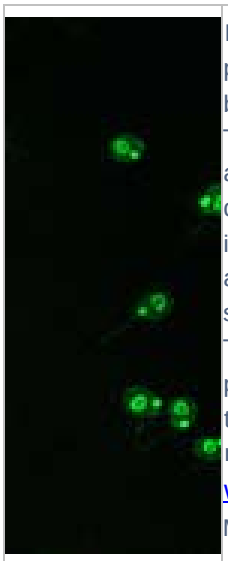
After months of development, CPAL has launched it's Molecular Ordering and Reporting Portal. Driven by LabNexus (Gaithersburg, MD), the portal offers a comprehensive ordering and reporting web-based method for molecular pathology testing. This portal allows for a variety of interactive ordering, data review and test interpretation abilities by our pathologist clients and send out departments. For more information on the CPAL LabNexus portal, please contact Dr. Wisotzkey, CPAL'S Director of Molecular Pathology, or Jill Johns, CPAL's Molecular Operations Manager.

Clinical Pathology Update

Automated Fluorescent ANA Testing implemented by CPAL

CPAL has recently launched an automated slide processor and initial screening system for ANA and nDNA testing by IFA. The automated methodology employs the AFT2000 specimen processor and HEp-2000 ANA-Ro kit. The ANA substrate slides uses HEp-2000 cells (with mitotic figures) grown and stabilized directly on the test wells and are transfected with the SSA/Ro autoantigen allowing for an added reportable pattern of SSA-Ro which previously may have been reported as Speckled. ANA titers will now only be reported from 1:40 to ≥1:1280. The ≥1:2560 dilution is discontinued.CPAL performs upwards to 28,000 fluorescent ANAs annually for its member hospitals. For more information on this assay, please visit the CPAL Website at www.cpallab.com, select the Tech Notes tab and click on ANA Method Change_03_2013 Technical Bulletin.

Automated Fluorescent nDNA Testing offered by CPAL



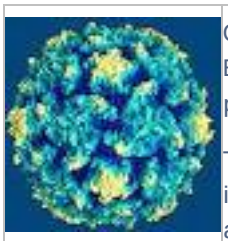
In conjunction with the launch of the new automated ANA platform, CPAL has also launched a new version of its nDNA testing by IFA. This test uses the same platforms as the new ANA IFA test. The nDNA test is based on utilizing the organism *Crithidia luciliae* as a substrate in immunofluorescence for the detection of anti-dsDNA antibodies. They possess an organelle with a network of interlocking circular dsDNA molecules. The lack of other nuclear antigens in this organelle means that using *C. luciliae* as a substrate allows for the specific detection of anti-dsDNA antibodies. The anti-dsDNA test confirms whether there are antibodies being produced to the genetic material in the cell. When the anti-dsDNA test is positive, a person is usually considered to have SLE. For more information on this assay, please visit the CPAL Website at www.cpallab.com, select the Tech Notes tab and click on NDNA Method Change_03_2013 Technical Bulletin.

Toxoplasma, Rubella, CMV and HSV (ToRCH) Diagnostic Tests available at CPAL

These diagnostic antibody tests are now available from CPAL. Often referred to as the ToRCH panel, these four organisms are associated with congenital infections transmitted from mother to fetus. The name of the test is an acronym for the organisms detected by this panel: *Toxoplasma gondii* (toxoplasmosis), rubella (German measles), cytomegalovirus (CMV), and herpes simplex virus (HSV). Although the four diseases are not particularly serious for adults who are exposed and treated, women who become affected with any of these diseases during **pregnancy** are at risk for **miscarriage**, still birth, or for a child with serious birth defects and/or illness. Thus, this testing is performed before or as soon as pregnancy is diagnosed to determine the mother's history of exposure to these organisms. This testing is also available for determination of immune status or to diagnose recent infections.

These tests offered by CPAL (Toxo-IgG and IgM, CMV-IgG and IgM, HSV 1 and 2-IgG, and Rubella-IgG) may be ordered as a panel or as individual diagnostics tests.

EBV Diagnostic Panel now offered by CPAL



CPAL has begun offering an EBV Diagnsotic Panel consisting of EBNA-IgG, VCA-IgG, VCA-IgM and EA9D)-IgG markers. These are performed via a chemiluminescence immunoassay method.

The Epstein-Barr virus (EBV), a member of the herpesvirus family, is found throughout the world. Studies show that up to 95% of all adults have antibodies against this common virus, meaning that they were infected at some point in their lives. Even though most infections with EBV go unnoticed or produce only very mild symptoms, in some cases, it can be associated with the development of serious conditions, including several types of cancer. EBV is transmitted by close person-to-person contact. Primary, or initial, infection with EBV may not produce symptoms or there can be a number of different symptoms, especially in young children. The most common medical condition associated with EBV is infectious mononucleosis (IM). EBV has been linked to the development of cancers and serious conditions, including the following Burkitt's lymphoma, Hodgkin lymphoma, Nasopharyngeal carcinoma, and EBV-associated non-Hodgkin lymphomas (usually B-cell lymphomas) have also been described in people infected with the HIV virus.

CPAL's EBV tests may be ordered individually or combined in various panel combinations.

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

"Life would be infinitely happier if we could only be born at the age of eighty and gradually approach eighteen."

Mark Twain

Cats make lousy lab pets.

CPAL Corner

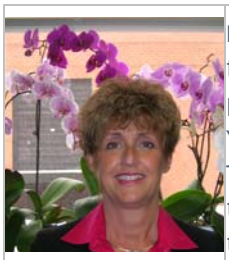
CPAL Laboratory Employees to Visit the Alliance Members

After a successful round of visits by send-out employees from the member hospitals, time has come for CPAL to visit its members. Starting in April and throughout this summer, we will be making arrangements for a small team of CPAL employees to visit the member hospitals as a continuation of the process to meet key personnel at each site, tour the laboratory operations, and get a better understanding of how things function before they get to CPAL. The CPAL staff are looking forward to the visits.

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!

Meet the CPAL Staff



Next up is **Jill Johns.** Jill is CPAL's Molecular Operations Manager focusing on CPAL's Flow Cytometry and FISH Diagnostics programs. Jill graduated with a Bachelor of Science degree from York College and completed her clinical rotation in Medical Technology at York Hospital. Before coming to CPAL, Jill served as the Hematology/Blood Bank Supervisor at Hanover Hospital and as the Assistant Laboratory Director at the Holy Spirit Hospital. Jill joined CPAL as a staff technologist in 2000. As plans developed for new Flow Cytometry and FISH Diagnostic programs at CPAL, Jill quickly embraced the challenge to develop and manage these areas. She has attained several certifications covering both cytometry and FISH diagnostics procedures and analysis. In her time away from CPAL, Jill likes to travel, especially to those warm Caribbean islands and is an avid flower gardener.

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!