

CPAL Newsletter

JULY 1, 2013

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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?

Welcome to Dr. Jennifer Thebo

The CPAL Laboratory would like to welcome Dr. Jennifer Thebo as its new Director of Clinical Pathology testing services. Dr. Thebo joined laboratory on May 31st. A complete bio on Dr. Thebo will be coming in the next issues of the CPAL Newsletter.

In this Issue...

The July issue of the CPAL Newsletter includes an update on the MediaLab integrated, cloud-based programs adopted by CPAL for Document Control, Inspection preparation and Competency/CE management, information regarding on launch of a new testing line to CPAL's Molecular Pathology menu – FISH Diagnostics- and the first FISH assay, HER2, and a discussion regarding the required platform change for CPAL's PSA test. In the CPAL Corner, coverage of CPAL's visit to Ephrata and a new Meet the Staff entry.

Administrative Update

CPAL adopts MediaLab for Document Control, CAP Inspection Preparation and Competency/CE Management



MediaLab is an on-line, integrated cloud-based solution designed for clinical laboratories.

Document Control - the Document Control system will be used by CPAL to ensure that all policies and procedures available to employees are up-to-date, that documents are approved and reviewed by authorized individuals, and that important historical information, such as records of approvals, signoffs, and controlled copies, is available. This replaces our previous document control system designed as an Access database.

Inspection Proof – the Inspection Proof program will be used by CPAL to prepare for on-site and self-inspections overseen by CAP. Preparation for an inspection involves uploading checklists that are applicable for CPAL and providing responses to those items. Responses can be simple text answers, links to policies and procedures in Document Control, or other uploaded files. When an inspection occurs, the electronic checklists are



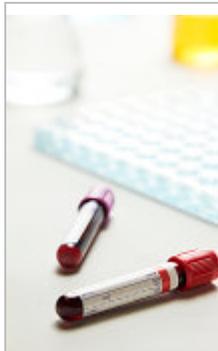
Compliance & CE

available to the inspectors.

Compliance & CE – is a complete learning management system for the laboratory, including safety, compliance, and CE courses written especially for the laboratory. With MediaLab Competency & CE, CPAL can build custom courses, create competency checklists, defining groups of users, view and print detailed reports, and more.

Clinical Pathology Update

Platform Change for PSA Testing at CPAL



Due to an Urgent Medical Device Recall of PSA reagents by Siemens received on June 27, 2013 and the lack of available replacement reagents for the Siemens Immulite 2000 system, PSA testing was changed to the Hybritech calibration method on the Beckman-Coulter DxI800. A comment included with each PSA result reflects this change. Prostate cancer is the most common type of cancer found in men in the United States, with an incidence of approximately one case for every ten men. It is also the second leading cause of cancer deaths among American men. A reliable test for detecting early stage prostate cancer can be of great value to the physician when the tumor is confined to the gland and effective treatment can be provided. Historically, a majority of prostate cancers had advanced beyond the gland at the time of diagnosis. The digital rectal examination (DRE) is a commonly used technique for prostate cancer detection; nevertheless DRE, as it is generally performed in medical practice, misses a significant number of cancers, including many organ-confined tumors. Elevated serum PSA concentration can only suggest the presence of prostate cancer until a biopsy is performed. Serum PSA concentrations can also be elevated in benign prostatic hypertrophy or inflammatory conditions of the prostate and other adjacent tissues. PSA is generally not elevated in apparently healthy men or men with non-prostatic carcinoma. Physicians should discuss the risks and benefits of PSA testing with their patients.

For more information on this assay method change, please visit the CPAL Website at www.cpallab.com, select the Tech Notes tab and click on the PSA_MC_06_2013 Technical Bulletin.

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)

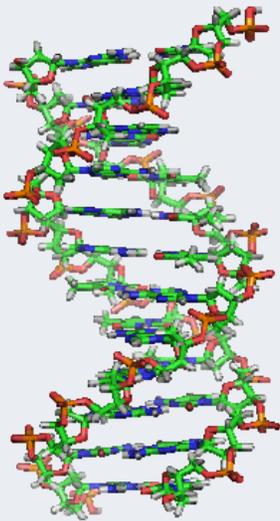
Molecular Pathology Services

Director, Molecular Pathology

Jeffrey Wisotzkey, Ph.D., HCLD, CC

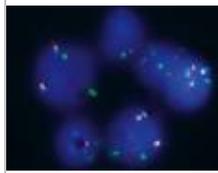
Operations Manager

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



Molecular Pathology Update

The CPAL FISH Diagnostics Program



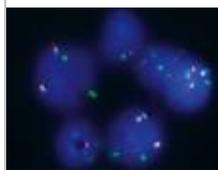
Fluorescence in situ hybridization (FISH) is a powerful molecular technology that is currently being implemented at CPAL for the analysis of a variety of neoplastic diseases (solid tumor and heme/onc). The analysis of HER2 amplification in breast cancer cells has been established and validated in the laboratory and this assay is currently available through CPAL. Other FISH assays currently in development include ALK, CLL, and BCR/ABL.

In situ hybridization is a technique that allows the visualization of specific nucleic acid sequences within a cellular preparation. Specifically, DNA fluorescence in situ hybridization (FISH) involves the precise annealing of a single stranded, fluorescently-labeled DNA probe to complementary target sequences. The hybridization of the probe with the cellular DNA site is visible by direct detection using fluorescence microscopy.

The ability to offer interactive, hands-on review and sign out of the FISH cases by the alliance pathologists places CPAL in an elite group of molecular laboratories. By using our internet portal through SoloWeb, pathologists located anywhere in the world can log in and review all aspects of their patient's FISH case. Once the review and report is completed, they can sign out the report and have it automatically upload into their specific laboratory information system and EMR.

For more information on CPAL FISH Program, please visit the CPAL Molecular Website at www.cpalmolecular.com, select the FISH tab.

PathVysion HER-2/neu Assay – LIVE at CPAL



The PathVysion HER-2 DNA Probe Kit is designed to detect amplification of the *HER-2/neu* gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer tissue specimens. Assay results are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in stage II, node-positive breast cancer treated with adjuvant cyclophosphamide, doxorubicin and 5-fluorouracil (CAF) chemotherapy. The PathVysion Kit is indicated as an aid in the assessment of patients for whom HERCEPTIN® (Trastuzumab) treatment is being considered.

Among all cancers in the U.S., breast cancer is expected to be the most common cancer (32% / 182,000) in women and to be the second most common cause of death from cancer (18% / 46,000) in 1995. After surgery, breast cancers with positive axillary nodes, which account for 30% of all breast cancers, are associated with a shorter disease-free survival and a shorter overall survival than node-negative breast cancers. It has been generally accepted that patients with breast cancer and positive axillary nodes at diagnosis should be offered adjuvant systemic treatment. Amplification or

For the Funny Bone



Charlene, I just got a nine page memo about the lab going paperless.

overexpression of the *HER-2/neu* gene has been shown to be an indicator of poor prognosis in Node-positive breast cancer. The fluorescence in situ hybridization (FISH) technique has been used to detect *HER-2/neu* gene amplification in human breast carcinoma cell lines. FISH appears to be an alternative technique capable of overcoming many of the inherent technical and interpretative limitations of other techniques, such as immunohistochemistry. For quantification of *HER-2/neu* gene amplification, FISH assesses not only the level of *HER-2/neu* gene amplification directly in the tumor cells while retaining the characteristic morphology of the tissue studied, but also the spatial distribution of oncogene copies in individual uncultured primary breast carcinomas.

The PathVysion Kit is designed for the detection of *HER-2/neu* gene amplification in formalin-fixed, paraffin-embedded human breast tissue specimens by FISH. The assay is rapid, non-radioactive, requires little tumor material, and is capable of detecting as few as 2 to 8 copies of the oncogene.

For more information on CPAL FISH *HER-2/neu* Assay, please visit the CPAL Molecular Website at www.cpalmolecular.com, select the FISH tab and then HER2.

CPAL Corner

Meet the CPAL Staff



The next employee to introduce you to is **Steph Frey**. Steph is one of CPAL's two Clinical Operations Managers focusing on Chemistry and Immunochemistry testing. Steph graduated with a Bachelor of Science degree from Millersville University and completed her clinical rotation at Harrisburg Hospital's School of Medical Technology. Before coming to CPAL, Steph served as a staff and charge technologist at Harrisburg Hospital. Steph joined CPAL as a staff technologist in 2000. Steph's penchant for organization and taking on new challenges made her a prime candidate for promotion into the Chemistry/Immunochemistry Operations Manager position at CPAL. Steph has quickly adapted to the challenge to develop and manage these areas. In her time away from CPAL, Steph likes to golf, bike, work out at the gym, and entertain her dogs, Gracie and Lucky.

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

"Time is what we want most, but what we use worst."

William Penn
1644 ~ 1718

CPAL Laboratory Employees Visit the Alliance - Ephrata



The first 'road trip' to visit the CPAL member laboratories took place on June 11th at Ephrata Community Hospital. The CPAL team, lead by Cindy Cooley (LIS), included Glenda Sinkovitz (Processing), Deb Coho (Clinical), and Janet Klinedinst (Molecular). The team took a tour of the Ephrata Laboratory Department during which they had the opportunity to meet with the laboratory staff and management. The visit ended with lunch during which the team had the opportunity to address questions for the Ephrata team.

Currently, CPAL is scheduled to visit the Summit Hospitals of Chambersburg and Waynesboro in August and York Hospital in September. Visits to the other CPAL members are in the process of being scheduled.

Sights from the Visit



Janis Wardrop and Kozette Zimmerman;
Medical Secretaries



Sherry Lennon and Michael Glatfelter;
Medical Technologists



Dr. Peter C. Cote, M.D.
Medical Director