Bladder Cancer Detection by Fluorescence In Situ Hybridization (FISH)

Rajal B. Shah, M.D., Associate Professor of Pathology and Urology, and Bryan Betz, Ph.D., Technical Director of MLabs Molecular Diagnostics Laboratory

Each year in the United States about 55,000-60,000 new cases of urothelial carcinoma, the most prevalent form of bladder cancer, occurs with about 12,500 deaths due to this disease. The natural history of urothelial carcinoma is defined by tumor recurrence and progression. Low-grade papillary tumors tend to recur with small risk of progression, while high grade tumors are characterized by both high risk of recurrence and progression to invasive cancer. Early detection of bladder cancer at its presentation as well as during its subsequent long term follow up is a key to the long term survival of patients affected by this cancer. Due to its enigmatic natural history, bladder cancer is one of the most expensive cancers to diagnose and treat.

ASSAYS FOR UROTHELIAL CARCINOMA DETECTION

Currently there are many non-invasive tests available that can assist cystoscopy examination to improve the sensitivity and specificity of bladder cancer detection, specifically for flat urothelial carcinoma and upper tract disease, which can be missed by traditional cystoscopy examination. Cytology is a widely utilized traditional adjunct to tissue diagnosis for detection and monitoring of bladder cancer. Cytology examination provides high specificity but low sensitivity, particularly for the detection of low-grade bladder tumors. The suboptimal sensitivity of urine cytology prompted development of new tests with improved sensitivity for bladder cancer detection. Antigen based methods (BTA-Stat, Immunocyt, and NMP22) and the cytogenetic/molecular FISH-based method (UroVysion™) offer alternative non-invasive modalities to supplement cystoscopy examination. Tests employing antigen-based methods can improve sensitivity, but typically lack high specificity. UroVysion™ FISH is unique in that it detects bladder cancer at the genetic level. Since this test simultaneously assesses multiple genetic targets within an individual cell, both sensitivity and specificity of bladder cancer detection is high. FISH is especially useful in patients with “atypical” or “equivocal” urine cytology as a reflex test to improve bladder cancer detection.
UROVYSION™ FISH TEST FOR UROTHELIAL CARCINOMA DETECTION

FISH is a molecular technique that utilizes fluorescently labeled DNA probes to detect genetic abnormalities within individual cells. Urothelial carcinoma cells easily shed into urine and are characterized by a high frequency of aneuploidy (abnormal chromosome number). The UroVysion™ FISH assay directly detects these chromosomally abnormal cells.

UroVysion™ employs a four-color, four-probe mix to detect specific regions of chromosomes 3, 7, 9, and 17 within individual cells that are shed into urine. The centromeric (CEP) probes 3, 7, and 17 aim to detect aneuploidy (gain) of these chromosomes, while the 9p21 locus specific probe (LSI) aims to detect loss of this specific region of chromosome 9. These chromosomal alterations are commonly associated with bladder cancer. The use of this multi-probe cocktail increases both the sensitivity and specificity of the assay over single or dual probes.

UroVysion™ FISH is typically used in conjunction with cystoscopy as a:

- Monitoring tool to detect bladder cancer recurrence.
- Diagnostic tool for high-risk hematuria patients.

It is in general unaffected by BCG therapy, instrumentation, benign prostate enlargement (BPH), hematuria, infection or inflammatory conditions.

HOW DOES UROVYSION™ FARE IN COMPARISON TO TRADITIONAL CYTOLOGY AND OTHER COMMONLY UTILIZED NON-INVASIVE ASSAYS?

Demonstrated Sensitivity (by Stage) and Specificity of Different Tests

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<th>pT1-T4</th>
<th>Overall Sensitivity</th>
<th>Specificity</th>
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(pTa=non-invasive papillary tumor, Tis= in situ carcinoma, T1= lamina propria invasion, T2= muscularis propria invasion, T3= extra vesicle tumor, T4= invasion of adjacent organs) [1-3]

Based on these and other studies, FISH has demonstrated a high degree of sensitivity and specificity for detection of urothelial carcinoma.

FIGURE 1: UroVysion™ FISH. (A) Normal result. Each of the colored fluorescent probes exhibit the normal value of 2 signals. Chromosomes 3, 7, 17, and the 9p21 locus are indicated by red, green, aqua, and gold, respectively. The cell nucleus is counterstained blue with DAPI, a DNA-specific stain. (B) Abnormal result. This cell demonstrates polysomy (more than two copies) of chromosomes 3, 7, and 17. Note also the characteristic nuclear enlargement and mottled appearance of the DAPI counterstain, both of which are abnormal cytologic features associated with neoplastic cells.
HOW IS A POSITIVE TEST DEFINED?

The UroVysion™ assay is performed by first processing urine to isolate cells and to prepare them onto slides. The fluorescently labeled DNA probes are then hybridized to the chromosomes within the cells. After two washes, the cell nuclei are counterstained with DAPI, a DNA-specific stain that fluoresces blue. Slides are now coverslipped and scored on a fluorescent microscope that is equipped with filters to allow visualization of the DAPI counterstain and the fluorescent probes (red, green, aqua, and gold for CEP 3, 7, 17, and LSI 9p21, respectively). During scoring, the entire slide is scanned for morphologically abnormal nuclei by DAPI stain (nuclear enlargement, irregularity, and/or mottled appearance). Once identified, each of the individual probe signals is enumerated within these cells. If no morphologically abnormal cells are present, then nuclei representing the most abnormal are scored.

Normal cells have 2 signals of each of the four probes, indicating the presence of the normal 2 copies of each chromosome (Figure 1A). Tumor cells from urothelial carcinoma patients most frequently present with polysomy (more than 2 copies) of chromosomes 3, 7, and/or 17. Polysomic cells are rarely if ever seen in urine even in small numbers is virtually pathognomonic for the presence of tumor. Polysomy is seen in over 90% of urothelial carcinoma cases. Isolated homozygous deletion of 9p21, or isolated trisomy (3 copies) of a single chromosome (3, 7, or 17), also occur in urothelial carcinoma but are relatively uncommon.

A case is considered positive for malignancy if ≥4 cells exhibit polysomy of two or more chromosomes (3, 7, and/or 17). This abnormality presents as a gain (3 or more signals) of multiple chromosomes within the same cell (Figure 1B). A second criterion for a positive test result is homozygous 9p21 deletion (0 signals of the LSI 9p21 probe) in ≥12 cells. These cutoffs were defined by the test manufacturer for the best combination of sensitivity and specificity. Trisomy of a single chromosome may be considered positive when 10 or more cells exhibit this change. For positive cases the percent abnormal cells is calculated which may help estimate tumor burden. This is determined by scoring 100 consecutive urothelial cells for abnormal FISH values.

WHAT IS THE CLINICAL SIGNIFICANCE OF A POSITIVE TEST WITHOUT CYSTOSCOPICALLY EVIDENT ABNORMALITY?

A positive FISH test in the absence of tumor evidence by cystoscopy or other modalities can pose a diagnostic and management dilemma. Such cases are often referred to as “anticipatory positive”. The significance and management of such cases remains controversial. However, this scenario has been associated with a high likelihood of disease recurrence or presence of disease in upper tract that may not have been visualized by traditional diagnostic modalities [4]. In our experience these patients often need extensive cystoscopic examination with biopsy sampling that also includes upper tract to locate malignant cells.

WHAT ARE THE LIMITATIONS OF THE UROVYSION™ TEST?

UroVysion™ testing provides no additional value in patients with positive cytology. A positive UroVysion™ result in the absence of other evidence of bladder cancer may indicate other genitourinary related cancers (ureter, urethra, renal, or prostate), or metastatic cancer involving the genitourinary tract. Non-neoplastic urothelial cells may rarely exhibit tetrasomy by FISH (4 copies of each of the four probes). This may be observed in reactive cells, umbrella cells, or cells in the G2/M phase of the cell cycle. If ≥4 cells exhibit tetrasomy, a case can be considered positive since these cells fulfill the criteria for polysomy. Thus, when tetrasomy is identified, this finding is specifically noted and this result should be interpreted with caution. However, this finding can be significant, particularly when high numbers of tetraploid cells are present (≥10), since tumors can also be tetraploid or near-tetraploid.

SPECIMEN REQUIREMENTS

The UroVysion™ FISH assay is performed on voided urine specimens. Greater than 33 mL of urine is recommended for optimal number of cells, however lower volumes may be adequate if there is a minimum 25 cells available for evaluation. Mix voided urine 2:1 (v:v) with preservative (PreservCyt or Carbowax). If urine is not shipped immediately after collection, refrigerate and ship via overnight courier within 24 hours.
Spotlight on Rajal B. Shah, M.D.

Associate Professor of Pathology and Urology
Director, Genitourinary Pathology Service
Co-Director, Prostate SPORE Tissue Core

Dr. Shah received his medical degree from Gujarat University, India and subsequent post graduate residency training in anatomic and clinical pathology from the Gujarat Cancer & Research Institute, India and St. John’s Hospital and Medical Center in Detroit, Michigan. He completed a two year fellowship in Urologic/Surgical Pathology at the University of Michigan and joined the faculty of the University of Michigan, Department of Pathology as an Assistant Professor of Pathology and Urology in 2001. He was promoted to the rank of Associate Professor in 2007.

Dr. Shah currently oversees the section of Urologic Pathology and also serves as fellowship director for the subspecialty training program in Urologic Pathology. He has broad clinical and translational research experience in the field of urologic cancers with over 70 peer reviewed publications in reputed journals.

Dr. Shah’s research focuses on translational application of prognostic and diagnostic biomarkers from bench to clinical practice, morphological and molecular classification of urologic cancers, and understanding outcome of urologic cancers. He has served as a director of the NIH funded U-M Prostate Specialized Program of Research Excellence (SPORE) tissue banking section. Currently, he serves as co-director of the NIH funded prostate SPORE tissue core and principal pathologist for this program.

SUMMARY

UroVysion™ offers a high degree of both sensitivity and specificity in urothelial carcinoma detection. The test has been FDA approved for monitoring tumor recurrence in patients with a history of bladder cancer, and as an aid for bladder carcinoma diagnosis in patients with hematuria. This assay offers the opportunity to improve the clinical management of patients with urothelial carcinoma. A negative FISH result increases the confidence for safe extension of cystoscopy intervals, while a positive FISH result warrants a through investigation and close follow-up with re-biopsy.

SELECT REFERENCES


HOW TO SEND A SPECIMEN

UroVysion™ testing will be offered through MLabs in the near future; testing is currently forwarded to Mayo Medical Laboratories.

For assistance 24 hours per day, 7 days per week, call MLabs at 800-862-7284 or visit our web site at www.mlabs.umich.edu.
Test Updates

New Tests

CLEAR CELL SARCOMA TRANSLOCATION ASSAY

The MLabs Molecular Diagnostics Laboratory began performing a Clear Cell Sarcoma Translocation assay effective July 1, 2008.

Greater than 90% of clear cell sarcomas harbor the reciprocal chromosomal translocation t(12;22)(q13;q12). This rearrangement joins the EWSR1 and ATF1 genes and leads to expression of EWSR1/ATF1 fusion transcripts. This test detects three EWSR1/ATF1 fusion transcript types: Type 1 (EWSR1 exon 8/ATF1 exon 4), Type 2 (EWSR1 exon 7/ATF1 exon 5), and Type 3 (EWSR1 exon 10/ATF1 exon 5) which collectively account for almost all t(12;22)-bearing clear cell sarcoma cases. Testing for EWSR1/ATF1 fusion is a useful diagnostic adjunct in the differential diagnosis of clear cell sarcoma, since malignant melanoma is not associated with this chimeric transcript.

Collection Instructions: Send fresh, frozen, or formalin-fixed paraffin-embedded tissue. Fresh tissue should be sent on a piece of gauze in saline, or in RPMI, within 16 hours of collection; refrigerate. Frozen tissue should be stored at -80 degrees C; do not allow to thaw at any time. Paraffin-embedded tissue should be stored at room temperature. Please include any pertinent clinical history.

HER2 AMPLIFICATION BY FISH

The MLabs Molecular Diagnostics Laboratory began performing HER2 Amplification by FISH effective July 1, 2008.

This test detects amplification of the HER2 gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded breast cancer tissue specimens. FISH is performed using PathVysion (Abbott Molecular, Inc) probes to the HER2 locus (17q11.2-q12) and the chromosome 17 centromere (D17Z1). Results are reported as a HER2:17Z1 copy number ratio and interpreted according to ASCO/CAP guideline recommendations. HER2 amplification status can be a useful adjunct indicator of prognosis, and can assist in the selection of patients for whom Herceptin (Trastuzumab) treatment is being considered. This test can also rule-out or confirm gene amplification in cases previously evaluated by HER2 immunohistochemistry (IHC), especially those withequivocal (2+) IHC results.

Collection Instructions: Submit a formalin-fixed, paraffin block of the breast cancer tissue; store at room temperature. Please provide a pathology report with each specimen, including the type of fixative and time of fixation (if known).

KRAS MUTATION DETECTION

Effective October 1, 2008, the MLabs Molecular Diagnostics Laboratory will begin performing KRAS Mutation Detection by Polymerase Chain Reaction (PCR) followed by sequencing analysis to detect KRAS mutation if present.

Activating mutations in the KRAS gene occur in approximately 20% of lung adenocarcinomas, 30-40% of colorectal carcinomas, and a variety of other human cancers. Mutations are single nucleotide substitutions, occurring most frequently within codon 12 or 13. These have been associated with a limited clinical response to epidermal growth factor receptor (EGFR) targeted therapies in lung and colorectal cancers, and may indicate prognosis. This test will detect all mutations within codons 12, 13, and 61 of the KRAS gene from formalin-fixed paraffin-embedded tissue blocks. Specimens should contain an adequate proportion of tumor (>40%) to ensure mutation detection.

Collection Instructions: Send fresh, frozen, or formalin-fixed paraffin-embedded tissue containing greater than 40% tumor. Fresh tissue should be sent on a piece of gauze in saline, or in RPMI, within 24 hours of collection; refrigerate. Frozen tissue should be stored at -80 degrees C; do not allow to thaw at any time. Paraffin-embedded tissue should be stored at room temperature.

Test Methodology, Reference Range, and Specimen Handling Changes

ALDOSTERONE, URINE

Due to the low volume of requests, the MLabs Chemistry Laboratory will discontinue performing Aldosterone, Urine. Effective October 1, 2008, requests for this test will be sent to Mayo Medical Laboratories:

Collection Instructions: Collect 24 hour urine specimen. Add 25 mL of 50% acetic acid (15 mL) for pediatric patients (<5 years) as a preservative prior to start of collection. Aliquot 11 mL (minimum 6 mL) into a plastic urine container and refrigerate. Record total 24 hour urine volume and collection dates/times on request form.

MLabs Spectrum
CALCITONIN

Effective August 19, 2008, Mayo Medical Laboratories revised the reference range for the Calcitonin assay to include all age groups for both males and females:

Reference Range: BASAL: Males: <16 pg/mL; Females: <8 pg/mL; PEAK CALCIUM INFUSION: Males: < or =130 pg/mL; Females: < or =90 pg/mL.

CAROTENE

Effective July 21, 2008, there was a change to the specimen collection and handling requirements for Warde Medical Laboratory’s Carotene assay. This test is now a “strict frozen”.

Collection Instructions: Collect blood in a red top or SST tube from a fasting patient (12 hour fast). Patient should not consume any alcohol for 24 hours prior to collection of specimen. Centrifuge, aliquot serum into plastic vial and freeze immediately. Protect specimen from light.

CHROMOGRAFIN A

Effective July 28, 2008, refrigerated specimens are no longer acceptable for the Chromogranin A assay. This change was made to avoid multiple freeze/thaw cycles prior to analysis of the specimen.

Collection Instructions: Collect specimen in a red top tube. Centrifuge, aliquot 2 mL (minimum 0.3 mL) of serum or plasma into a plastic vial and freeze.

DILUTE RUSSELL’S VIPER VENOM TEST

The reference range for the Dilute Russell’s Viper Venom Test (DRVVT) changed as follows, effective June 20, 2008. Note that the DRVVT is a component of the Lupus Anticoagulant Screen panel.

Reference Range: DRVVT <41 seconds; DRVVT Ratio <1.2; LA CONFIRM negative.

GLUCAGON, PLASMA

Effective June 19, 2008, Mayo Medical Laboratories changed their test methodology for the Glucagon, Plasma assay to extraction followed by immunoassay.

Reference Range: < or = 80 pg/mL.

PITUITARY TUMOR MARKER, ALPHA SUBUNIT

Effective June 17, 2008, Mayo Medical Laboratories changed their test methodology for the Alpha-Subunit Pituitary Tumor Marker (Alpha-Subunit Pituitary Glycoprotein Hormones) to immunochemiluminescent assay (ICMA).

Reference Range: Pediatric: age < or = 5 days: < or = 50 ng/mL; age 5 days - < 3 months: < or = 10 ng/mL; age 3 months - < 2 years: < or = 1.2 ng/mL; age 2 years – puberty onset: < or = 1.2 ng/mL; Tanner II – IV: < or = 1.2 ng/mL; Adults: Males: < or = 0.5 ng/mL; Premenopausal females: < or = 1.2 ng/mL; Postmenopausal females: < or = 1.8 ng/mL.

Collection Instructions: Collect specimen in a red top or green top tube. Centrifuge, aliquot 2 mL (minimum 0.3 mL) of serum or plasma into a plastic vial and refrigerate.

SEROTONIN RELEASE ASSAY

Effective August 11, 2008, the Serotonin Release assay is sent to BloodCenter of Wisconsin.

Collection Instructions: Collect specimen in a red top tube. Centrifuge, aliquot 5 mL of serum into a plastic vial and refrigerate. Citrated or ACD plasma is acceptable if serum is not available.

STOOL, AEROBIC CULTURE

Effective June 18, 2008, all Stool Culture specimens are screened for Shiga-like toxin (SLT) at an additional charge. Previously, Shiga-like toxin testing was performed only during the summer months, if Hemolytic Uremic Syndrome was suspected, or if the stool was bloody.

TB GOLD QUANTIFERON

Effective August 11, 2008, the MLabs Chemical Pathology Laboratory has changed the collection method for the QuantiFeron - TB Gold test.

The new system utilizes three special collection tubes provided by the manufacturer: gray top (NIL), red top (TB antigen), and purple top (Mitogen). Collection kits available from MLabs consist of an appropriate transport bag, the three collection tubes, and instructions for collecting the QuantiFeron samples.
**VGKC AND GAD65 TESTING**

Effective June 18, 2008, Voltage-Gated Potassium Channel (VGKC) and Glutamic Acid Decarboxylase (GAD65) Autoantibody testing have been added to the following Mayo Medical Laboratory Panels:

- VGKC and GAD65 have been added as reflex components of the Myasthenia Gravis Evaluation, Adult.
- VGKC and GAD65 are included as part of the Myasthenia Gravis Evaluation, Thymoma.
- VGKC is included as part of the Paraneoplastic Autoantibody Evaluation, Serum.

**VITAMIN B1, WHOLE BLOOD**

Effective July 10, 2008, Vitamin B1, Whole Blood, is sent to Mayo Medical Laboratories.

Collection Instructions: Collect specimen in a green top tube (sodium heparin) following an overnight (12 hour) fast. Freeze and send 5 mL intact whole blood specimen. Protect specimen from light. Do not freeze glass vacutainer tubes; collect in plastic vacutainer tube or transfer blood to a plastic tube prior to freezing.

Reference Range: 80 - 150 nmol/L.

**VITAMIN D 1,25-DIHYDROXY**

Mayo Medical Laboratories changed their test methodology for Vitamin D 1,25-dihydroxy to cartridge extraction/LCMS/MS effective June 2, 2008.

Collection Instructions: Collect blood in a red top or SST tube from a fasting patient (4 hour fast). Centrifuge, aliquot 1.5 mL of serum into a plastic vial, and refrigerate.

There will be a reference range change for this assay effective October 14, 2008:

Reference Range: <16 years: 24 – 86 pg/mL; Males >=16 years: 18 – 64 pg/mL; Females >=16 years: 18 – 78 pg/mL. Normal patients who have increased exposure to sunlight may have values above the normal range.

While 1, 25-dihydroxy vitamin D is the most potent vitamin D metabolite, levels of the 25-OH forms of vitamin D more accurately reflect the body’s vitamin D stores. Consequently, Vitamin D 25-Hydroxy (order code 25HD) is the preferred initial test for assessing vitamin D status. However, in the presence of renal disease, 1, 25-dihydroxy vitamin D levels may be needed to adequately assess vitamin D status.

**Discontinued Tests**

**CYTOMEGALOVIRUS CULTURES & SHELL VIALS**

The MLabs Virology Laboratory no longer performs Cytomegalovirus Cultures or Shell Vials on blood or bone marrow specimens. Cytomegalovirus DNA by PCR, Quantitative, is performed in place of culture for blood specimens.

**RUBELLA VIRUS ANTIBODY, IGM**

Effective July 1, 2008, Mayo Medical Laboratories has discontinued Rubella Virus IgM Antibody testing.

MLabs and Mayo Medical Laboratories will no longer forward specimens for rubella IgM-class antibody testing. If acute rubella or Congenital Rubella Syndrome (CRS) is suspected, it is recommended to communicate with your state health laboratory or the CDC to evaluate your patient. Michigan clients may contact the MDCH Bureau of Epidemiology at 517-335-8165 for assistance in evaluation of your patient.

In 2005, the Centers for Disease Control and Prevention (CDC) announced the absence of endemic transmission of rubella in the United States, largely due to successful vaccination programs. Fewer than 10 cases of rubella were reported in 2004, and the majority of these cases occurred in individuals born outside the United States. The incidence of congenital rubella syndrome (CRS) has also been significantly reduced, with a total of 4 cases of CRS being reported to the CDC during 2001-2004.

Given the low prevalence of rubella in the United States, routine serologic testing for IgM-class antibodies to this virus may yield false positive results, which can negatively impact patient care. This is especially problematic when rubella IgM testing is included in the routine screening of asymptomatic, pregnant women.

Rubella Virus Antibody, IgG will continue to be available for the determination of immune status to rubella.
MLabs Q & A

WHEN DOING EMPLOYEE HEALTH SCREENS FOR RUBElla, RUBEOla, MUMPS AND VARICELLA, ARE TITERS NECESSARY WHEN THE SCREEN IS POSITIVE?

Question answered by Duane Newton, Ph.D., Director of MLabs Microbiology and Virology Laboratories

The term “titer” when applied to serology testing pertains to the quantitative level of antibody present in a sample that is directed against the target of interest. Historically, detection of antibodies directed against Rubella virus, Mumps virus, Rubeola virus, etc. was performed using manual, labor-intensive methods (such as immunofluorescence or hemagglutination assays). By performing serial dilutions of the patient’s serum sample, a quantitative value, or titer, could be reported using these methods. Virtually all clinical serology testing being performed currently has migrated to some type of instrument performing enzyme immunoassays (EIA) for qualitative detection of antibodies. Although this provides only an answer of “antibody detected” or “antibody not detected,” the benefits of using these methods on automated instruments allows for increased throughput, improved sensitivity and specificity, and shorter turnaround-time for reporting results. The thresholds for positivity for these EIAs have also been correlated to quantitative titers determined using the conventional methods so that the positive and negative qualitative results are clinically appropriate. MLabs often receives requests to test for “antibody titers,” which is most often due to the carryover in historical terminology used for performing serology testing rather than a true clinical need or desire to determine quantitative antibody levels. Qualitative testing performed by MLabs for the viruses mentioned above do not require additional follow-up testing using quantitative methods because 1) for negative samples, quantitative testing will not increase the sensitivity, and 2) for positive samples, the threshold for positivity correlates with clinically relevant (i.e., protective) levels of antibodies, so quantitative testing will not provide any additional information.

MLabs News

U-M DEPARTMENT OF PATHOLOGY NEWS

Congratulations are to be extended to Thomas M. Annesley, Ph.D., Professor and Director, Drug Analysis and Toxicology. Dr. Annesley received the “Presidential Citation of the National Academy of Clinical Biochemistry” - the elected academy of the American Association of Clinical Chemistry (AACC) - and the inaugural award for “Outstanding Contribution to Clinical Mass Spectrometry”.

Suzanne H. Butch, MA, MT(ASCP)SBB, Administrative Manager of the Blood Bank & Transfusion Service was installed as president of the honorary fraternity Alpha Mu Tau. The mission of Alpha Mu Tau is to recognize persons who have made outstanding professional contributions to the field of clinical laboratory science and to enhance the profession by providing scholarships to support educational endeavors.

Jeffrey Myers, M.D., Dan Visscher, M.D., and Ul Balis, M.D. are prominently featured in the July 2008 issue of CAP Today’s story “Informatics to the rescue in fixing ‘blunt end’ AP errors”. The article highlights a number of initiatives in Anatomic Pathology including work flow redesign, hand off procedures, critical values reporting management and other informatics initiatives to improve efficiency and patient safety.