Department of Pathology

Annual Report 2011-2012

University of Michigan
Department of Pathology

University of Michigan
Department of Pathology

Department of Pathology 2012

University of Michigan Medical School Department of Pathology

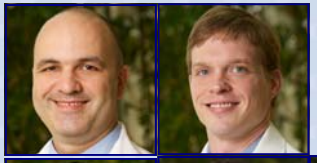
Jay L. Hess, M.D., Ph.D.
Carl V. Weller Professor and Chair

This has been another exciting year for the Department of Pathology. We have continued our focus on Service Excellence, working to improve patient care as well as the experience of being a member of the Department of Pathology. Our capabilities in the area of personalized medicine expanded with the launching of Paradigm, a sequencing-based diagnostic company to provide next generation sequencing services for care of cancer patients and to support clinical trials. In concert, we have been actively revising our clinical training programs to better prepare our residents, fellows and faculty for the exciting age of genome-wide molecular diagnostics that is upon us.

Paradigm

A non-profit joint venture with International Genomics Consortium to provide sequencing-based diagnostics

We saw a major expansion of our Anatomic Pathology (AP) faculty with the recruitment of Drs. Aleodor Andea and Paul Harms in dermatopathology, Rohit Mehra and Scott Tomlins in genitourinary pathology and Drs. Fancisco Diaz, Leigh Hlavarty, Carl Schmidt, and Lokman Sung in forensic Pathology. Avneesh Gupta, Kilak Keesha and Allecia Wilson be joining our Forensic Pathology team in July 2013. Clinical Pathology also significantly added to its ranks. Dr. David Keren rejoined us as Associate Director of the Clinical Laboratories after more than twenty years as an Adjunct professor and Medical Director of Warde Laboratories. Dr. Jo-Anne Vergilio and Nathanael Bailey joined the Department in hematopathology and Dr. Michael Bachman in molecular microbiology. In the Division of Sponsored Research, our newest addition, Dr. Andrew Muntean will join an interdisciplinary group working to develop better therapies for acute leukemia. Dr. Douglas Fullen took over as full time Director of Dermatopathology, succeeding Dr. Lori Lowe who has served ably in that position since 1996, and Dr. Michael Roh assumed leadership of Cytopathology following Dr. Claire Michael's departure for a new opportunity at Case West-



Drs. Aleodor Andea, Paul Harms Rohit Mehra & Scott Tomlins joined our Anatomic Pathology Faculty in FY 2012

Drs. David Keren, Nathanael Bailey and Jo-Anne Vergilio joined our Clinical Pathology faculty in FY 2012

Introducing Our New Faculty

Drs. Michael Bachman and Andrew Muntean joined our Research Faculty in FY 2012

Drs. Francisco Diaz, Leigh Hlavarty, Carl Schmidt and Lokman Sung joined the Department in FY 2012 as part of the Forensic Team serving Wayne County.

Department of Pathology

- **Anatomic Pathology**
- **Clinical Pathology**
- **Pathology Education**
- **Pathology Informatics**
- **Sponsored Programs**
- **Translational Research**
- **Michigan Center for Translational Pathology**
- **MLabs Outreach Programs**
- **Ann Arbor VA Health System Laboratories**
- **Finance and Administration**

ern University. We also will be bidding farewell to Dr. Peter Lukas, who has served as Assistant Director of the Residency Program and who will be succeeded by Dr. Scott Owens in that important role and to Dr. Kent Johnson who will be moving to Emeritus status after a long and distinguished career with the Department.

The number of cases processed in AP fell slightly (0.9%), likely due in part to the reduced activity associated with the implementation of Mi-Chart EMR. The Clinical Laboratories performed 5.8 million billable procedures, a 2% increase over FY11. Of note, through a concerted effort involving multiple departments, our blood product expenses declined from 13.3 to 12.8 million, and our sendout costs expenses, when normalized for overall activity declined for the fourth straight year. This year also saw the introduction of a number of new technologies into the labs. The microbiology laboratory became one of fewer than ten hospital-based clinical labs to implement MALDI-TOF for the detection of microorganisms, allowing for the more rapid detection of "routine" organisms. The Clinical Chemistry laboratory installed four mass spectrometers for therapeutic drug monitoring. The Molecular Diagnostics laboratory continues to grow, with a 55% increase in specimen test volume.

Our investigators continued to generate important high impact work, particularly in the areas of biomarker discovery, epigenetics, drug discovery, aging, and inflammation. Our research funding grew from $16,126,924 to $17,016,938 with an improvement from 10th to 8th in NIH funding. Our graduate program in Cellular and Molecular Pathology continues to thrive and attract top tier candidates under the able leadership of Dr. Nicholas Lukacs.

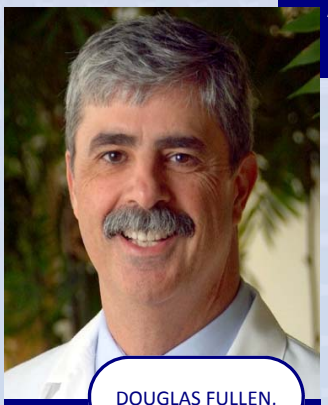
While there are many positive developments, we are facing challenging times ahead in the healthcare system. The opening of Mott Hospital and implementation of MiChart, among other initiatives, is putting a significant drag on the UMHS operating budget. We also face the possibility of sequestration, reductions in indirect medical education and implementation of draconian sustainable growth rate intervention. One of the consequences of the down turn in financial performance as well as anxiety regarding the future is a delay in decision-making for the much needed clinical laboratories. With financial support for the NCRC, development and the medical school funding model, it will be more important than ever to strive for efficiency and to make sure that every investment we make maximizes our ability to achieve excellence in each of our missions.

Despite the challenges, it is a privilege to be a pathologist, particularly at a great institution like the University of Michigan. The opportunity to improve patients' lives has never been better. That is why we are here. I hope that you find this Annual Report to be a valuable resource for understanding the broad scope of work that is done in this outstanding Department.

Jay L. Hess M.D. Ph.D.

SCOTT OWENS, M.D.

Associate Director
Residency Programs



DOUGLAS FULLEN,

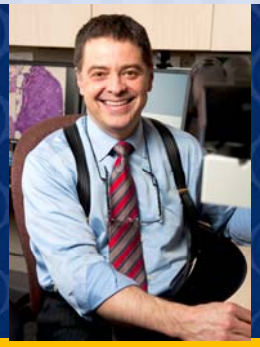
Director of
Dermatopathology

MICHAEL ROH, M.D.

Director of
Cytopathology

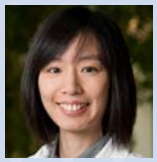
Division of Anatomic Pathology

Jeffrey L Myers, M.D.
A. James French Professor of Pathology
Director, Division of Anatomic Pathology
Director, MLabs Outreach Program



Anatomic Pathology continues to experience significant growth in service matched by ongoing success in recruiting faculty. Education and research missions remain strong with sustained successes in, 1) recruiting to a growing portfolio of subspecialty fellowships, 2) funding research programs and collaborative projects, 3) peer-reviewed publications, and 4) expanding and maintaining a national and international presence as opinion leaders, educators, and clinician scientists.

Practice growth combined with attrition continues to drive faculty recruitment efforts. Dr. May Chan (Assistant Professor) and Dr. Julie Jorns (Assistant Professor) joined the faculty in July 2011 to meet needs in dermatopathology and breast pathology, respectively. Both were replacement positions. Dr. Amer Heider (Assistant Professor) arrived in September 2011, joining Dr. Raja Rabah as a core member of our pediatric pathology group.



May Chan, MD
Dermatopathology

Julie Jorns, MD
Breast Pathology

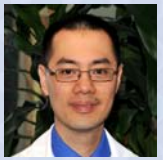
Amer Heider, MD
Pediatric Pathology

In addition, integration with the Wayne County Medical Examiners Office through a signed Professional Services Agreement brought four new fully credentialed faculty to our Center of Excellence in Forensic Pathology: Drs. Francisco Diaz (Clinical Lecturer), Leigh Hlavaty (Assistant Professor), **Carl** Schmidt (Associate Professor), and Lokman Sung (Clinical Lecturer).

Francisco Diaz, MD

Leigh Hlavaty, MD

Carl Schmidt, MD



Lokman Sung, MD

These will be joined by Avneesh Gupta, MD and Kilak Keesha, MD in July 2012 and Chantel Njiwaji, MD and Allecia Wilson, MD in August 2012.

Additional faculty were recruited in the last two quarters of FY2012 and will join the faculty in July 2012 as listed below.

Aleodor Andea, MD
Dermatopathology

Paul Harms, MD
Dermatopathology

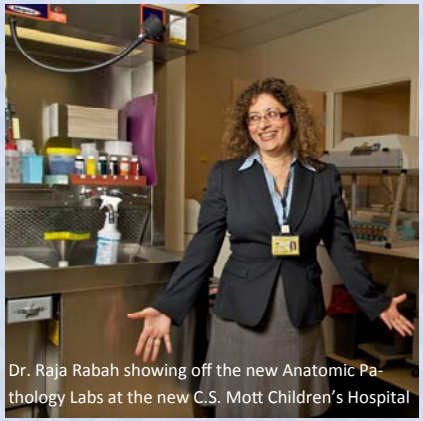
Rohit Mehra, MD
GU Pathology

Scott Tomlins, MD, PhD
GU Pathology

Anatomic Pathology

- Surgical Pathology
- Pediatric Pathology
- Dermatopathology
- Neuropathology
- Medical Renal Pathology
- Cytopathology
- Autopsy and Forensic Pathology

Safety, quality, and service remain high priorities in anatomic pathology. Our All Faculty and Staff Quality Assurance meetings remain an important vehicle for driving Lean principles and tools into our clinical operations. AP leadership and management participated in launch of a departmental service excellence initiative.


Dr. Raja Rabah showing off the new Anatomic Pathology Labs at the new C.S. Mott Children's Hospital

In the second quarter, we moved into new office and laboratory space in the new C.S. Mott Children's Hospital. This required shift in not only faculty but also laboratory and administrative personnel. As a consequence we are much better positioned to be more tightly integrated into a multidisciplinary model for providing age-appropriate care to our Mott Hospital patients and families. It is especially important that we can now offer onsite support for intraoperative consultations.

Education programs remain strong as demonstrated by ongoing successes in existing fellowships, recruitment of a very strong residency alumnus to a recently accredited fellowship in Pediatric Pathology, and applications for new fellowships in Neuropathology and Forensic Pathology. AP faculty continue to play key roles in support of our residency program and in medical school teaching, accounting for over 430 hours of contact time with University of Michigan 1st, 2nd, and 4th year students.

Success and vitality in our research activities remains very strong as evidenced by continued visibility in high-impact peer-reviewed journals. AP faculty contributed over 180 publications to the peer-reviewed literature, a 17% increase compared to the year before. Despite an increasingly challenging funding climate, research expenditures remained steady at 1% above FY2011 levels.

CLINICAL ACTIVITIES

Surgical Pathology

Dr. David Lucas led the Surgical Pathology section again this year. A total of 88,940 pathology specimens, including a combination of intramural and extramural cases, were processed in 2012 compared to 89,785 in 2011 and 80,690 in 2010. This represents a 0.9% decrease compared to FY11 but a 10.2% increase over the last two years and nearly 30% (27.1%) compared to FY07. Among our "inside" surgical pathology practices only our breast (BE) and pediatric (IP) services saw substantial increases of 12.8% (253 cases) and 19.6% (357 cases) respectively. The total number of patient specimens acquired from procedural areas within the UMHHC was nearly unchanged from the previous year and accounted for 66.8% of cases. In contrast outside ("transfer") cases reviewed for patients referred to UMHS for care grew at an annual rate of 10.3%. The number of extramural consultation totaled 10,976 compared to 10,598 in FY11, reflecting a 3.6% annual increase.

Faculty productivity increased despite relatively flat case volumes. Expressed as a 12 month rolling average, faculty generated an average of 636 RVUs/FTE/month in June 2012 compared to 612 RVUs/FTE/month in June 2011. This continues to reflect disproportionate impact of RVUs compared to case accession numbers (*i.e.* ↑RVUs/case) in several key surgical pathology services.

Pediatric and Perinatal Pathology

The pediatric and perinatal pathology service continued to flourish under the leadership of **Dr. Raja Rabah**. Dr. Amer Heider joined the faculty as a core member of our pediatric and perinatal pathology team in September 2011. A brand new state-of-the-art anatomic pathology laboratory opened in the new C.S. Mott Children's Hospital in December 2011, and Drs. Rabah and Heider moved to offices in the new hospital. This move provided the department of pathology and the pediatric perinatal pathology team more visibility and greater opportunities to interact more closely with our clinical colleagues resulting in improved care for our young patients.

As summarized in Table 1, pediatric surgical cases grew at an annual rate of nearly 20%, accessioning 2,177 cases from the Mott Hospital ORs as well as a number of transfer cases and staging bone marrows. Although the pediatric case volume is increased, the TAT is showing continuous improvement as depicted in **Fig 1**. Case volume and TAT for placentas remained steady as shown in **Fig 2**.

In addition to the surgical cases, the service covers all pediatric autopsy cases from Mott and, effective January 2012, all fetal examinations. Thirty seven pediatric autopsies and 43 fetal examinations were done through

June 2012.

Table 1: Pediatric Pathology Clinical Activity, FY10 – FY12

	FY10	FY11	FY12	%
Peds (IP)	1655	1820	2177	19.6%
Placentas (PL)	1166	1478	1456	(1.5%)

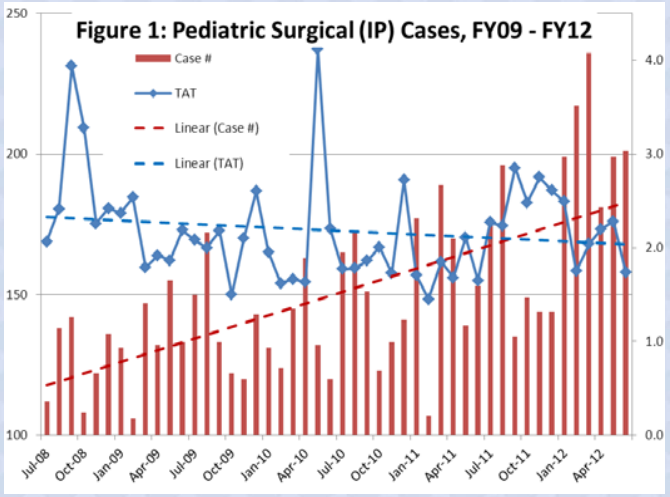


Figure 1 – Pediatric surgical (IP) case volumes increased nearly 20%. Despite increased workload, service levels held steady with average turnaround times of less than 2 days

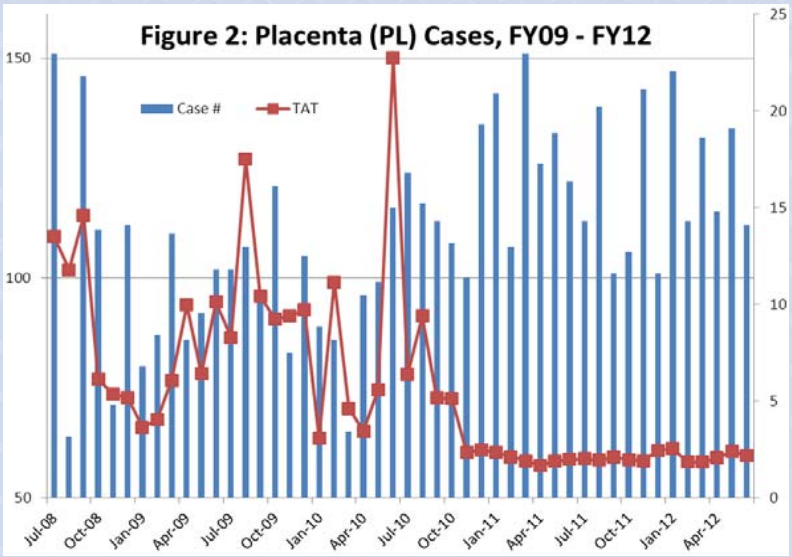


Figure 2 – Placenta (PL) case volumes were largely unchanged with sustained service delivery levels (mean turnaround time around 2 days).

The team participated in over 150 multidisciplinary and teaching conferences at Mott and Women's Hospital and over 600 patients were discussed. Over 40 pediatric autopsy cases were reviewed in several morbidity/mortality meetings and grand rounds with different pediatric/perinatal subspecialties.

Dermatopathology

The Dermatopathology Service receives diagnostic case material from four primary sources: (1) UMMC (ID) cases; (2) outside contractual (MD) cases; (3) outside cases reviewed for referred patients (TD); and (4) personal consultation cases.

The Dermatopathology Service continues to be a high volume service (**Table 2**) and has seen substantial growth over the last two years driven primarily by outside (MD) and transfer (TD) cases. Combined with modest growth in UMMC (ID) cases this offsets a small decrease in consultation cases over that same time period to result in a net increase of 16.1% in FY12 compared to FY10.

Table 2: Dermatopathology Clinical Activity, FY10-FY12

	FY10	FY11	FY12	% change (FY11 - FY12)	% change (FY10 - FY12)
ID	13,168	13,441	13,716	2.0%	4.2%
MD	5,269	9,691	7,412	(23.5%)	40.7%
TD	1,958	2,828	3,566	26.1%	82.1%
Consults	2,410	2,106	2,263	7.5%	(6.1%)
TOTALS	22,805	28,066	26,957	(5.7%)	16.1%

Doug Fullen and **Lori Lowe** served as Co-Directors of Dermatopathology through FY2012. Drs. Alexandra Hristov (UCSF) and May Chan (Harvard) joined the faculty in June and August 2011, respectively. In the last quarter of FY11, the same search committee that successfully recruited Drs. Hristov and Chan also recruited Dr. Aleodor Andea to an incremental position intended to support practice growth and create a new Dermatopathology Molecular Research Laboratory (DMRL) as part of a strategy to establish our dermatopathology practice as a center of excellence for molecular diagnostics applied to cutaneous malignancies. Dr. Andea joined the faculty in the first quarter of FY2013 as Director of the MPRL and will also serve as Director of our Dermatopathology Fellowship beginning in

January 2013. In addition, Dr. Paul Harms, a graduate of our dermatopathology fellowship training program, was appointed as Clinical Lecturer effective July 1, 2012. Dr. Harms will fully participate in the dermatopathology service while also pursuing research projects in the laboratory of Dr. Arul Chinnaiyan. In addition to his full-time dermatopathology service responsibilities, Dr. Rajiv Patel participates in the soft tissue and orthopedic pathology service. Dr. May Chan participates in the general surgical pathology ("Room 1") service.

We continue our active involvement in the University of Michigan Multidisciplinary Melanoma Clinic (MDMC) and Tumor Board, Multidisciplinary Cutaneous Oncology Clinic (MCOC) and Tumor Board, Cutaneous Lymphoma Conference and Tumor Board, and the University of Michigan Cutaneous Oncology "Destination" Program. Dermatopathology plays an integral role in all of these programs.

Neuropathology

Sandra Camelo-Piragua, Constance D'Amato, Andrew Lieberman and Paul McKeever contributed to the Neuropathology Service. Ms. D'Amato is Active Emeritus.

There were just over 1200 neurosurgical cases examined this year, including 230 personal consultation cases (see Figure 3). The nerve and muscle biopsy service is now staffed by Drs. McKeever and Camelo-Piragua. Inside (IB) and outside (MM) nerve and muscle biopsies declined by -8.0% (15 cases) and -16.4% (35 cases), respectively. This was offset by a 3.7% (24 cases) increase in UMHS surgical cases and a 66% (91 cases) increase in consultation cases for an overall annual growth rate of 5.4%. The Brain Tumor Board of the University of Michigan Cancer Center and Hospitals, supported weekly by a neuropathologist, reviewed more than 150 neuro-oncology patients with challenging diagnostic evaluations. Also supported by the neuropathology service was a weekly neuromuscular disease conference and monthly neurosurgery CPC.

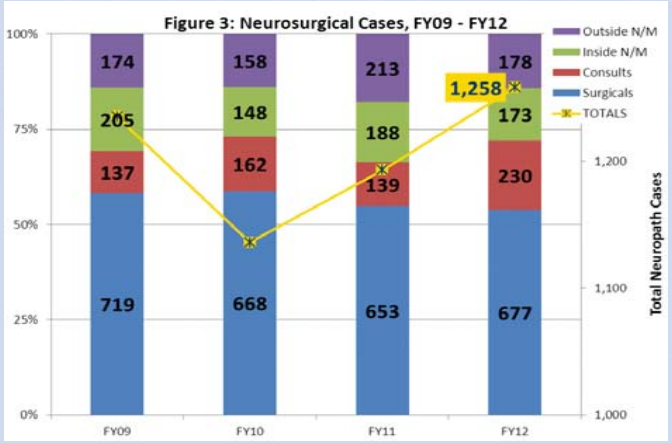


Figure 3 – Neuropathology Case Volumes, FY09-FY12

Neuropathology case volumes grew at an annual rate of just over 5% due mainly to growth in UMHS surgicals and consultation cases.

There were 223 University Hospital brains examined at autopsy. Of these, 53 brains were examined at formal Brain Cutting Conference. Also examined at Brain Cutting Conference were 17 cases of chronic neurodegenerative disease referred by the Michigan Alzheimer Center. Beginning in June 2012 brain cutting occurred weekly and was staffed on a rotating basis by all three neuropathology faculty with the goal of shortened turnaround time for CNS autopsies. Consensus conference was expanded to twice weekly to enable rapid turnaround of difficult cases.

The neuropathology faculty taught medical students during the M2 neuroscience sequence and house officers, including an evening introductory course in diagnostic neuropathology. A fellowship in neuropathology was accredited and recruitment is underway to fill this spot for a July 2013 start.

Medical renal pathology

Led by **Dr. Paul Killen**, our renal biopsy service continued to show strong growth, accessioning 1,166 cases in FY12 compared to 984 in FY11 (18.5% annual growth rate) and 641 in FY07 (81.9% growth over 5 years). Growth in practice was driven in large part by a change in protocol for managing UMHS renal transplant patients launched in FY11. Whole slide scanning remains an aspirational goal as a method for archiving and virtual review of biopsies from renal transplant patients.

Dr. Kent Johnson, Professor of Pathology and long time member of the faculty primarily responsible for the renal biopsy service, transitioned to Active Emeritus

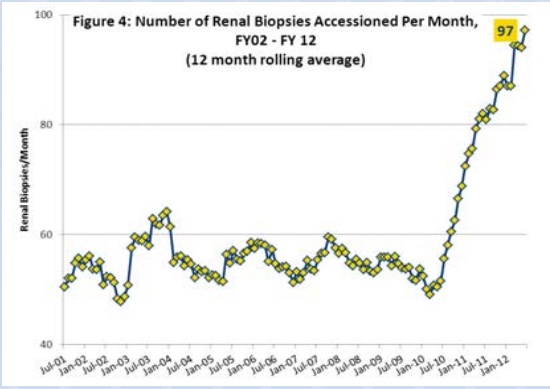


Figure 4. Renal biopsies continued to show strong growth beginning in July 2010 as a consequence of a change in protocol for managing transplant patients. Expressed as a 12 month rolling average, we are now accessioning nearly 100 cases monthly.

status at the end of FY12. A search committee under the leadership of Dr. Paul Killen, Head of our Renal Biopsy Service and Director of Electron Microscopy, is actively recruiting to address the gap created by Dr. Johnson's retirement.

Cytopathology

A number of transitions occurred in cytopathology in the course of FY2012. **Dr. Michael Roh** assumed leadership responsibilities as Director of Cytopathology, Medical Director of the Cytopathology Laboratory, and Program Director for the Cytopathology Fellowship, on an interim basis January 1st and permanently effective July 1, 2012. After 17 years of service, Dr. Claire Michael stepped aside from all leadership positions at the end of the 2nd Quarter and resigned from the department at the end of the 4th Quarter to take a leadership position in the Department of Pathology at Case Western University. Dr. Stewart Knoepp resigned in the 2nd Quarter to enter community practice in the region. Amer Heider joined the Division in September 2011 with a primary focus in pediatric pathology but a secondary focus in cytopathology. A search committee under the leadership of Mike Roh continues to actively recruit to an open position.

Brian Smola continues to serve as interim supervisor while Kalyani Naik remains on temporary leave to play a lead role in implementing the Soft LIS system in Pathology Informatics. Brian is a member of the LIS build team and actively involved in building and implementing the new Soft LIS system.

Total gynecologic specimens for the year were 32,866; a 3.4% decrease from last year (**Table 3**). This is in line with the expected national average decrease as a result of changes in follow-up Pap test recommendations for women with negative HPV.

Table 3: Cytopathology Clinical Activity, FY10-FY12

	FY2010	FY2011	FY2012	% change
Gyn Total	36392	34014	32866	(3.4%)
Non-Gyn Total	9398	9812	9664	(1.5%)
Non-Gyn Exfoliative	6867	7123	7034	(1.3%)
ASP Total	2531	2604	2630	0.9%
ASP 1	977	962	862	(11.6%)
ASP 2	1276	1423	1526	6.8%
ASP 3	278	219	242	9.5%

Non-gynecologic specimens numbered 9,664 a 1.5% decrease from last year. Exfoliative non-gyn specimens totaled 7,034, a 1.3% decrease from last year. Fine needle aspirations (FNAs) totaled 2,630, a 0.9% increase from last year. FNAs performed at the Cancer Center (ASP3) numbered 242, representing a 9.5% increase from last year; assisted FNAs (ASP2) numbered 1,526 a 6.8% increase from last year while aspirates performed by clinicians without our assistance (ASP1) numbered 862 representing a 11.6% decrease from last year. This continued increase in the assisted FNAs reflects our continuous communications with our clinical colleagues reinforcing the value of cytology assistance on site and its impact in the improved outcome for the patients. It also reflects an increased demand on laboratory personnel, cytotechnologists, fellows and faculty to provide the needed service.

Cytology continued to focus on maintaining high service delivery levels as summarized in **Table 4** and continued to employ Lean principles and tools in laboratory management.

Table 4:

Cytopathology Turnaround time (7 day week)

	FY10	FY11	FY12
GYN	3.8	4.0	5.1
NGYN/FNA	1.7	1.7	1.5

Summary of Lean Activities and Service Initiatives in Cytopathology

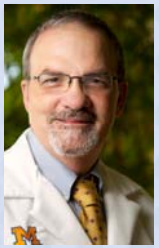
- A team consisting of Brian Smola, Kent Traylor, Jeanette Gohl, Michael Roh and Stewart Knoepp evaluated the current process of reporting cytopathology and proposed a different work flow process that has the potential of improving transcription turn-around time; reduce lost requisitions and the rate of addendums and transcription corrections. The proposed changes were piloted near the end of the 2010-2011 and were implemented smoothly during 2011-2012.
- Cytopathology staff actively participated and presented at AP QA meetings.
- In follow-up to an inventory management value-stream map done in the past, with collaboration from our website committee, Kalyani Naik and Brian Smola developed a web-based inventory management sys-

tem that is currently in use. The idea, then in its development stage, was presented at the quality assurance meeting and was presented again in completed form. The web-based tool will provide not only Cytopathology, but the entire department with an effective and efficient tool for ordering and, more importantly, tracking of those orders.

- A web-based solution is currently being discussed with the Pathology Web Committee for all daily QA/QC activities such as stain QC, refrigerator temperature, equipment maintenance, etc. Brian Smola developed an Excel based solution to a multiple paper log system and presented to the Web Committee on July 9th. The program will be user defined with the hope that other departments may also participate.
- Laboratory staff continues to be actively engaged in problem solving and practicing Lean thinking in a standardized manner utilizing the A3 and root cause analysis tools. Volunteers are sought to lead small groups to study any individual problem and develop an A3. A 10 minute discussion is devoted in our monthly laboratory operations meeting for the presentation of each A3.
- A "leaner and greener" approach to triage of appropriate ThinPrep Pap test vials for HPV testing was formulated and is being piloted at the current moment. This countermeasure was enacted in response to a low but finite number of errors in inadequate identification of all ThinPrep Pap test vials for HPV testing triage in a timely manner. Data is being collected to compare error rates with the prior and current protocols.

In collaboration with the breast pathology service, cytotechnologists continue to be involved in utilizing the VIAS system for scoring ER/PR and Her2Neu expression in breast tumors. As of January 2011, Brian Smola and Julie Jorns led the training of our cytotechnologists. A total of 4 cytotechnologists are currently trained (Sue Clozza, Binita Naylor, Kim Luckett, Brian Smola) and are performing scoring on approximately 750 breast biopsies annually.

The end of FY12 marks the three-year anniversary for the implementation of the telecytology program designed to cover the endocrinology/thyroid fine needle aspiration program from Domino's Farm. The onsite adequacy assessment via the web was successfully implemented with no major difficulties and continues to grow 3 years later. The service has grown to involve two procedure rooms at Domino's Farms which operates two days per week. This requires the commitment of one cytotechnologist for about 4-6 hours in 6-10 days per month.



Autopsy and forensic services

FY2012 continued to be a time of change for our autopsy practice under the leadership of **Dr. Jeffrey Jentzen**, Director of Autopsy and Forensic Services. This section continues to provide faculty and resident support for both UMHS and the VA hospital, while also supporting forensic pathology, autopsy and death scene investigation for the Washtenaw County Medical Examiner (WCME).

Effective October 2011 the Director of Autopsy and Forensic Services also assumed responsibilities as Chief Medical Examiner for Washtenaw County. In September 2011, the Washtenaw County Medical Examiner Office attained accreditation by the National Association of Medical Examiners (NAME). It is one of only sixty offices in the United States to have attained full accreditation. In addition, all eight of the medical examiner death investigators earned certification by the American Board of Medicolegal Death Investigators (ABMDI).

The Director provides autopsy coverage for 30-40 percent of days and the remainder is distributed among eight other faculty. The coordinator of the autopsy service is assisted by two FTE autopsy assistants who also contribute to on-call coverage. A dedicated Administrative Assistant provides

The Wayne County Medical Examiner's Office has new, state–of-the-art facilities in Detroit, MI with plenty of natural light in which to work.

clerical, administrative, and computer support. Another member of the staff monitors the on-line death investigation software, MDIog, completes all death certificates, and provides administrative coverage for the medical examiner. This has facilitated centralization of all death certificates and provided additional support for the autopsy and forensic services.

A total of 520 autopsies were performed in FY2012 in the UM morgue, compared to 516 in FY2011. The 520 autopsies included 207 UMHS autopsies, up just over 11% from 186 in FY2011. The UMHS hospital autopsy percentage rate increased from its previous level of 15.8% in FY2011 to 19.4% in FY2012. A total of 313 autopsies and 20 external examinations were performed for the WCME, an increase of 20% over the previous year.

Effective October 2011, the autopsy section contracted with the Wayne County Medical Examiner Office (WCMEO) to provide professional forensic pathology services and to process histology and toxicology specimens from the office. This collaboration greatly enhances our role as one of the top centers of forensic pathology in the country. This required the recruitment of four additional forensic pathologists who will join the existing four pathologists at WCMEO in the first quarter of FY2013. Dr. Carl Schmidt will continue to serve as the Chief Medical Examiner for Wayne County. From January through June 2012, the Wayne staff pathologists performed 996 autopsies and 301 inspections.

For the third year, the Department sponsored Advances in Forensic Medicine and Pathology, a two-day conference on topics related to advances in death investigation. The conference attained its highest attendance at 125 and received superior evaluations from the participants.

Improvement initiatives of the section continue to revolve around autopsy turnaround time and communication with the clinical staff. Gross pathological diagnoses are routinely communicated to the clinical staff immediately following completion of the autopsy. We continue to work with the office of Decedent Affairs and Risk Management to improve the autopsy service to the UM hospital patients. A major goal for the Wayne Office will be to attain NAME accreditation in the coming year.

Application for an ACGME accredited forensic fellowship is in process with the intent of transitioning the Wayne County fellowship program to the University of Michigan for July 2013. The fellow will obtain training and experience in all aspects of forensic medicine including toxicology, criminology, forensic anthropology, forensic pathology, and courtroom testimony. The forensic autopsy experience will be augmented with cases from the WCMEO.

RESEARCH ACTIVITIES

The Anatomic Pathology faculty remains remarkably productive despite the demands of patient care (**Table 5**). Despite an incomplete dataset, twenty seven faculty reported an average of 6.8 (median 6) peer-reviewed publications for a total of 184 papers either in print or in press at the end of FY2012 compared to 5.1 (median 5) in FY2011. This reflects a 17.2% increase compared to a year ago. In addition, faculty reported the results of their work in abstract form on 111 occasions, a 23.3% increase over last year. Twenty-eight faculty served as invited lecturers, speakers or visiting professors on 101 occasions, for an overall average of 3.6 (median 3) per participant. Clearly, our faculty remain top-of-mind when looking for cutting edge speakers in anatomic pathology. In addition, fifteen different faculty reported being members of 34 editorial boards, including a Senior Editor for *Cancer Research* as well as Associate Editor for *Clinical Cancer Research and Laboratory Investigation* (Dr. Kathleen Cho), and Associate Editor for *BMC Cancer* (Dr. Celina Kleer).

Table 5: Academic Productivity in AP, FY10-FY12

	FY2010	FY2011	FY2012	% change
publications	176	157	184	17.2%
abstracts	80	90	111	23.3%
invited lectures	108	120	101	(15.8%)
editorial boards	27	29	34	17.2%
FTEs funded	4.5	4.9	4.5	(9.7)
research expenditures	$3,473,969	$4,125,489	$4,167,734	1.0%

Research expenditures remained strong despite strong pressures on extramural funding, reflecting 38.1% growth compared to FY2006 and nearly recovering to FY2009 levels (**Figure 5**). The total number of funded FTEs showed minor downward fluctuation, dropping from 4.9 to 4.5, sustaining the gains realized in FY2010 compared to FY2009 (3.9 FTEs) and FY2008 (3.6 FTEs). Maintaining this level of funding in today's environment reflects the remarkable success of our laboratory investigators, all of whom also have substantial commitments to patient care.

AP funding accounted for an additional $51,515 allocated in support of projects in which AP faculty and trainees served as Primary Investigators (**Figure 6**). This reflects a 39.4% increase compared to FY11 but a 44.1% drop compared to peak spending in FY07, the first year of the AP Project Funding Program.

We hosted our third Annual Research Day on February 18, 2012 in collaboration with Hematopathology and Molecular Pathology. The day included 33 abstracts presented as posters (25) and platforms (8). Our Keynote Speaker was Dr. Christopher Corless from Oregon Health and Science University. The target audience was departmental trainees and faculty with the goal of increasing collaboration and projects.

The Molecular Pathology Research Laboratory (MPRL) continues to be an important asset for faculty in AP. Funded projects executed with support from the MPRL in which AP faculty were either Primary Investigators or collaborators were well represented at our Annual Research Day and also resulted in multiple abstract presentations at the 2012 Annual Meeting of the USCAP as well as manuscripts in press or in print in peer reviewed journals.

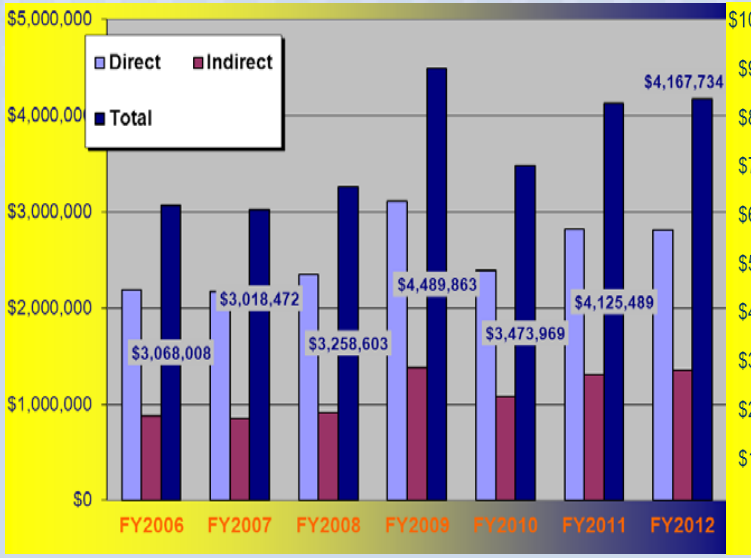
Drs. Rich Lieberman and Peter Lucas were promoted to Associate Professor, and Celina Kleer to Professor of Pathology effective September 2011.

EDUCATIONAL ACTIVITIES

Education is an essential and vibrant component of our mission. Anatomic Pathology continues to provide a robust experience for trainees, including standard rotations in autopsy, surgical and cytopathology as well as required and elective rotations in various subspecialties. Fellowships in breast pathology (1), cytopathology (2), gastrointestinal pathology (1), dermatopathology (2), genitourinary (1), pediatric (1), pulmonary (1) and surgical pathology (3) were filled by competitive candidates in the 2011-2012 academic year. In the coming fiscal year our portfolio of fellowships will expand to include forensic and neuropathology. Trainees continued to actively participate in various research projects during the course of the year and served as authors or co-authors for 26 different abstracts presented at the 2012 annual spring meeting of the USCAP in Vancouver.

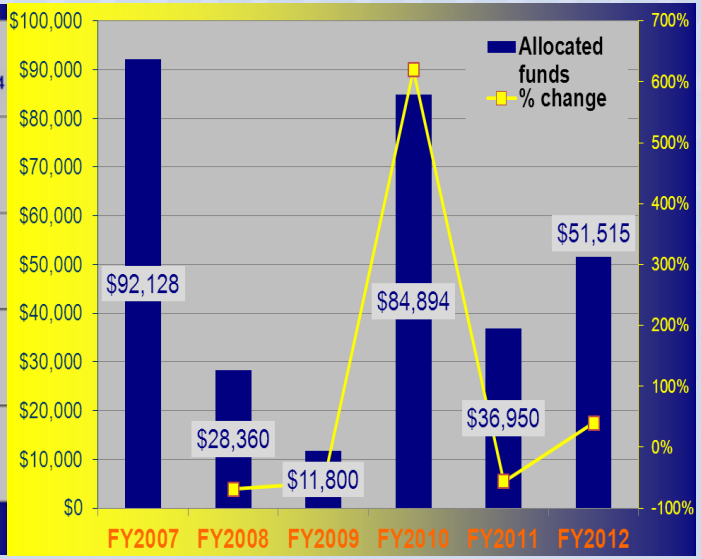
Educational programs within our autopsy and forensic services continue to benefit from our integrated hospital and medical examiner service. Residents complete three one-month rotations on the autopsy service to comply with ACGME autopsy requirements. Medical students receive exposure to autopsies during their second year. A one-month rotation dedicated to forensic medicine is offered to senior medical students. Educational conferences in autopsy pathology include a weekly autopsy gross conference, a monthly extended gross conference emphasizing clinico-pathological correlations, and presentations in mortality conferences serving the clinical services within the hospital. A monthly didactic forensic

Figure 5 – AP Research Expenditures, FY06 -FY11



Research expenditures remained steady in FY12 compared to FY11, reflecting a nearly 40% increase since FY2006.

Figure 6 – AP Project Funding, FY07 -FY12



Funding for AP Projects grew slightly in FY12 compared to FY11 to a total of $38,500.

pathology conference along with multidisciplinary forensic sign-out conference also is provided by the faculty.

Active and emeritus faculty in Anatomic Pathology continued to play significant roles in the medical school, accounting for just over 437 recorded contact hours. AP faculty had primary responsibility for first and second year courses in pathology as lecturers, laboratory instructors, advisers and mentors. In addition, two residents (Norah Frisch and Alero Inyang) and two fellows (Beatrice Lee and Allison Young) participated in M2 laboratories, logging a total of 10 additional contact hours. Electives for senior students remained popular and were supported by a number of active and emeritus AP faculty including Drs. Andy Flint, Julie Jorns, Amir Lagstein, Jon McHugh, Scott Owens, Judy Pang, Lindsay Schmidt and Angela Wu. Multiple faculty also participated in teaching dental students.

Nearly all faculty in Anatomic Pathology participate in supporting an impressive array of multidisciplinary conferences including Tumor Boards for bone and soft tissue, brain, breast, endocrine oncology, gastrointestinal, genito-urinary, gynecologic, liver, pediatric, and lung tumors. Faculty also regularly participate in various other conferences including brain cutting, dementia brain cases, diagnostic dermatology, cutaneous T-cell lymphoma, nephrology, nerve and muscle, multiple pediatric subspecialties (GI, hematology-oncology, lung, surgery) and adult non-neoplastic lung disease. Educational conferences targeting primarily pathology trainees in which faculty participate include weekly slide and didactic teaching sessions.

Four invited speakers visited our department through the *A. James French Visiting Professorship* (Ralph Hruban from Johns Hopkins, John Reith from University of Florida, Maria Merino from NCI, and Cheryl Coffin from Vanderbilt) each presenting a lecture and slide seminar.

Multiple faculty participated in our fifth on-campus CME workshop, *New Frontiers in Pathology*, presented in collaboration with the A. James French Society. Dr. Elaine Jaffe served as guest faculty and the A. James French Lecturer. We attracted over 100 attendees whose evaluations reflected high praise for the world-class quality of this annual event.

Our CME offerings included the third year of *Advances in Forensic Medicine and Pathology*, hosted in collaboration with the Washtenaw County Medical Examiner's Office in May 2012 at The Inn at St. John's in Plymouth, MI. Feedback was extremely positive and this will continue to be an annual component of our CME programs.

A. James French Visiting Professors

Ralph Hruban, M.D.

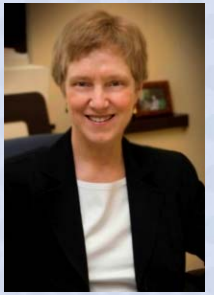
Johns Hopkins Univ.

John Reith, M.D.

U of Florida

Maria Merino, M.D.

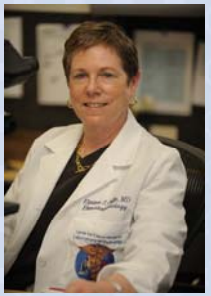
NIH/NCI.



Cheryl Coffin, M.D.

Vanderbilt Univ.

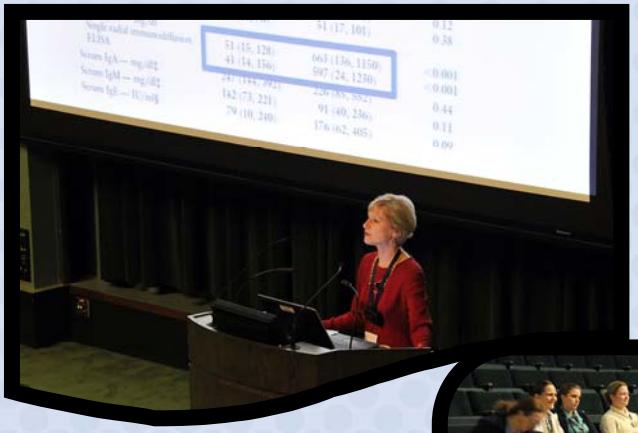
A. James French Lecturer



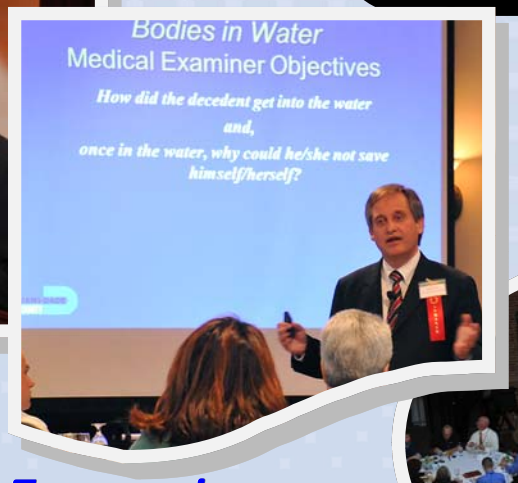
Elaine Jaffe, M.D.

NIH/NCI

Advances in Forensic Medicine and Pathology, May 2012



New Frontiers in Pathology



Advances in Forensic Medicine and Pathology

Division of Clinical Pathology

Jeffrey S. Warren, M.D.
Alfred S. Warthin Professor of Pathology
Director, Division of Clinical Pathology

The University of Michigan Health System (UMHS) Clinical Pathology Laboratories encompass Specimen Processing and the Sendout Laboratory; more than twenty UMHS off-site limited function laboratories, phlebotomy stations and point-of-care testing facilities; a 24 hours per day/7 days per week inpatient Phlebotomy Service; and full service hospital-based laboratories that include Hematology (which encompasses Special Hematology, Automated Hematology, Flow Cytometry, and Coagulation); Chemical Pathology (which encompasses Special Chemistry, Automated Chemistry, Immunology, Toxicology-Therapeutic Drug Monitoring, and Endocrinology and UMHS-wide point-of-care testing oversight); Cytogenetics; Microbiology/Virology (which includes Molecular Microbiology); the Blood Bank/Transfusion Medicine Service (which encompasses the Therapeutic Apheresis/Hematopoietic Progenitor Cell (HPC) Procurement Unit, and FDA-approved Good Manufacturing Process – compliant HPC Processing Laboratory, and an Immunohematology Reference Laboratory); Histocompatibility; and Molecular Diagnostics. The Clinical Laboratories and personnel provide extensive testing capacity and consultative/logistical support to the MLabs Program. Pathology Informatics, Specimen Processing, and Pathology Administration continue to provide logistical, operations, and regulatory support for the Pediatrics Biochemistry and Molecular Diagnostics Laboratories, Pediatrics Blood Gas Laboratories, and the Pediatrics Pulmonary Laboratory.

The Clinical Laboratories were again ably supported in many areas by the Division of Clinical Informatics directed by Dr. Ulysses Balis and managed by Ms. Kathy Davis. The overarching 2011-12 Clinical Informatics initiatives directly related to the Clinical Laboratories have included training and implementation of UMHS MiChart upgrade of the current LIS to Cerner 015 and guidance in the vetting and selection of a commercial document control system. While implementation of SCC/Soft as the new laboratory information system was postponed pending MiChart deployment, extensive procedure building and testing continued in preparation for implementation.

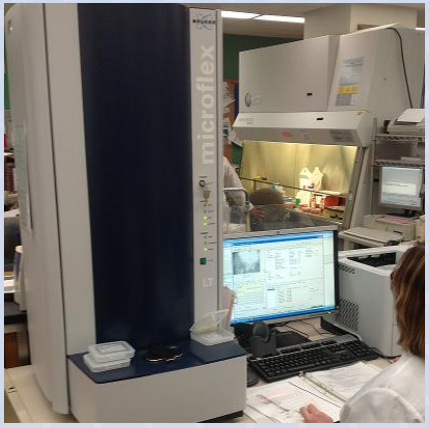
The Laboratories continued to experience growth in both clinical volume and scope of activity. Many of these advances are noted below and in greater detail within section reports. 2011-12 was marked by intensive focus on improvement of operations, service, and efficiency. 5.8M procedures (billed units) (>10M individual assays) were performed in FY 2012, a 2% increase over FY 2011 (5.6M). Gross laboratory revenue was $392M, an increase of 3% over FY 2011 ($373M). Clinical Pathology laboratory expenses increased from $35.4 to $36.4M. Blood product expenses decreased to $12.8M from $13.3M in FY 2011, while overall Pathology reference test (sendout) expenses were $7.1M (from $6.4M). Sendout reference testing expense, normalized for MLabs growth and overall UMHS clinical activity, decreased for the fourth consecutive year. The total number of Clinical Pathology Laboratory (and Phleboto-

Clinical Pathology Sections

- Blood BankTransfusion Medicine
- Chemistry
- Microbiology—Virology
- Hematology
- Specimen Processing
- Phlebotomy
- Cytogenetics
- Molecular Diagnostics
- Histocompatibility
- Immunology

my) employees at the end of FY 2012 was 511.

Many specific achievements within laboratories and by individual faculty members are detailed within individual laboratory reports and faculty annual reports, respectively. Major 2011-12 accomplishments included the successful occupation of the new Mott Children and Women's Hospital, establishment of a STAT laboratory within the Emergency Department, successful $500,000 above-threshold capital equipment acquisition for two new LC-MSMS analyzers and 2 new GC-MS analyzers in support of immunosuppressant drug monitoring, the procurement of space for Molecular Microbiology, initiation of a successful partnership with the Southeastern Michigan American Red Cross for highly productive blood procurement at UMHS sites, and successful completion of our biannual CAP self-inspection. The Histocompatibility Laboratory received platinum level sustainability recognition and the Cytogenetics Laboratory received gold level sustainability recognition by the University of Michigan. The Microbiology Laboratory implemented MALDI-TOF as a platform for microorganism detection. This technology, available in fewer than ten hospital-based clinical laboratories in the United States, has allowed for more rapid identification of "routine" organisms, and sets the stage for identification of unusual infectious organisms. The Histocompatibility Laboratory created an ASHI-approved Director-in-Training Program, placed finishing touches on the implementation of the HistoTrac Laboratory Management system, and added three novel clinical assays (anti-endothelial cells antibodies, anti-MICA, and anti-HLA C1q binding). These assays are particularly notable because they are offered by very few other HLA laboratories in the United States. The Chemistry Laboratory (Immunology section) validated, among other new assays, a novel graft-versus-host disease panel that includes serum measurements of elafin, soluble TNF-alpha receptor, soluble IL-2 receptor alpha, and REG3a.



Matrix-assisted laser desorption/ionization (MALDI) Time of flight (TOF) mass spectrometer

The Faculty Group Practice and Office of Clinical Affairs continued to support the multidisciplinary Laboratory Formulary Committee established in 2008. Established at the behest of Pathology and staffed by Pathology leadership, the committee has vetted 47 expensive laboratory tests using an intensive, medical evidence-based UMHS expert opinion-based process. This program has established a robust process for the regulation of expensive test utilization and management of sendout costs through the Committee and via utilization of the inpatient order entry system (CareLink).

Kristina Martin has very effectively led Pathology on-site Southeastern Michigan American Red Cross blood drive efforts. Specifically, her efforts have greatly facilitated the increase in donated units from 612 in 2009 to greater than 900/year in 2010 and 2011. Donations are on pace to exceed 1,000 units in 2012. She leads an extensive agenda of Clinical Laboratory Operations initiatives as well as coordination of CP Operations meetings (every two weeks), compilation of the CP Dashboard, regulatory inspections, Clinical Laboratory Communications, Gemba walks (every two weeks), Pathology -UMHS Nursing liaison activities, external site visits, and numerous special ad hoc projects.

John Perrin has again very effectively served as the Clinical Pathology QA Coordinator where he manages all data collection, participates in QA data analysis, leads monthly QA meetings, and actively participates in problem-solving activities and the development of innovative solutions to operations and communications challenges.

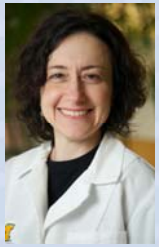
Brenda Schroeder, Laura Blythe, Beverly Smith, and Robin Kunkel, the Laboratory Chief Technologists and Supervisors, and the Laboratory Directors revamped Laboratory-wide communication (Pathology website, Laboratory Communication Committee, CP Dashboard, a standing informal communication meeting, and several Lab-specific newsletters), and UMHS patient care unit-specific communication. The Service Excellence and Employee Recognition programs, through the dedicated work of many, continued to thrive in 2011-12. The entire Laboratory creatively and effectively improved productivity

through many thoughtful rework exercises. The Safety Committee, led by Brenda Schroeder continued its robust and novel Safety Inservice program and implemented biweekly scored "Safety Walks" through the laboratories. The Clinical and Anatomic Pathology Laboratories posted an outstanding CAP self-inspection performance in May, 2012.

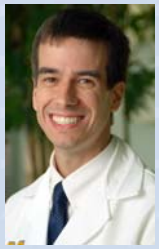
A major ongoing goal for Clinical Pathology has been to continue to raise the academic profile of the Division. Pursuit of this overarching goal has been actively approached through support of high profile visiting faculty; support of current faculty scholarship through Divisional discretionary funds; addition of fellow training slots; and through strategic faculty recruitments. Many medical technologists contributed to the academic visibility of the Division through abstracts, publications, and presentations at national meetings. These activities are highlighted in the Section reports.

Four new faculty joined the Division of Clinical Pathology in 2011-12.

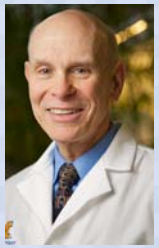
Michael Bachman, M.D., Ph.D., arrived from the University of Pennsylvania to join the Microbiology Laboratory service. Dr. Bachman brought an NIH-funded research program focused on the role of iron in microbial pathogenesis. Dr. Bachman has a joint appointment in the Department of Microbiology-Immunology and is a UM Provost Scholar via the Distributed Health Technologies initiative.



Jo-Anne Vergilio, M.D., arrived from Children's Hospital Boston and Harvard Medical School to join the Hematopathology service. Dr. Vergilio is Director of the Hematology Laboratory and has academic interest in BRAF mutations in Langerhans cell histocytosis and the pathogenesis of diffuse large B-cell lymphomas in pediatric patients.



Nathanael Bailey, M.D., returned to the University of Michigan from Providence Hospital in Southfield, Michigan. Dr. Bailey joined the Hematopathology and Molecular Diagnostics laboratory services. Dr. Bailey completed Molecular Genetic Pathology fellowship training here at the University of Michigan in 2011. His academic interests are in both hematopathology and molecular pathology, specifically molecular pathogenesis and glycoproteomic characterization of malignant lymphomas.



David Keren, M.D. rejoined the Department as Associate Director of Clinical Pathology after more than twenty years of service as an adjunct professor in the department and Medical Director of Warde Laboratories (Ann Arbor, Michigan). Under Dr. Keren's leadership, Warde Laboratories experienced unprecedented growth, now serving more than 100 client hospitals from across the United States. Among numerous national posts, Dr. Keren is immediate past President of the American Board of Pathology, Chair of the Clinical Chemistry Test Development and Advisory Committee for the American Board of Pathology, and a member of the FDA Advisory Committee for the Immunology Devices Panel. His chief academic interests are in the areas of clinical chemistry, hemoglobin analysis, and protein electrophoresis.

The many accomplishments of the laboratory staff, administrative staff, support staff, laboratory supervisors and chief technologists, and laboratory directors are a testimony to outstanding dedication and professionalism. Please see individual reports from the sections, laboratories, and faculty of the Division Clinical Pathology.

<u>Combined Hematology Laboratory (Hematology, Bone Marrow, Flow Cytometry, Coagulation)</u>

Under **Dr. Megan Lim's** leadership, the Hematopathology Laboratory continues to offer an extended menu of tests in hematology, coagulation, and flow cytometry, with more than 1 million total test orders in FY 2012.

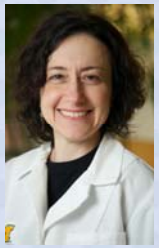
- The volume of complete blood count (CBC) testing—a key benchmark of laboratory activity-- was increased from 450,000 CBCs performed to 500,000.
- The volume of HP specimens in flow cytometry and smears and fluids increased in FY 2012, while TH and HR remained stable: in-house bone marrow aspirate and biopsy (2510), TH (1598) HR (672). FC (3798: 9.3% increase), smears and fluids (2502: 14%).
- Overall test volumes in the clinical flow cytometry laboratory increased

by over 9% between fiscal 2010 and fiscal 2011.

- The total RVU for the section increased by 8.0% since FY 2011, representing a 42% increase in the last 5 years.

Combined revenue for the Hematology and Coagulation sections has increased ~3.5% in the last fiscal year.

CLINICAL HEMATOLOGY LABORATORY



Dr. Jo-Ann Vergilio joined the HP section in January 2012 to assume the position of Directory of Clinical Hematology Laboratory. Under her leadership, the Clinical Hematiology Laboratory has made some significant process improvements. In collaboration with Pediatric Hematology-Oncology, the laboratory has undertaken an effort to assess and streamline processes that relate to turnaround time (TAT) for CBC/DIFF/ANC of infusion patients. This has resulted in an electronic "real-time" tracking system being implemented in order to actively monitor specimen transit through the Hematology Lab. With the opening of Mott Children's Hospital (MCH), the Hematology Laboratory trained two phlebotomists to support the procurement and processing of bone marrow specimens to support the increased demand. In addition, this past year, a CORE Lab Committee was created with administrative and technical participants from Hematology and Chemistry. This committee's charge is to anticipate and address future needs of a new CORE laboratory that will provide automated high volume testing as well as specialty services to the medical community.

After 43 years of exceptional service to the Department, Nancy Renner, Administrative Manager of Hematology, announced her retirement effective July 2012. Efforts are underway to identify her successor. During the past year, three more of our exceptional staff received Pathology recognition awards for their outstanding service and commitment to patient care: Gerald Davis, Usha Kota, and Susan Clark. Additionally, three medical technologists were promoted to a Med Tech II status given their contributions to laboratory operations: Julie Bensinger, Priti Patel, and Dena Ryan. To support our exceptional staff in a commitment to continuous quality improvement, we also established a LEAN process improvement subcommittee, which is driving our efforts to achieve excellence in patient care and customer service.

COAGULATION SECTION

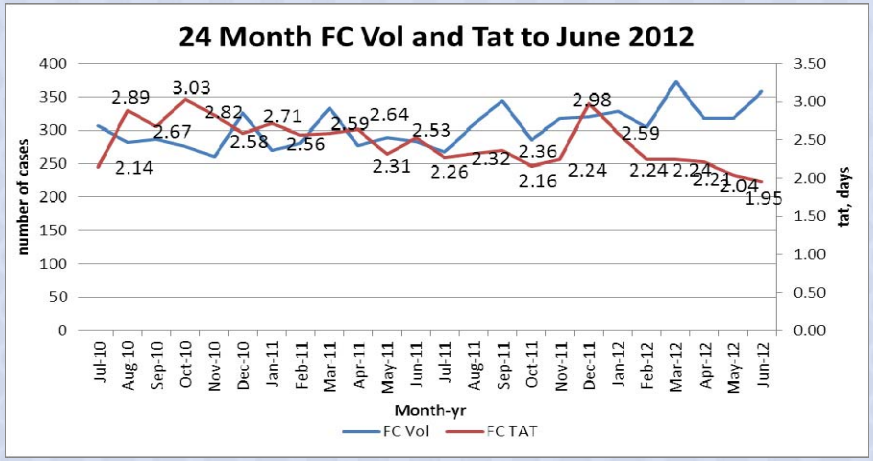
Under the leadership of **Dr. Steve Pipe**, the Coagulation Laboratory engaged the clinical services of UMHS to improve laboratory utilization, guide new assay development and enhance consultation services. Dr. Pipe and Sara Gay served on the Anticoagulation Subcommittee to the Pharmacy and Therapeutics Committee where they worked to evaluate the impact of interventions on outcomes, prepare clinical practice guidelines for anticoagulants, monitor adherence to these guidelines, and developed and launched an inpatient pharmacist-assisted anticoagulation service. This resulted in 2 poster presentations on UMHS performance metrics in anticoagulation at the inaugural Thrombosis and Hemostasis Summit of North America. In addition, Dr. Pipe was instrumental in formalizing a coagulation rotation for the hematopathology fellows as well as in providing ongoing educational support to the fellowship programs in pediatric hematology and oncology, internal medicine hematology, and the blood bank.

The laboratory's overall coagulation testing volumes were slightly decreased in FY 12 as compared to FY 11 (4%), however, 95% of inpatient turn-around times for aPTT's were less than 1 hour from time of receipt in the coagulation laboratory.

CLINICAL FLOW CYTOMETRY LABORATORY

Under the leadership of **Dr. Lloyd Stooman**, the overall test volumes in the Clinical Flow Cytometry Laboratory increased by more than 10.4% over FY 2011. In spite of this significant increase, the laboratory was able to decrease turn-around times by over 12.3%. In conjunction, the laboratory developed work-flow tracking using Flow

Cytometry Portal, implemented 8-10 color panels, customized work-flow and ordering policies to support MLabs clients, improved the online biorepository and improved the virtual microscopy portal integration.



IMPROVEMENTS IN SERVICE ORGANIZATION AND QUALITY ASSURANCE/ CONTROL

The Hematopathology section is actively pursuing the Joint Commission's Ongoing Professional Practice Evaluation (OPPE) program. This program is a process where an evaluation process is first designed, then data is gathered, aggregated, analyzed and reported. An evaluation of the data and generation of action items completes this process. This year, OPPE metric data collection has been initiated for the HP section. Based in part on early results of this data collection, a number of quality assurance projects were undertaken:

- An online tool for ordering cytochemical stains in the Hematology Laboratory was developed and is available for use.
- Cameras were installed on the multiheaded microscope and the flow cytometry microscope in the Hematology UH signout room with image capture and telepathology capabilities.
- In order to streamline the accessibility of patient data, the HP section began sending all Transfer case paperwork to surgical pathology for real time scanning instead of sending out to an offsite third party. This process allows for immediate and easy accessibility and patient data as well as decreasing paperwork storage in the Heme Suite.
- Efforts are underway to standardize signout room disposal of confidential paperwork.

Work continues on the ordering, reporting and distribution of Hematopathology reports with the anticipated implementation of the new LIS. Integrated reports are anticipated for the HP section.

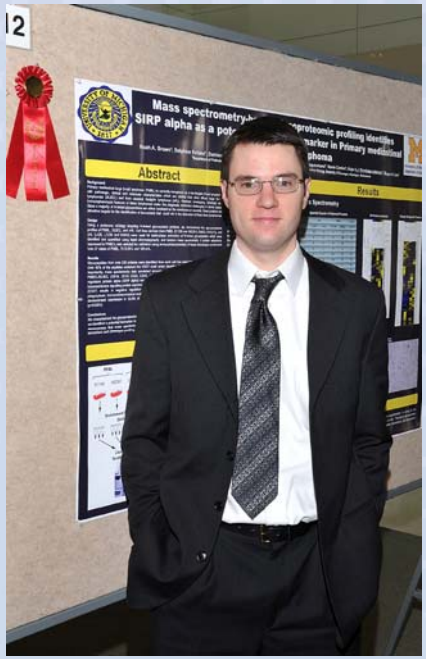
HEMATOPATHOLOGY EDUCATION – FELLOWS/ HOUSE OFFICERS/ TECHNOLOGISTS

Dr. Megan Lim, Director of the Hematopathology Fellowship Program is pleased to announce that Dr. Lauren Smith has been selected as our new Assistant Director of the Hematopathology Fellowship Program, effective July 1, 2012.

In December 2011, the Hematopathology Fellowship Program underwent ACGME Review and has been renewed for the full five-years. In preparation for this review, we received input from our fellows as to what we may be able to do to continue to improve our training program. In response to fellow suggestions, we revised the Molecular Diagnostic and Coagulation rotations for the HP Fellowship and the bone marrow procedure activity to include individualized training with one PA over a designated 2 week period. New microscopes were purchased and installed in the Hematology UH signout room for use by trainees while on the Hematopathology service, and an online didactic outline for trainees on hematology rotations has been updated and is ready for popu-

lation with multimedia materials on the Pathology website. The University of Michigan Hematopathology Fellowship Website has been constructed to showcase the program and to allow a place for resources to be localized. We have also improved the Laboratory Management curriculum by enhancing the CAP inspection activities for the fellows as well as restructuring the attendance at laboratory management meetings.

Our House Officers and Fellows, mentored by our faculty, presented 8 scientific abstracts at national meetings. Dr. Noah Brown (HO III) received recognition for his research abstract presented at the Department of Pathology APHPMP Research Symposium.



Dr. Noah Brown, 3rd year House Officer, with his 2nd Place Research Abstract Poster at the Anatomic Pathology-Hematopathology-Molecular Pathology Research Seminar

Chemical and Clinical Immunology Pathology Laboratory

The Chemistry Section, under the leadership of **Donald Giacherio, Ph.D.** and the administrative management of Sue Stern, experienced an approximate 2.5 % increase in overall testing volume this year. The lab produced nearly 8.3 million individual patient test results. In addition, the lab serves as a reference lab for the multicenter SWAN Study (Study of Women's Health Across the Nation), performing over 1000 lipid profiles for the study. The major focus of lab activity this past year centered on three main projects; the opening of the new Children and Women's hospital with emphasis on setting up a STAT lab within the Emergency Department, the continued work on building and testing lab procedures for the new SOFT laboratory information system, and implementing MiChart programs within the Emergency Department. The outstanding efforts of Sue Stern, Merry Muilenberg, Mara Williams, Dave Harro, and all the lab staff on these projects must be acknowledged.

The Chemistry Section continued its efforts at utilizing lean principles to continually improve the turnaround times for testing. Daily monitoring and posting of STAT test turnaround time (TAT) data and continued cooperative efforts by all staff to improve performance led once again to a consistent trend towards overall TAT reductions. Approximately 22 % of the over 76,500 samples a month processed on the Chemistry automation line are STAT's. Currently, less than 1.0 % of STAT samples take over 1 hour to complete, and greater than 98 % of STAT samples are verified in less than 45 minutes from time of receipt in the lab. **Figure 1** shows the TAT trends for the past year, and **Figure 2** details the continuous improvement realized over the past 5 years. The ongoing activities of lean team groups in chemistry and the suggestions from weekly team huddles have led to the implementation of multiple changes

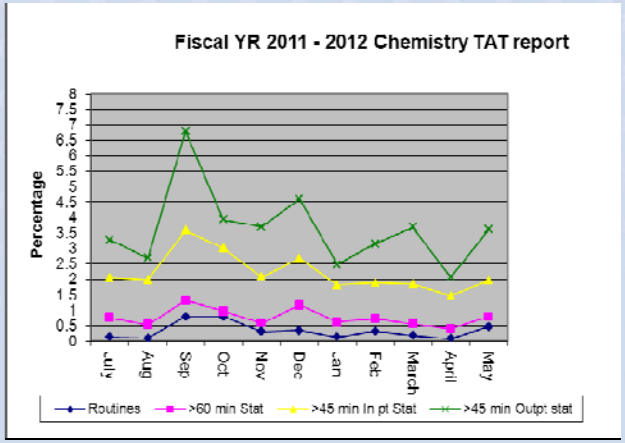


Figure 1: Turn-around time trends

that continue to positively impact workflow. Lean team members from the lab continue to actively participate in successful and ongoing projects aimed at reducing error rates within the lab and simplifying processes for sharing samples across laboratory boundaries. The lab has continues its progress as one of 7 UMHS sites to receive additional training of all staff as part of a Lean Implementation Teams program to spread lean in the workplace. Multiple groups both internal and external to UMHS have come to tour the lab and see the visual cues utilized as part of this LIT program.

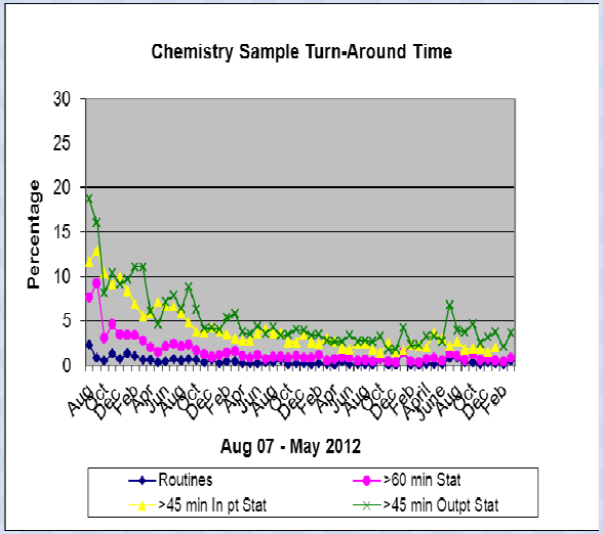


Figure 2: STAT Sample Turn-Around Times

The Automation section of the lab completed contract negotiations then validated and installed four new ADVIA 1800 Chemistry analyzers. This implementation should position the automation section to handle continued test volume growth over the next 5 years, as well as significantly reduce maintenance requirements. The extraordinary efforts of Eric VasBinder in seamlessly shepherding the implementation of new analyzers needs to be acknowledged. New versions of automation line operating software and Centralink data handling middleware were installed over the course of the year. These enabled gains in improved efficiency of staffing the automation line and in problem resolution through constantly updating real time sample tracking. The movement of 25 hydroxy Vitamin D testing to the automation line significantly reduced sample handling and aliquoting for the specimen receipt area of the lab. Testing for beta-hydroxybutyrate was validated and implemented on the ADVIA 1800 analyzers, with the intent of replacing the qualitative serum ketone assay with this improved quantitative test for patients with ketoacidosis or those on ketogenic diets. A multi-week trial of heparin plasma separator tubes on Cancer Center infusion patients spearheaded by Eric VasBinder produced noticeable improvements in turnaround time due to elimination of clotted samples. Plans for a larger scale implementation of the program are underway.

In the Special Chemistry Section, contract extensions were negotiated for the Roche COBAS Integra analyzers as well as the Diasorin Liason immunoassay analyzers. Oversight of the STAT Lab functions in both the adult and pediatric Emergency Departments was managed by Special Chemistry personnel. Contract negotiations to upgrade blood gas analyzers in the operating rooms of University Hospital, Mott Hospital, and the Cardiovascular Center were finalized and installation of the new Gem Premier 3500 analyzers has begun. The Special Chemistry group continued its support of intra-operative PTH testing in the OR's of University Hospital and the Cardiovascular Center. The lab performed io-PTH testing on over 300 parathyroidectomy surgery patients over the past year.

The Toxicology section implemented a new immunoassay screening assay for Methadone and its major metabolite to better serve the needs of the high risk OB-GYN and Adult Treatment Service groups. Efforts to better utilize GC-MS drug screening continued with ongoing educational efforts led by Matthew Elkins and a redesign of Carelink and MiChart order entry programs. Lab leadership and department administration completed an over $500,000 capital program request to acquire 2 new LC-MSMS analyzers and 2 new GC-MS analyzers to position the lab to better serve both the transplant program for immunosuppressant drug monitoring and multiple clinical areas with improved drug screening capabilities.

The Immunology section of the lab evaluated and validated serum protein electrophoresis testing by capillary electrophoresis. The switch from conventional electrophoresis to this more automated CE technology resulted in a labor savings and better ability to handle the consistently increasing workload of this testing. The lab has continued the development of ELISA assays to support graft versus host disease detection in the bone marrow transplant population. These assays include elafin, soluble TNF-alpha receptor 1, IL-2 receptor alpha, and REG3a. These assays are now robust enough to begin clinical trials. The Immunology group also validated hemoglobinopathy testing on the Sebia Capillarys as a secondary identification technique for hemoglobin variants.

The lab has continued its leadership role in Point of Care (POC) testing both within the hospitals and at the off-site health care centers. Chemistry staffs the laboratories within the Emergency Departments and contin-

ues to perform Troponin I testing and blood gas / electrolyte testing with rapid TAT for adult ED patients, and blood gas / electrolyte testing and STAT urinalysis for pediatric ED patients. The lab leadership continues to play a key role in the ongoing efforts to replace POC glucose meters within UMHS with approximately 500 new technology meters. The POC team has also played an active role in researching potential new colon cancer screening tests for fecal occult blood and has begun the process of implementing a new immunochemical test across UMHS sites.

The lab continues its significant role in education. Pathology residents on a monthly rotation through the lab meet daily with Dr Giacherio or Dr Annesley and spend additional time with the supervisory staff and senior clinical technologists. Six medical technology students spent 4 weeks each rotating through the lab sections. The lab hosted two Pediatric Endocrinology fellows for a one week of laboratory testing exposure, and 2 Allergy Fellows for a one day exposure to IgE allergy testing by immunoassay. One afternoon a month, Department of Pediatrics residents come to the laboratory for tours and interactions with the supervisory staff. Numerous high school groups tour the lab in an effort to promote medical technology as a career field.

Clinical Microbiology/Virology Laboratories

Dr. Duane Newton led the Clinical Microbiology and Virology Laboratories again this year, seeing continued increases in volumes exacerbating the impact of constricted space. His major foci of the last year were on identifying opportunities to increase efficiency without compromising service. The following are a few examples of the multiple technical, administrative, and educational activities undertaken this past fiscal year to maintain and enhance the quality of clinical services provided for our patients.

In the molecular diagnostics area, a dedicated staff focused on molecular testing was brought on board. We successfully negotiated for additional space in Mott/UH South enabling us to redistribute instruments and personnel to improve processes. An RFP review and instrument evaluation were conducted for HBV, HCV and HIV viral load assays, with the change to Abbott platforms and assays now nearly complete. We continue the evaluation of systems for qualitative molecular testing and anticipate completion in the summer of 2012.

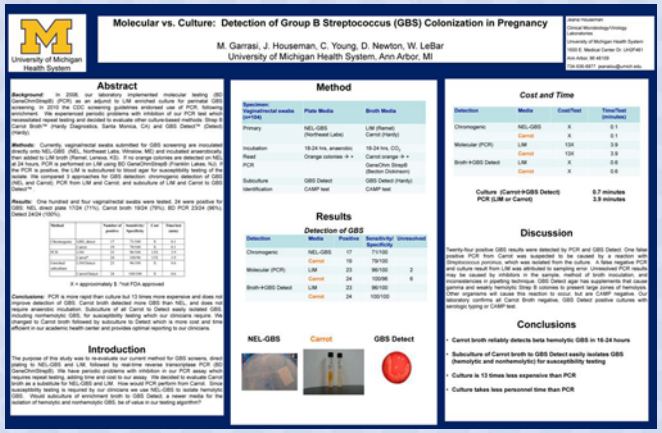
A second major area of activity has been the addition of MALDI-TOF as a platform for microorganism identification. The laboratory will initially utilize the technology for routine identification of aerobic bacteria and yeast from positive blood cultures. Working with the Antimicrobial Stewardship Team, we designed a study to examine the impact of this rapid identification on time to optimal antibiotic therapy to inform the literature on the value and impact of new technologies and approaches.

In addition, we continue to utilize and optimize our expanded Quality Assurance program which includes mechanisms to more rapidly identify, respond to, and track quality variances that occur throughout the lab. We have instituted a laboratory QA with laboratory managers notified of problems that might occur through the total testing process. These forms are reviewed by the Senior Technologists with trend monitoring and results communicated during section meetings, and then reviewed by the Director and discussed during staff meetings. We have also instituted systems for monitoring QC data in our molecular areas using Westgard rules. This has not only raised awareness of QA/QI amongst the laboratory staff, but it has also made it easier for the technologists to interpret testing data objectively using the electronic tools that were developed. This has resulted in improved satisfaction among employees performing the testing as well as decreased errors, repeat runs, and short samples.

Finally, we have organized a multidisciplinary working group that includes members from the Microbiology senior staff, the Antibiotic Stewardship team, Adult and Pediatric Infectious Diseases, Pharmacy, and Infection Control, whose function is to meet quarterly to discuss strategies to improve the approach to testing and/or reporting of results from the microbiology laboratory. Meeting on a regular basis has provided a forum for both the clinicians and laboratorians to discuss issues or problems with the goal of utilizing our resources in a manner which optimizes the quality of care provided to our patients.

In the educational arena, all laboratory personnel continued to provide instruction to Pathology House Officers and Infectious Disease Fellows and residents on diagnostic procedures used in the Microbiology/ Virology Laboratories. We also provided several laboratory preceptorships for medical students, pharmacy students, and PharmD residents

during the year. Infectious Disease Laboratory rounds were held each weekday during which staff members and assigned Pathology House Officers interacted with ID team members to answer questions, demonstrate laboratory diagnostic procedures and discuss interesting findings. Numerous in-service education programs were held during the course of the year with individual technologists and Pathology House Officers giving presentations to staff members.


Molecular vs. Culture: Detection of Group B Streptococcus (GBS) Colonization in Pregnancy

M. Garrasi, J. Houseman, C. Young, D. Newton, W. LeBar
University of Michigan Health System, Ann Arbor, MI

Abstract

Method

Cost and Time

Results

Discussion

Introduction

Conclusions

The laboratory's administrative manager, both supervisors and most of our Sr. Technologists attended one or more regional or national scientific meetings during the year. Several other staff members attended national and regional scientific meetings of interest. All of the above-mentioned individuals were involved in presenting posters at national meetings, and a previously presented poster was ultimately published. The laboratory continues to be active in multiple research projects that involves many bench-level technologists and provides them with opportunities to attend scientific meetings, which additionally enhances the academic visibility of the laboratory and department.

In addition, the Laboratory subscribed to two audio conference programs which provided a total of 5 conferences during the year that were available to all staff members and Pathology House Officers as part of our ongoing CME program. Pathology residents and faculty also provided monthly in-service programs to the laboratory staff.

Blood Bank/Transfusion Medicine

In an effort to provide excellence in patient care and to make the best use of this life-saving resource, **Dr. Robertson Davenport** and the Transfusion Committee worked diligently to promote adherence to transfusion guidelines. This resulted in reductions in total blood component utilization in all areas except for cryoprecipitate. Activity in the Cellular Therapies Laboratory decreased slightly, despite an overall slight increase in the total number of patients transplanted. This also reflects a greater proportion of autologous transplants, and improved efficiency in collection of autologous donors. Activity was also impacted by the move of the Bone Marrow Transplantation program to the new hospital. Overall activity in the Apheresis Procedures Unit slightly the previous year. This was largely due to a decrease in the number of autologous HPC collections. Greater efficiency in autologous HPC collection was the result of improved mobilization regimens, particularly the earlier use of plerixafor.

Blood Product	2010	2011	Percent change
Red Blood Cells	28,478	25,698	-9.8
Platelets	67,861	61,093	-10.0
Plasma	12,836	10,951	-14.7
Cryoprecipitate	4,482	4,873	8.7

Cellular Therapy Lab	2010	2011	Percent change
Units processed[1]	531	496	-6.6
Bags frozen	738	692	-6.2
Transplants, autologous	127	158	24.4
Transplants, allogeneic	67	48	-28.4
Transplants, unrelated	56	53	-5.4
Transplants, total	250	259	3.6

Reference laboratory activity also decreased from the previous year. This reflects the overall decrease in transfusion activity, as well as the decrease in allogeneic HPC transplants.

Professional billing activity decreased from the previous year, primarily reflecting the creased number of HPC donor encounters.

The blood bank worked extensively with the Transfusion Committee and member of the departments of Surgery, Medicine, Anesthesiology, and Pediatrics on implementation of the massive transfusion protocol. The blood bank also worked extensively with MCIT to assure implementation of MiChart compliance with FDA regulations.

Members of the Blood Bank medical and technical staffs participated in Pathology house officer teaching, Hematology fellow teaching, M2 and M4 medical student teaching, the transfusion component of nursing orientation, and many interdepartmental conferences.

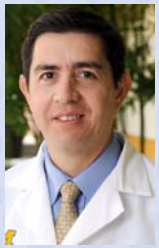
The continuing education course Current Topics in Blood Banking was successful again this year. This is one of the longest running and best recognized continuing education course in the field nationally.

Our staff were also well represented in professional organizations. Andrea Mickey was past President of ASCLS-MI and Annual Meeting Chair. Louann Dake served on the AABB Immunohematology Reference laboratory Standard Committee, the Molecular Testing Standards committee and the Standards Program Unit. Andrea Hickey, Louann Dake, Theresa Downs, Pam Cornwall and Heidi Armelogos all gave presentations at regional and national meetings.

Apheresis Proc. Unit	**2010**	**2011**	**Percent change**
Therapeutic apheresis	1113	1101	-1.1
HPC collections	466	423	-9.2
LDL apheresis	326	332	1.8
RBC exchange	43	41	-4.7
Total procedures	1948	1897	-2.6
Reference Laboratory	**2010**	**2011**	**Percent change**
Antibody identifications	1123	1053	-6.2
ABO resolution	76	89	17.1
M-Labs/referrals	23	22	-4.3
BMT	942	894	-5.1
Eulates	236	231	-2.1
Adsorptions	252	303	20.2
Titers	123	130	5.7
Total activity[1]	3449	3202	-7.2
Prof. Billing	**2010**	**2011**	**Percent change**
Gross charges	$757,662	$696,406	-8.1
Charge units	2,421	2,290	-5.4

[1] Includes procedures not listed above

Histocompatibility and Immunogenetics Laboratory



Dr. Daniel Ramon and the Histocompatibility laboratory are pleased to announce the creation of the Histocompatibility Laboratory Fellowship. We are very happy with the recruitment of our first fellow. The ASHI regulation requires a minimum of two years to provide the Histocompatibility Laboratory Director accreditation in addition to other requirements. We believe that the incorporation of a fellow to our laboratory will bring new energy and leverage for our clinical and academic activities.

As part of our efforts to improve the risk assessment of the patients listed for organ transplantation at UMHS, along with the accreditation to run the Flow Cytometric Crossmatch assay that we obtained last year, we were able to validate and incorporate a new Endothelia Precursors Cell Crossmatch. This crossmatch will allow us to monitor the presence of non-HLA antibodies. The specificity of these antibodies remains unknown, and belongs to a group of antibodies known as Anti Endothelial Cells Antibodies (AECA).

Another assay validated and implemented by our laboratory during the year detects circulating antibodies against MHC class I-related chain A (MICA). These antibodies, as well as anti-HLA antibodies, contribute to antibody mediated rejection and are related with poor transplant outcomes.

The lab also validated a new Luminex solid phase assay to measure the capability of the Anti-HLA antibodies to bind C1q molecule. This new assay will improve our donor selection process and the post-transplant management of patient with anti-HLA antibodies.

The histocompatibility laboratory continues with the implementation of a new HLA specific laboratory information system called HistoTrack. Fifty percent of the operation was launched on 5/21/12; we are very close to finalizing the other fifty percent and expect to be running all of our laboratory information with HistoTrack in the next two months.

Under the leadership of Timothy Williams, our HLA serology supervisor, and with the efforts of our entire team, the Histocompatibility Laboratory has been recognized as a Platinum Level Sustainable Laboratory by the Office of Campus Sustainability. We are working to eliminate unnecessary printing of results, going to an all-digital format.

Molecular Diagnostics Laboratory

The Molecular Diagnostics laboratory is directed by **Dr. Kojo S. J. Elenitoba-Johnson**. Dr. Thomas Wilson is the Associate Director, and the laboratory's Technical Director is Dr. Bryan Betz. Jennifer Sanks, our Technical Supervisor, stepped down and Jennifer Bergendahl is currently filling this role along with that of Laboratory Manager.

This has been a very productive year for the laboratory, with four new tests and two updated tests being brought online, with seven more in development for 2013. Over the past year, the laboratory experienced a 55% increase in specimen volume on top of the 43% increase the prior year. This resulted in an average 1.25 day increase in turn around times (excluding the June 2012 outlier). The increased volume was accommodated by increasing weekday service (8:00 am—8:30 pm) and adding Saturday service (12:00 pm—8:30 pm). In the Fall of 2012, service hours will again be extended to include Sundays (12:00 pm—8:30 pm). In addition, three new technologists were brought on board and a part-time technologist moved to full time. To support the increased test volumes, in May 2012, a capital equipment request was submitted for 4 new instruments: A real-time PCR thermal cycler (ABI7500), two additional thermal cyclers (ABI9700) and an automated DNA extraction instrument (Qiagen BioRobot EZ1 Advanced XL). A replacement –80 degree freezer was also requested.

With an increase in specimen volumes and a shift in testing towards more labor-intensive assays, the day-to-day testing operations were restructured several times to include increased technologist coverage in these areas to maintain the laboratory's standards of quality and efficiency. Once the newly-acquired technologists are fully trained, further restructuring of testing rotations is planned in a continuous effort to reduce test turnaround time and increase customer satisfaction.

The Molecular Diagnostics Laboratory is also heavily involved in the educational mission of the Department. Monthly lab meetings are conducted during which a member of the staff or faculty will give a presentation on a new or current test being performed in the laboratory. This helps to give residents, fellows, and staff an introduction to new testing, and to give further information as to why certain testing is performed. The laboratory lso conducts regular monthly Administrative Project Meetings, which include the director, technical director, attendlngs, supervisor, R&D technologist and fellows/residents associated with the laboratory. These meetings aid in organizing ongoing projects and provide information on new and updated tests and assay problems/issues.

A monthly resident/fellow molecular conference is also conducted. Here the resident/fellow presents a current or proposed molecular test that Includes a discussion on the clinical Indication and test interpretation as well as considerations involved in designing, developing, and validating that test in the laboratory. The topic is chosen under the guidance of the molecular laboratory faculty.

New Tests

IDH/IOH2 Mutation for AML & Glioma

MALT (18q21) Rearrangement by FISH

ALK Rearrangement for NSCLC by FISH

PDGFRA Mutation for GIST

Updated Tests

BRAF V600E/V600K mutation
T-Cell Clonality (TRG gene rearrangement

In Development

Next gen Multi-gene mutation sequencing

BCR/ABL quantitative values report

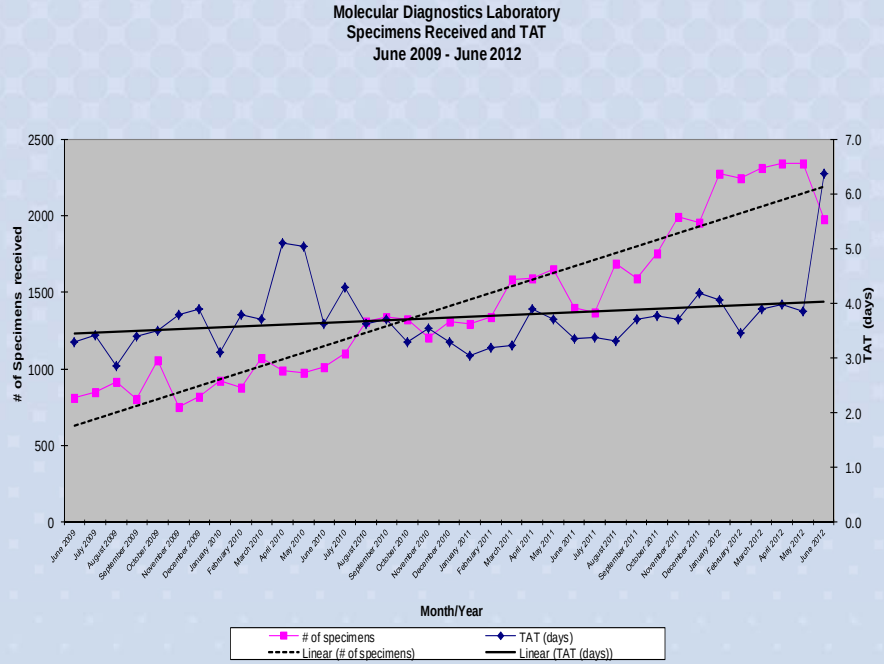
IGH/CCNDI t(U;14) translocation by FISH

Factor V Leiden Mutation—updated

MTHFR C677T mutation test—updated

Prothrombin 20210 mutation

Expanded EGFR mutation test



Cytogenetics

The Cytogenetics Laboratory, led by **Dr. Diane Roulston**, again experienced an increase in sample volume during the past fiscal year, with a total of 4,613 tests requested, for a 3.1% increase over the prior fiscal year. The overall gain was due to increased oncology FISH testing. (See appended Table.) Thomas Glover, Ph.D. (Professor, Department of Human Genetics) continued to provide invaluable expertise and sign-out coverage of constitutional genetics cases and locum tenens continued some assistance with sign-out. The overall number of oncology and constitutional cytogenetic tests totaled slightly lower than the previous year (-73, -2.3%). While the bone marrows had a high volume from July – November 2011, a noticeable drop occurred for Dec 2011 – Feb 2012, for an overall decrease of -3.2% for the year (-69 cases). This decrease was partially offset by an increase in solid tumor and lymphoma samples (+35, +13.3%). For constitutional karyotypes, slight decreases were noted in blood, amniocentesis and tissue samples (includes products of conception), and no change occurred for chorionic villus samples. (See Table for details.)

The overall number of FISH tests increased again this year, with a total increase of 14.7% over FY2011. The increase was due mainly to increased oncology FISH requests, and bringing all CLL FISH panel testing in-house. Several new probes were validated: *IGH* and *TRA/D* for lymphoma and *N-MYC* for neuroblastoma.

New equipment procured for the laboratory included software upgrades for the automated karyotyping system (Cytovision) in order to interface with MiChart and with a new fluorescence microscope. The new microscope expanded capacity to develop new FISH tests, such as for multiple myeloma.

The lab administrators replaced two experienced technologists this past year (one will begin in July 2012) and promoted two others to Tech II positions. Furthermore, due to incremental increases in volume in FY2011, one clerical/patient care position and two part-time work study assistants were added; all have made significant contributions for increased lab productivity. Employee engagement discussions over the past year were extensive and involved all laboratory management and staff; committees were formed and many changes implemented, including LEAN-style "huddles" for three different sections (prenatal, FISH, and blood/bone marrow), which includes all laboratory staff.

Other significant activities included development of the MiChart lab interface, the Cerner 015 upgrade, and continued SCC/Soft LIS programming. The prenatal team coordinated moving operations for assisting with chorionic villus sampling in the FDC(PAC) to the new Children and Women's Hospital. The laboratory was also pleased to participate in the UMHS "Green Lab" initiative for environmental conservation, and achieved Gold level status.

Sample Volumes in Clinical Cytogenetics Fiscal Year 2011-2012

Sample Type	# of Tests	Increase (Decrease)	% Change
Bone Marrows	2,085	(69)	(3.2)
Tumor/Lymph Nodes	298	35	(13.3)
PB Constitutional	350	(15)	(4.1)
Prenatal: Amnios	144	(8)	(5.3)
Prenatal: CVS	120	0	0
Tissues (POC)	115	(16)	(13.7)
Subtotal (Chroms)	**3,098**	**(73)**	**(2.3)**
Tissue Culture Only	**10**	**7**	**233**
Tissue Culture for AM, CT or TI	15	N/A	N/A
FISH			
Genetics	273	(44)	(13.9)
CMA FISH	177	(65)	(26.9)
Oncology	1,124	183	19.4
Panels	93	52	126
Total FISH	**1,490**	**191**	**14.7**
Total Tests	**4,613**	**140**	**3.1**

Nine Pathology residents, and fellows from clinical training programs in Molecular Genetics in Pathology (1), Hematopathology (1), and Maternal Fetal Medicine (2), performed rotations in the Cytogenetics Laboratory. The residents and fellows all gave brief talks for the technologists, making a much-appreciated contribution to continuing education. Three cytogenetics technologists attended the annual Great Lakes Chromosome Conference in Toronto, and one senior technologist attended the annual meeting of the national Association for Genetic Technologists.

The laboratory continued to benchmark well with maintaining Approved Laboratory status for participation in clinical trials for the Children's Oncology Group (COG). The past year saw the laboratory's highest score achieved thus far (91%), well over the minimum required for approved status (55%). Dr. Roulston served on the Cytogenetics Committee for COG, and served as chair of the SWOG Cytogenetics Committee and study coordinator for the SWOG 9007 Study Section.

Division of Pathology Education

Barbara J. McKenna, M.D.
Endowed Professor of Pathology Education
Director, Division of Pathology Education

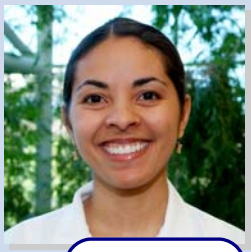
Education is a core mission of the department, and the quality and breadth of its Education programs reflect this commitment. Our faculty is involved in the education of undergraduate students and dental students, and integral to the education of medical students, graduate students, residents, and specialty fellows. Similarly, our trainees are part of the educational process for their more junior counterparts. The strong foundation in our existing educational programs is the basis upon which novel ways of teaching and learning can be built, and from which new programs can grow.

Graduate Medical Education—Pathology Residency Program

The Department offers both individual and combined residency programs in Anatomic and Clinical Pathology to its 28 residents, continuing a longstanding tradition of excellence in pathology training. During the 2011-12 academic year, many of the plans developed the previous year were implemented. The Pathology Education Series, a set of morning conferences with topics that include clinical perspectives, laboratory management, professional development, personalized medicine, and case-based learning, was highly successful. Most of the presentations were captured into an online archive of learning materials, and CME credits were available for those for whom they are relevant. The new, competency and milestone-based rotation goals and objectives were in place, with new evaluations of residents tied to their performance of these objectives. Earlier introduction of subspecialty training and elective rotations was established. The previous Curriculum Workgroup was transitioned to the permanent Residency GME committee, with Drs. Jonathan McHugh, David Keren, David Lucas, Peter Lucas, Thomas Annesley, and Barbara McKenna as members, along with chief and assistant chief residents Drs. Kurt Bernacki and Randall Butler. Education staff, including Laura Blythe, Pamela Howard, Marie Sassano, and Beverly Lange contribute to both planning and implementation of the programs. Restructuring of parts of the Clinical Pathology curriculum to focus the experiences on laboratory leadership.

CHIEF RESIDENT

Kurt Bernacki, M.D.



ASST. CHIEF RESIDENT

Randall Butler, M.D.

While focusing on what is new and changing, it is important to note that the accomplishments of our residents continue much as they have in the past. One of the easiest ways to gauge this success is by considering the large number of publications in peer-reviewed journals, oral or poster presentations, and many additional manuscripts in preparation that involve our residents. Michigan residents also serve on committees of several national pathology organizations, including the United States and Canadian Academy of Pathology, the American Society for Clinical Pathology, and the College of American Pathologists. Our residents

Pathology Education

- **Graduate Medical Education**
- **Pathology Residency Program**
- **Fellowship Programs**
- **Medical Student Teaching**
- **Molecular and Cellular Pathology Graduate Program**

have been invited to speak at national and regional meetings and educational conferences, as well. Their success and accomplishments are also evident in their post-residency destinations. All are placed in excellent fellowships or jobs.

Graduate Medical Education—Fellowship Programs

The number of clinical fellows training in the department has increased substantially in recent years, and continues to grow. Over the past year, eighteen fellows have been engaged in twelve fellowships, including the ACGME-accredited fellowships of Cytopathology, Dermatopathology, Hematopathology, Molecular Genetic Pathology, Pediatric Pathology and Surgical Pathology, as well as subspecialty fellowships in Breast, Gastrointestinal, Genitourinary, Gynecologic and Pulmonary Pathology, and Informatics. Each of these fellows has contributed significantly to the missions of patient care, education, and scholarship. The fellowship in Blood Banking and Transfusion Medicine has accepted fellows for coming years, the Neuropathology and HLA/Tissue Typing fellowships have been accredited and are recruiting, and the Forensic Pathology fellowship application is in process.

Each of the ACGME-accredited programs, including the core residency program and the fellowships, must comply with a schedule of Internal Reviews by the University's Graduate Medical Education Committee and the Accreditation Council for Graduate Medical Education (ACGME). Successful ACGME Site Visits were conducted for the Core Residency Program and the Hematopathology and Molecular/Genetic Pathology fellowships.

Medical Student Teaching

Once again, pathology faculty has devoted hundreds of hours to teaching first, second, and fourth year medical students. The Component I curriculum for first year medical students includes introductory histopathology lectures in the fall and spring, culminating in a set of spring laboratories. Drs. Gerald Abrams and Stephen Ramsburgh have concluded their outstanding tenure as the Histopathology Course Directors, and handed the reins to the able duo of Drs. Michael Roh and Scott Owens. Component II, the curriculum for second year medical students, includes pathology lectures and laboratories in each sequence, given and conducted by a rotating set of pathology faculty, organized by areas of expertise, and coordinated by Dr. Paul Killen. Medical student evaluations of the pathology teaching in both components is consistently high. Plans are underway to refine the teaching laboratories to best meet the needs of future physicians. In the meantime, it is gratifying to note that the web-based resources for the Pathology Laboratories, using virtual slide technology, are among the highest-ranked resources in a recent survey of University of Michigan medical students

Fifty fourth year medical students enrolled in senior pathology elective rotations during the 2010-11 academic year. These rotations gave each student a broad overview of the field of pathology, while permitting them to concentrate part of their time in an area of most relevance to their future goals. The M4 elective rotations occurred under the direction of Dr. Jonathan McHugh, who has continued to improve the experience, along with a number of faculty mentors who meet with students regularly, advise, and grade them on each rotation. The course is compliant with requirements recently put forth by the Dean's Office: goals are clearly articulated and provided in electronic and written format at the beginning of the rotation, the grading schema is clearly explained, a mid-term evaluation is performed, and documentation of students' activities are maintained.

Molecular and Cellular Pathology (MCP) Graduate Program

The Molecular and Cellular Pathology (MCP) Graduate Program, under the direction of Nicholas W. Lukacs, Ph.D., has 23 students who are presently in Pathology Department laboratories performing their Ph.D. thesis research. This past year 5 students wrote, defended and successfully completed their preliminary exams that allowed them to pass to candidacy and begin their 3rd year in the program. In April we finished the recruiting for the Fall, 2011 class for the Program in Biological Sciences (PIBS) and successfully recruited 5 of the 7 high quality students, indicating the vitality of the graduate program. This recruiting success can be attributed to the tremendous effort made by the students, faculty and administrative staff that participated in the recruiting weekend. In addition to the successful recruiting year we also had 6 students successfully complete their graduate research careers by defending their thesis and have continued their training in clinical and investigative sciences.

The MCP graduate students produce high quality research that has resulted in publications in top tier journals. In addition, the students have also participated in other academic activities, including mentoring of younger students and undergraduates. Perhaps the most impressive extramural accomplishment that the MCP students perform on an annual basis is the organization of the annual Department Research Symposium that is held in

the fall each year for past 10 years. The MCP students invite an internationally known keynote speaker that gives the final talk in a half-day symposium that highlights short research talks from faculty, graduate students and post-docs. During the symposium they also organize a poster session that this past year had ~45 posters from laboratories in the Pathology Department. This event has become a true success and highlights the student's enthusiasm, collegiality, and passion for research.

Finally, this year we lost our longstanding Student Service Representative, Laura Hessler, who went onto a new position but we replaced her with Laura Labut who came from the Chemistry Department and has a wealth of experience in Student Services. We look forward to another productive and outstanding year for our graduate student organization.

Our Leaders and Best

PETER LUCAS, M.D., PH.D.

Assoc. Professor

NICHOLAS LUKACS, PH.D.

Professor of Pathology

PAUL KILLEN, M.D., PH.D.

Assistant Professor

JONATHAN MCHUGH, M.D.

Assistant Professor.

SCOTT OWENS, M.D.

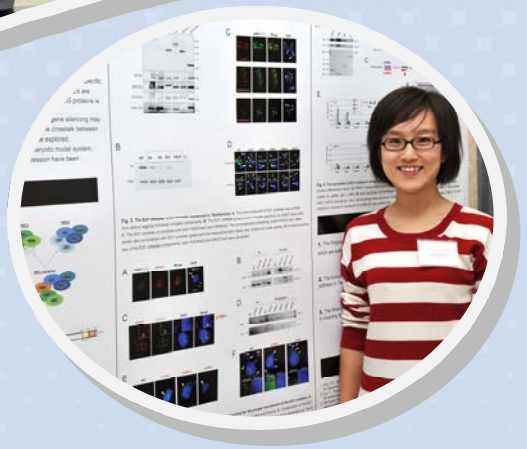
Assistant Professor

MICHAEL ROH, M.D., PH.D.

Assistant Professor

Pathology Research Symposium

Keynote Speaker Dr. Vishva Dixit, Vice President of Early Research Discovery, Genentech, shows off his UM Football received from our Ph.D. Students



Shan Gao, postdoctoral fellow in Dr. Yifan Liu's laboratory with her research poster.

2012-2013 PATHOLOGY RESIDENTS AND FELLOWS

University of Michigan
Department of Pathology


Randall Butler, MD
HO IV
CHIEF RESIDENT


Megan Alderman, MD
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Charles Harmon, MD
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Carolyn Haus, MD
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Andrew Hanosh, MD
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Carlos Murga, MD
HOI


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Nathan Shaller, MD
HOI


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Reena Singh, MD
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Amir Behdad, MD
FELLOW
HEMATOPATHOLOGY


Monisha Dandekar,MD
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MGP PATHOLOGY


Thomas Hocker, MD
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CYTOPATHOLOGY


Daniel Leino,MD
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Andrew Schubeck, MD
FELLOW
HEMATOPATHOLOGY


Abhishek (Ajay) Shukla,MD
FELLOW
CYTOPATHOLOGY


Kurt Bernacki, MD
CLINICAL LECTURER
SURGICAL PATHOLOGY


John Blau, MD
CLINICAL LECTURER
PATHOLOGY INFORMATICS


Melissa Bombery,MD
CLINICAL LECTURER
SURGICAL PATHOLOGY

Nora Frisch,MD
CLINICAL LECTURER
GYNECOLOGIC PATHOLOGY

Suntrea Hammer, MD
CLINICAL LECTURER
GASTROINTESTINAL PATHOLOGY

Jane Morrison, MD
CLINICAL LECTURER
SURGICAL PATHOLOGY

Carlo Valentino,MD
CLINICAL LECTURER
BREAST PATHOLOGY

Joshua Warrick, MD
CLINICAL LECTURER
GENITOURINARY PATHOLOGY

Chen Zhang, MD,PhD
CLINICAL LECTURER
PULMONARY PATHOLOGY

Division of Pathology Informatics

Ulysses G. J. Balis, M.D.
Associate Professor of Pathology
Director, Division of Pathology Informatics

Similar to prior years, the 2011-2012 period witnessed significantly increased departmental demand for support and implementation services from the Informatics Division. Significant development thrusts for Informatics were essentially unchanged from the prior year, with 1) LIS Implementation, 2) MiChart Readiness, and 3) MLabs Interface and reporting development/support remaining the highest three development activities. Support of the extant clinical informatics software and hardware systems similarly remained the single highest operational priority. Over the past year, the Division attained a significant milestone, in that it became the largest U.S. healthcare curator of a healthcare-centric VMWare virtualization solution, with it now hosting over 800 virtual servers, supported by a physical abstraction layer of over 200 CPU cores. This reality was shared in the technical press, through a series of VMWare press releases. (e.g. http://searchhealthit.techtarget.com/healthitexchange/CommunityBlog/the-it-of-pathology-in-support-of-lis/). Similarly, the Division passed the two-Petabyte storage threshold this past year, when combining both clinical and research infrastructure segments. Not surprisingly, as soon as this expanded resource became available to the department at large, utilization quickly reached 90%, indicating that there remains significant pent up demand for data storage.

Highlighted Clinical Activities:

Cerner 015 Upgrade

With the Cerner 3.06 product approaching end-of-life, the Division successfully implemented the upgraded 015 version in Q1 of 2012, thus allowing the department to continue operation with full vendor support to as late as Q4 2015. Key features made possible by this upgrade include ICD10 compatibility and full HIPAA audit capability (not-installed; under consideration for purchase by UMHS compliance). The implementation was essentially uneventful, with the overall process highlighting the outstanding *esprit de corps* now in place between Pathology Informatics and MCIT.

Continued SCC-Soft Implementation

A major thrust of the division has and continues to be the implementation of the new LIS. Although a number of external IT mandates from MCIT episodically paused some aspects of SCC configuration, the year was highly significant in that most laboratory areas have reached 95% or better readiness, with a June 1, 2013 activation date now being locked in place. Current project thrusts include AP workflow and reports optimization, electronic order entry, and definition of specimen tracking workflow models. With work completed to date, the issue

Pathology Informatics

- Academic Support
- Clinical Support
- Help Desk and Desktop Support
- MLabs Support
- Integration Support
- Pathology Informatics Fellowship

of go-live readiness has transitioned to go-live feature set capabilities, with overall project risk now being significantly mitigated.

EMPI Activation

Concomitant with the phase I activation of Epic on February 1, 2012, the Division's EMPI solution similarly went live, thus providing to MLabs the capability of true patient identity reconciliation across disparate health organizations and provider accounts. This functionality was the result of over three years of planning and implementation efforts, with it representing a level of identity management sophistication that only a handful of reference lab providers currently offer. It is anticipated that this solution will allow the department to easily meet upcoming meaningful use criteria for quality metrics, by virtue of being able to generate seamless patient results records across a plurality of clinical ordering sources. Moreover, this capability exceeds current UMHS patient identity functionality, and may become a significant solution for the enterprise at large. Towards this goal, the current EMPI solution is implemented on a fully virtualized and scalable architecture, which should easily meet future enterprise needs.

Website Content Management System (CMS)

Designed as an answer to the longstanding need for self-empowerment among departmental faculty and staff, the CMS was internally developed from the ground up, utilizing agile development techniques. Based on an entirely open-source development stack, the tool is instantiated as a royalty-free solution and allows the development team full control of every aspect of its functionality, without third-party encumbrances or licensing issues. With it now being in place for nine months, operational experience has been very satisfactory, with end users already having created nearly 800 new pages of self-managed content. This metric alone represents a significant body of effort; content that has been successfully transferred to departmental faculty and staff from the core Web development team, thus freeing up significant effort for new product development as opposed to site maintenance.

Expansion of MLabs Integrated Reporting and XML Interfaces

With the rapid expansion of MLabs clinical volume for molecular results, and increased number of such clients, there was emergent need to scale the extant integrated reporting tool such that error detection/resolution and automated report assembly could be streamlined. Representing over 120 separate programmatic innovations, the current Integrated Results tool fully meets the current order volume and plurality of clients, delivering upwards of 600 reports per week. At present, the tool is scaled to easily meet 10,000 reports per week, with this value representing a comfortable margin for excess capacity. Additionally, the Division has been successful in cross-training additional staff to support this tool, thus allowing for improved continuity of services should the lead developer be unavailable.

Professional Component Billing

The division successfully completed the technical implementation of a number of interfaces and data extraction reports, thus facilitating the Department's Professional Component Billing Initiative. All interfaces and reports were thoroughly cross-referenced against core schema tables for correctness of data and extraction logic. The new data extraction infra-

structure has been in place for nearly a year with no untoward results reported.

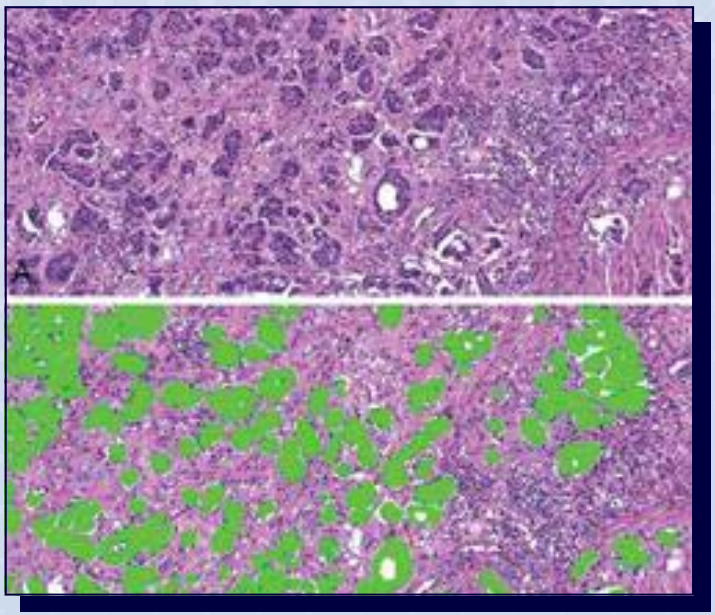
Highlighted Research Activities:

Continued Efforts with Spatially Invariant Vector Quantization (SIVQ)

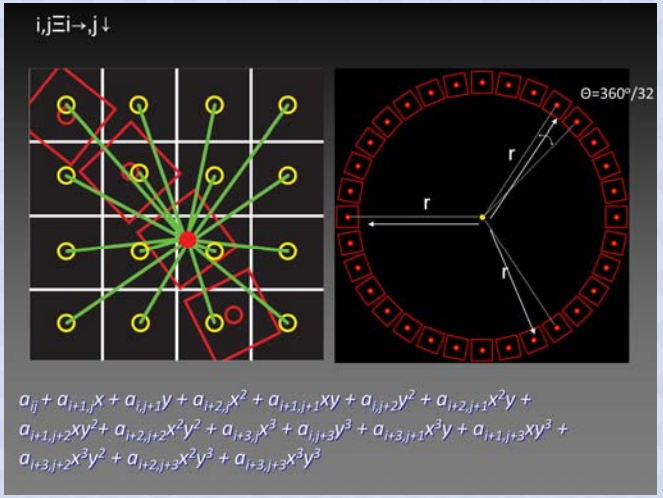
The Division has received both national and international attention for its efforts and publications related to SIVQ. At present, UM Technology Transfer is negotiation the licensing of the software discovery package to three interested parties. Dr. Jason Hipp, the Division's most recent fellowship graduate, has moved on to the NCI, where he is implementing SIVQ as an integral component of a new personalized medicine clinical core for high-throughput LCM tissue procurement, in support of NCI's innumerable clinical trials.

Thiopurine Metabolite Computational Assays

The Division, in partnership with Dr. Peter Higgins of the GI Division of Internal Medicine, is now participating in an R01-funded five year project to implement calculated thiopurine testing on a national/international basis, based upon the LIDDEx virtualization cloud technology, which was devel



Spatially Invariant Vector Quantization (SIVQ) is used to identify cancerous regions for closer pathologic examination.



This algorithm represents the underpinnings of the SIVQ system using circular search coordinates instead of traditional square coordinates.

oped by the division and was recognized by the NCI with an innovation award. The thiopurine technology is compelling as an exemplar of so-called encoded data results, as it offers superior ROC performance over conventional molecular testing, as currently offered by Prometheus Laboratories.

Appendix A. Large and Mid-sized Implementation Projects

1. C&W opening (logistics, IT site preparation and operational support)
2. Cerner 015 upgrade, department-wide
3. MiChart ADT financials activation
4. MiChart orders interface pilot activation
5. Completion/activation of the three-year EMPI project (Enterprise Master Person Index)
6. Departmental Website Content Management System
7. Installation of UHS Cerner classic
8. Network operations room renovation
9. Technical billing with an entirely new Oracle abstraction layer (virtualized N+1 redundant)
10. Billing enhancements for compliance standards
11. Death Registry support and maintenance
12. Histotrack interface support and activations logistics in partnership with the HLA laboratory
13. Freeview Image Archival tool – major version update

14. Cytovision - major version update
15. Winscribe – major version update
16. XML interface activation for CSIL/scaling of architecture to support 1000+ reports/day
17. New electronic payroll system
18. VMWare virtualization layer major upgrade
19. VM blade farm installation
20. Migration of Pathnet 015 storage to EVA fabric storage solution (N+1 architecture)
21. Major network topology upgrade in primary data center
22. Standardization of data center backbone to dual 10 Gb fabric
23. Tape backup systems upgraded to LT05 form factor
24. Server farm migration to Windows 2008
25. UMHS active directory – total UMHS integration (completion of a five year project)
26. Continued SCC-Soft readiness activities
27. Website migration of all legacy Novell server services to contemporary PHP platforms
28. Sysmex/WAM upgrade and full rules validation
29. Completion of incremental bi-directional laboratory instrument interfaces
30. Completion of Outlook migration, infrastructure updates and user/resource data archival
31. Migration of Infusion center orders to Atlas Ordering Tool
32. Research high-performance cluster upgrades (in process)
33. Nursing homes account expansion for MLabs in Atlas (two accounts)
34. Metric-based process for analyzing progress for completion of an interface
35. Radiometer upgrades - troubleshooting and support
36. Ongoing MiChart support, including: patient identity, merges, and error queue management
37. Support of UMHS Health Information Exchange (HIE) interface infrastructure
38. Continued support & development of JVHL interface modifications
39. IT support and data extraction support enabling Professional Component Billing
40. Implementation of full rack-level redundant switching in the primary data center
41. Establishment of service-level agreements and intradepartmental support models for: mobile devices, iphones and ipads. iPad rollout to residents.
42. Completion of multiple AP tracking / Cassettron workstations
43. Completion of CHCB interface readiness activities
44. Completion numerous additional Integrated Reports clients for MLabs, using the locally-developed XML integration engine (coding efforts and support provided by Dr. Jerome Chang)
45. Expansion of the core MLabs IT support team

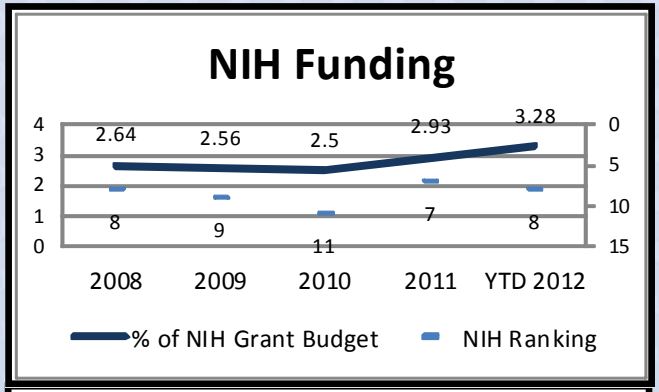
Dr. Steve Smith was one five Pathology Visions Award winners from the Digital Pathology Association.

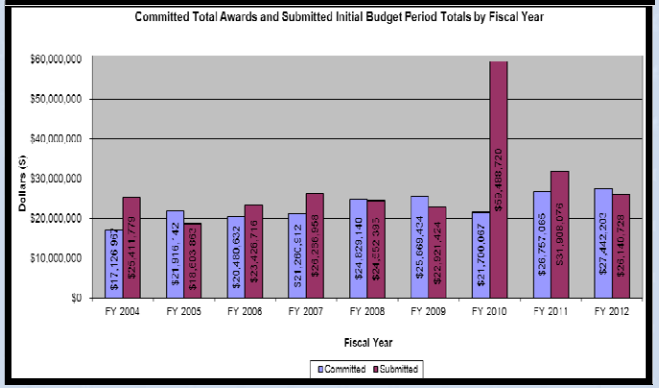
Dr. Jason Hipp receives the award for Best Scientific Paper at the International Academy of Digital Pathology Annual Meeting.

Division of Sponsored Research

Jay L. Hess, M.D., Ph.D.
Carl V. Weller Professor and Chair
Director, Division of Sponsored Research
Steven L. Kunkel, Ph.D.
Endowed Professor of Pathology Research
Co-Director, Division of Sponsored Research
Senior Associate Dean for Research

The Division of Sponsored Research continues to thrive despite a challenging funding environment. Our research funding grew to 16,938,151 with an improvement from 11th to 7th in NIH funding between 2010 and 2011. Our market share for 2012 is on track to exceed the prior year's performance. The ranking data is expected to change as more grant funds are accounted for in 2012.





Dr. Colin Duckett assumed an important leadership role this year as the Director of NCRC Program Development. In this

Sponsored Programs

- **48 Principal Investigators**
- **81 Research Faculty**
- **$27.44 Million in Research Funding**
- **Ranked 7th nationally in NIH Funded Research**
- **10 Endowed Professorships held by PI's**

position, he will be playing a central role in building research programs and coordinating research efforts on the North Campus

The Department is very actively involved in FastForward, an exciting initiative supported by the Medical School to accelerate discovery and led by Dr. Steve Kunkel, Senior Associate Dean for Research. One important advance has been the investment in and support of a Biorepository to be managed by the University of Michigan startup Paradigm. Drs. Jay Hess, Cory Hogaboam, Gregory Dressler, Yali Dou, Andrew Lieberman and Richard Miller all serve as co-champions developing plans for strategic initiatives in areas including personalized medicine, immunotherapy, epigenetics, protein misfolding and aging. The wide range of faculty members involved in strategic research initiatives at Michigan is a strong testimony to the strength of research in the Department of Pathology and our optimism and commitment to research improving patients' lives in the future.

Dr. Colin Duckett

Colin Duckett, Ph.D. Professor of Pathology and Internal Medicine named Director of NCRC Program Development

Division of Translational Pathology

Kojo S. J. Elenitoba-Johnson, M.D.
Henry Clay Bryant Professor of Pathology
Director, Division of Translational Pathology
Director, Molecular Diagnostics Laboratory

The Division of Translational Research includes the mass spectrometry-driven proteomics resource, the analytical flow cytometry core, the tissue procurement resource and the molecular pathology research laboratory. The updates for the individual constituents of the Division are discussed under separate headings below.

PROTEOMICS RESOURCE FACILITY (PRF)

The PRF is a resource service that supports the research needs of those both within and outside the Department and University, led by **Kojo S. J. Elenitoba-Johnson, M.D.** (Director), Venkatesha Basrur, Ph.D. (Lab Manager), Kevin P. Conlon (Senior Research Lab Specialist), and Damian Fermin, Ph.D. (Proteome Informatics Specialist). This facility provides the following services:

- **Protein identification by LC-MS/MS sequencing:** *In-gel* and *In-solution* processing
- **Identification of post translational modifications (PTMs):** Phosphorylation, acetylation, methylation, ubiquitination, and citrullination (new) serine, threonine, and tyrosine. This service is charged as protein identification by LC-MS/MS sequencing. Any specific reagents needed (such as IMAC column for phosphopeptide enrichment) are supplied by the user.

The above services include cutting the gel slices (if needed), protease (trypsin) digestion, desalting/fractionation (where applicable), LC-MS/MS analysis, and database search (X!Tandem/TPP). Results are delivered via an email link (internal users) and/or Excel file format (external users). In-solution digestion includes an SCX fractionation (3 fractions). If an enzyme other than trypsin is to be used, the user will have to provide them at the time of sample submission.

- **Differential protein expression analysis:** Relative quantitation using cICAT – Cleavable Isotope Coded Affinity Tags, iTRAQ – Isobaric Tags for Relative and Absolute Quantitation, and SILAC – Stable Incorporation of Labeled Amino acids in Culture

The majority of the projects submitted to PRF deal with the identification of interacting proteins, post-translational modification, and determining the relative quantitation of differentially expressed proteins. To accomplish these analyses, PRF employs *in-gel* or *in-solution* digestion of the samples with trypsin followed by acquisition of data-dependent MS/MS spectra using ion-trap instruments.

Over the past year, the PRF has provided services to 38 Principal Investigators, both internal and external to the University of Michigan. Seven manuscripts have been accepted or published in peer-reviewed journals with the proteomic data generated at the PRF, with three more currently under review.

Translational Pathology

- **Proteomics Resource Facility**
- **Flow Cytometry Core Laboratory**
- **Virtual Slide Imaging**
- **Tissue Procurement Service**
- **Molecular Pathology Resource Laboratory**

FLOW CYTOMETRY CORE LABORATORY AND VIRTUAL SLIDE SCANNING SERVICE

These services are led by **Lloyd M. Stoolman, M.D.** (Director) and Ronald Craig, Ph.D. (Operator/Manager)

Flow Cytometry Core Laboratory http://www.pathology.med.umich.edu/pathflowcore/ provides access to a research grade Becton-Dickinson LSR-II (3-laser, 10-color, 13-parameter, plate loader) flow cytometer , networked data storage and web-based scheduling system. More than 40 undergraduates, graduate students, post-docs, research associates and principal investigators from 14 laboratories used this instrument in 2011-2012 for a total of 2,270 hours: 1,870 hours of Departmental use, 98 hours of non-departmental use, which was recharged, and 302 hours of downtime for service maintenance. The laboratory decommissioned the FC-500 5-color flow cytometer due to declining usage and rising service contract expenses. The LSR-II is heavily used between 7:00 am and 7:00 pm. It is available 24/7 and off hours usage is rising. Users report that this Core contributed to 21 publications in peer reviewed journals, 2 abstracts and a minimum of 25 NIH grants (active).

Pathology Virtual Slide Scanning Service generates diagnostic quality (200-1000X) digital slide scans using an Aperio XT-robotic slide scanner, a Zeiss Axiomat computer-controlled photomicroscope with "mosaic" stitching software and networked Image servers. This year, 4700 slides were scanned, a year-over-year increase of 60%, with scans for education and clinical support (71% of scans) exceeding those for research projects (29% of scans).

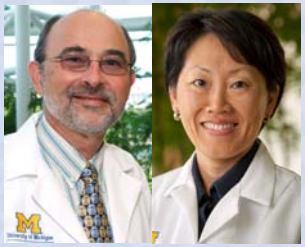
The Virtual Slide Scanning Service maintains secure virtual slide servers and custom databases to support educational, clinical and research applications within the Department of Pathology. Networked image serviers currently have ~10 terabytes of online storage that contain ~13,000 virtual slides Current projects include the following:

- **Hematopathology Slide Library** This project encompasses a systematic scanning of Hematopathology slides with educational value, providing a searchable database/user interface that links Hematopathology reports to virtual slides and the electronic medical record (Search-Tag Portal).
- **Lymphoma Conference Virtual Slide Project** This project encompasses a systematic scanning of Hematopathology slides for Lymphoma conference and the training of fellows and residents in virtual slide annotation, presentation, quality assurance.
- **Special Conferences and Case Reviews** This project includes scanning slides for use by faculty in presentations at conferences and meetings. In addition, slides that have been approved for review by individuals outside the institution are scanned and hosted , including case submissions for the ASCP, CAP and others, as well as for diagnostic reviews.
- **The Core continues to support The Virtual Microscope Teaching Project.** This Project encompasses a collection of virtual slide servers, teaching laboratory websites and personnel that jointly support the use of Virtual Microscopy in teaching programs on the Medical Campus. The Virtual Slide Scanning Service supports the Project by producing new slide scans and consulting. The Project now supports educational websites in Medical Histology, Medical Histopathology, Medical Organ Systems Pathology, Dental and Graduate Student Histology and Histopathology with 500+ campus users.
- Investigators report that this Core contributed to 8 peer-reviewed publications, 5 abstracts, and 5 NIH grants (active).

Aperio XT Robotic Slide Scanner—4700 slides imaged in FY12

ONLINE BIOREPOSITORY

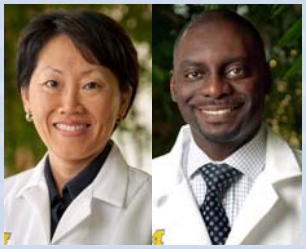
Under the guidance of **Drs. Lloyd Stoolman and MeganLim**, the Online Biorepository was created in FY12 by adding fields to our custom clinical flow cytometry and hematopathology report databases that specify the number/location of frozen aliquots for the 7000 specimens in the flow cytometry collection (representing 20 years of specimen collection), as well as the Hematopathology cases used to build tissue arrays. The database is searched via the search portal, a multipurpose user interface that conducts keyword or free-text searches of completed Flow Cytometry and Hematopathology reports. A search generates a compact list of accession numbers and specimen locations with links to relevant pathology reports, flow cytometry data, virtual slides and the electronic medical record. As part of this project, Dr. Megan Lim established a state-of-the-art liquid nitrogen storage facility in her laboratory to house the Flow Cytometry collection. The project created a sustainable Biorepository outside the Clinical Laboratory and developed an intuitive online search tool to facilitate management.



TISSUE PROCUREMENT RESOURCE (TPR)

This effort has been coordinated primarily by **Dr. Megan Lim and Dr. Kojo Elenitoba-Johnson.**

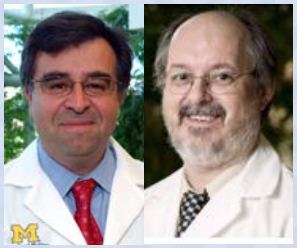
The TPR continues to make progress in archiving tissue material from hematopoietic malignancies, primarily lymphomas. Currently, the majority of these have been retrospective from existing material in fixed-paraffin-embedded tissue. The lymphomas have been reclassified according to the new WHO classification. The tissue microarray library has been expanded to include more than 2,000 cases of malignant lymphomas. With regard to frozen tissues, the Hematopathology tissue repository has archived approximately 800 specimens.



Additionally, this year the service developed, organized, annotated and stored samples in a flow cytometry repository consisting of more than 10,000 cryopreserved specimens.

MOLECULAR PATHOLOGY RESEARCH LABORATORY (MPRL)

Lead by **Thomas J. Giordano, M.D., Ph.D. (Director) and Dafydd G. Thomas, M.D., Ph.D. (Associate Director)**, the Molecular Pathology Research Laboratory (MPRL) completed another successful year in its mission to assist faculty and trainees in the Department of Pathology with lab-based research projects. In addition, we have expanded the scope of MPRL client base by formally incorporating its services into the Tissue Core of the UMCCC, which has been renamed the Tissue and Molecular Pathology Core. The MPRL has been working on expanding our technical abilities in FISH studies while continuing to provide tissue embedding and frozen sectioning (in part thru the UMCCC Tissue Core), DNA extraction, RNA extraction, protein extraction, PCR, quantitative RT-PCR, DNA microarray analysis thru the UMCCC Microarray Core, DNA sequencing thru UM DNA Sequencing Core, western blots, *in situ* hybridization, chromogenic *in situ* hybridization (CISH), quantitative *in situ* antigen detection (via AQUA analysis), laser capture microdissection thru the UMCCC Tissue Core, tissue array construction, and immunohistochemistry.

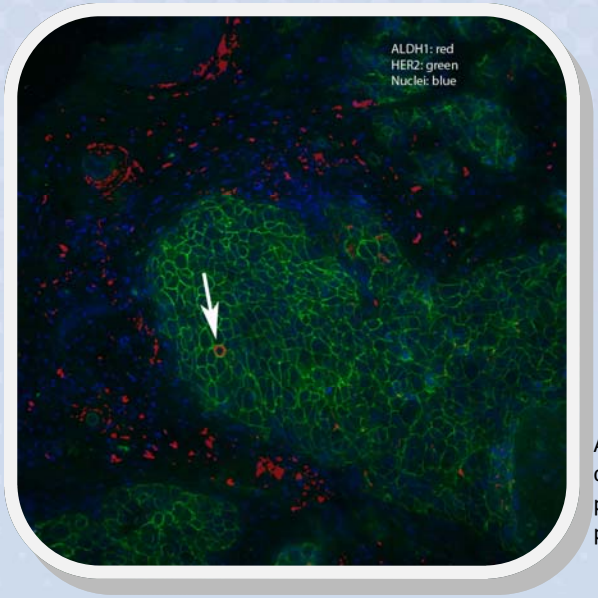


It has been a successful year for the MPRL. Since the last annual report, we have been involved in the publication of 14 manuscripts in high impact journals, in addition to the presentation of 13 abstracts for the United States and Canadian Academy of Pathology, the Society for Pediatric Pathology (SPP), the American Association for Cancer Research, the American Society of Clinical Oncology, and the annual San Antonio Breast Cancer Symposium. Scholarly activities also included membership in the SPP Research Committee, abstract review for the fall and spring meetings of the SPP, moderation of the poster discussion at the spring meeting in Vancouver, and serving as an ad hoc reviewer for several journals.

As before, most of the projects have involved the construction of tissue microarrays followed by immunohistochemistry. The construction of TMAs has become much more streamlined due in large part to the addition of Jaclyn Puhlman to our lab. She has rapidly learned how to make TMAs and we can now offer a rapid turnaround time on making these valuable resources. The MPRL is intimately involved in offering high quality rapid immunohistochemical staining as an adjunct to clinical trials for sarcoma in addition to all the SPORE programs at the University.

It has been noticed that over the past year there has been an increased demand for more sophisticated assays, such as quantitative IHC using the AQUA platform, FISH, and ISH. In order to meet this increased demand, the laboratory – with the kind financial help of Dr. Myers – upgraded a fluorescence microscope to be able to perform automated FISH image acquisition on a high density TMA section. We have also started to offer in-situ hybridization using the ACD assay (www.acdbio.com) and subsequently have shown that we can perform AQUA style quantitative ISH. The expectation of the MPRL is that requests for assays of this sophistication will become the norm rather than the exception over the next couple of years.

The main research interest of Dr. Thomas has been the use of the AQUA platform to identify stem cells in breast cancer resection and correlate their expression with distant temporal metastasis. Dr. Thomas has also been attempting to define an AQUA signature to intrinsically subtype breast cancer specimens. This will have a profound effect on breast cancer management as the oncologists want to stratify patients into groups: which should or should not be offered adjuvant chemotherapy.

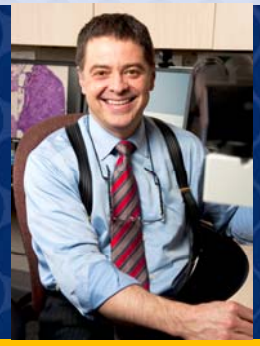


AQUA image of invasive ductal carcinoma demonstrating HER2 positivity (green) and rare ALDH1 positive stem cells (red). 200X

Project	Status
Immunohistochemical project involving use of ERG1/Fli1 antibody to help diagnose of EWS.	Abstract presented at USCAP. Manuscript submitted
PCR project involving viral causes of placental infection. RNA and DNA were extracted from placental samples with chronic villitis and RT-PCR performed for a variety of viral pathogens	Ongoing
DFSP TMA made and attempts to perform break-apart FISH for the t17;22	Ongoing
EWS Project: Novel Chr4:19 translocation. Cases identified. FISH probes ordered and first round of FISH just completed. RT-PCR performed and demonstrated no evidence of classic EWS translocation in index cases. DUX4;CIC PCR was positive	Ongoing
FISH project for MDM2 in cutaneous pleomorphic lipoma	Abstract presented at USCAP. Manuscript published in AJSP
Multiple immunohistochemical stains	Results presented at USCAP. Project ongoing
In situ hybridization probe prepared	Ongoing
Sequencing of KCNJ5 gene in adrenal tumors. Validated and extended recently published results of KCNJ5 mutations of adrenocortical tumors associated with overproduction of aldosterone.	Ongoing
Mucoepidermoid carcinoma TMA constructed. Immunohistochemistry completed. FISH for t11;19 translocation performed and waiting for analysis. Spindle cell carcinoma TMA constructed. Immunohistochemical stains performed	Ongoing
Hirschsprung disease cases identified and stained for calretinin	Abstract presented at Soc. Ped Path Meeting
Cases of GVHD identified and stained using ISH for LGR5. Semi-quantitated ISH (SQUISH) performed on GVHD cases	Ongoing
Performed multiple immunohistochemical stains	Ongoing
Performed multiple immunohistochemical stains on cell smears and cell pellets.	Abstract presented at USCAP. Two manuscripts published.
FISH analysis of brain lymphoma TMA underway	Ongoing

MLabs Outreach Program

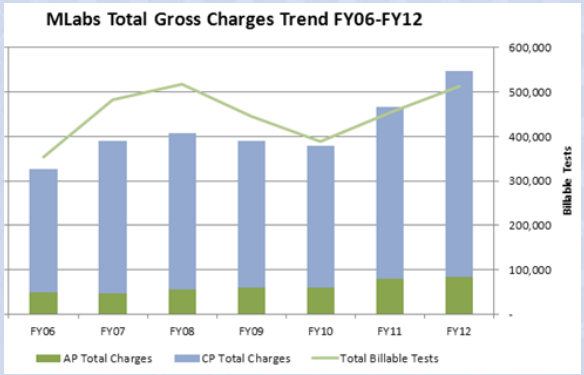
Jeffrey L Myers, M.D.
A. James French Professor of Pathology
Director, Division of Anatomic Pathology
Director, MLabs Outreach Program



Established in 1985, MLabs is the University of Michigan Health System's outreach laboratory division. MLabs' vision is to drive tomorrow's health care solutions with cutting edge personalized laboratory information and consultation. MLabs functions as a portal to provide easy access to the expertise and sophisticated testing needed for our clients - pathologists, clinicians, health care systems and commercial reference laboratories – so that they can meet today's diagnostic challenges. As MLabs celebrates its 27th anniversary, it has become a recognized leader for advanced diagnostic testing, helpful consultations and exceptional customer service.

Our mission is to deliver the highest quality laboratory results to meet the needs of today's patients in a cost effective manner by offering:

1) Cutting edge molecular diagnostic and interpretive services.
2) A complete menu of laboratory tests for personalized care.
3) Nationally recognized and accessible faculty for consultation.
4) Dedication to creating and supporting strategic partnerships.
5) On-time delivery of effective and comprehensive reports.



MLabs Client Services provides personalized service from 6:30 am to 11:00 pm, Monday through Friday, and from 8:00 am to 4:00 pm on Saturday to provide our clients the best customer experience possible. Specimen Processing provides personalized service during off-hours to ensure round-the-clock attention to client needs.

Additions to our staff this year include Brad Gibson as MLabs IT support specialist and Marianne Mara, MLabs IT applications support specialist in Pathology Informatics dedicated to supporting MLabs informatics initiatives including primarily client interface projects. We hired two new client service representatives, Jeff Bauer and Terrance Still, to replace staff that resigned during the year. Sue Yopek, MLabs Administrative Assistant, retired from her position in May. A complete list of our staff who represent MLabs to the Department, Health System, Clients and those patients served by all can be found on the next page.

GROWTH

The MLabs Division's client portfolio includes over 500 accounts, with active management of approximately 125 physician offices, 5 full-service referral hospitals, 10 sub-specialty

MLabs Outreach Programs Serving

- **Physicians' Offices**
- **Hospitals**
- **Reverse Reference Laboratories**
- **AP Consultations**
- **Extended Care Nursing Facilities**
- **Managed Care & Laboratory Network**

referral hospitals, 3 national reference labs, 4 extended nursing care facilities, and various 'other' clients accounting for gross charges exceeding 5 million dollars. Servicing the needs of this diverse mix of clients is a MLabs team of dedicated professionals with over 100 years of combined experience in laboratory medicine along with the combined effort of the Department of Pathology's faculty and staff.

MLabs continues to experience year-over-year growth realizing a 17% increase in total gross charges and 13% increase in tests billed over FY11. MLabs had its most successful year to date as evidenced by gross charges exceeding 54 million dollars. Working together, the MLabs team successfully acquired 40+ new clients during FY12, representing new business across all market segments.

MARKET SEGMENTS SERVED

The MLabs Division plays a significant role in providing reference laboratory services within a 150 mile radius of Ann Arbor and our reach for molecular diagnostic services, anatomical pathology specialized services and surgical pathology consultations is national.

MLabs categorizes its business into 6 Market Segments:

Physician Office – all Specialties

Hospital – both full service and those sending specialized testing

Reverse Reference Laboratories – commercial/independent labs

AP Consultations

Nursing Home – extended nursing and acute care facilities

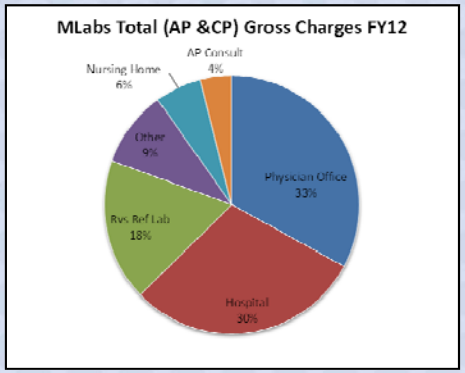
Other – Miscellaneous 'catch all' category (8999 REFR)

Physician Office Market Segment (33% of Total Gross Charges)

MLabs provides laboratory testing to over 125 individual offices in the greater Washtenaw county service area. The majority of this testing is sent to MLabs by two primary care providers in this region, Integrated Health Associates (IHA) and Allied Primary Care (HVPA). Another large percentage is from several local dermatology offices and 3 large dermatology offices in the Grand Rapids area. FY12 experienced a slight decrease in total gross charges for this market segment, a reflection of changes in insurance mix and referral pattern within individual physician offices. The dermatology offices within this market segment present the biggest opportunity for growth FY13. We are pleased that greater than 50% of the testing from these physician offices is received and resulted electronically through our interfaces.

Hospital Market Segment (30% Total Gross Charges)

MLabs is the primary reference laboratory and provides full esoteric testing to 5 hospitals in Michigan. MLabs provides specialty services, e.g., renal, muscle, nerve biopsies, flow cytometry and molecular diagnostic testing to an additional 10+ hospitals throughout the state. MLabs served another 75+ hospital clients around the country that routinely use the Department of Pathology surgical pathology consultative service. MLabs experienced a 21% increase in gross charges over FY11 from our hospital market, primarily from the specialized services requested from our Grand Rapids accounts



Reverse Reference Laboratories (18% of Total Gross Charges)

The year-over-year increase in the Reverse Reference Lab market segment reflects the outstanding combined effort of the Molecular Diagnostic Laboratory, MLabs focused marketing effort and Pathology Informatics ability to keep up with challenging IT demands of this unique market. With increased competition and advances in technology, molecular diagnostic testing will become a commodity similar to other esoteric testing. MLabs will continue to stay on the cutting edge of precision molecular diagnostics to maintain our position as a national provider of this specialized testing. One can see from the figure below both the rapid growth in this market segment as well as the impact when a large account brings this specialized testing in-house (June 2012).

AP Consultations

Our Surgical Pathology faculty comprises one of the strongest groups of diagnostic pathologists in the world. MLabs continues to receive accolades regarding the increased level of personalized service provided to those referring consultation cases to us.

Extended Care Nursing Facilities

MLabs continued to provide laboratory and phlebotomy services to 4 regional nursing home and acute care facilities in support of the institution's strategic initiatives and added its 5th acute care facility, Regency at Bluffs Park, in January. We expect volume from Bluffs to increase significantly in FY13 once they are at their full 80-bed capacity.

FY 12 INITIATIVES

MLabs Logo and Branding

MLabs and our partner, Spin Advertising, successfully created a new Logo that best captures what we are about – the strength and expertise of UMHS and its Department of Pathology combined with the ability to deliver that expertise in a manner that meets the industry standards of the reference laboratory business. Additionally, we are developing a new website that will provide our clients with a professional, coordinated useful tool to assist them when using our services.

MLabs Booth at National Meetings

During FY12, MLabs created a booth and exhibited at four national meetings; ASH, USCAP, ASCO, and AACC increasing awareness of our molecular diagnostic and consultation services.

Sales and Marketing

MLabs primary sales and marketing effort is focused on making certain that pathologists, hospitals, and reference laboratories everywhere recognize The University of Michigan MLabs as the center of excellence for specialized laboratory testing, especially molecular diagnostics and pathology consultative services.

Informatics

MLabs' success is closely tied to our ability to meet the information technology demands of our clients. Our MLabs IT staff, along with Pathology Informatics, were able to complete the following client requests and make steady progress on the others.

MLabs Connect (Atlas) Upgrade successfully completed

Interface (XML) to CSI Laboratories successfully completed

Interface (Atlas) to Community Health Center Branch Co success fully completed.

MLabs/MolDx BCR/ABL Trend Graph and International Scale (IS) reporting completed.

MLabs consult e-reporting pilot successfully completed.

Interface (Atlas) to Partners Internal Medicine – steady progress.

Interface (Atlas) to eClinicalWorks – steady progress.

MLABS MANAGED CARE AND LABORATORY NETWORK INVOLVEMENT

Joint Venture Hospital Laboratories (JVHL) is the largest laboratory network in Michigan and is organized as a limited liability company, equally owned by its hospital laboratory members. The University of Michigan Health System (MLabs) became an equity member of JVHL in 1997 and serves on its Executive, Quality Assurance and Operations Committees.

Great Lakes Laboratory Network (GLN) is a network of hospital laboratories geographically located primarily on the western side of the state. MLabs became a member of GLN in 1996, but does not participate in managed care contracts through GLN. MLabs plays an advisory role through representation on the Steering Committee.

MLabs helps facilitate Departmental issues pertaining to contractual obligations as a member of Joint Venture Hospital Laboratories and Great Lakes Laboratory Network. MLabs serves as a resource for the UMHS Managed Care Operations Office with lab related issues from their various contracted groups, e.g., IHA, HVPA.

ACKNOWLEDGEMENT

The MLabs Division had a remarkable year; its success reflects the efforts of each and every individual within the Department of Pathology, their commitment to service and their ability to push forward with innovative solutions to meet the sophisticated needs of our Clients.

L to R Dustin Suntheimer, Sales Representative; Sue Valliere, Manager of MLabs; Dr. Jay Hess, Chair of Pathology

MLabs was well represented at local, regional and national meetings in FY 2012

Ann Arbor VA Health System

Stephen W. Chensue, M.D., Ph.D.
Professor of Pathology
Chief, Pathology and Laboratory Medicine
Ann Arbor VA Health System

The VA Ann Arbor VA Healthcare System (VAAAHS) is a University of Michigan affiliated tertiary health care provider for veterans; one of three tertiary medical centers in the Veterans Integrated Service Network (VISN) #11 serving the veteran population of Michigan, and portions of Ohio, Indiana and Illinois. The VAAAHS Pathology and Laboratory Medicine Service (PALMS) maintains a close relationship with the University Department of Pathology at every level. All pathologists in the VAAAHS have medical school appointments and participate in university activities in a manner similar to other departmental sections. Recruitment for VAAAHS pathologists is a joint activity and candidates are selected on the basis of academic performance and potential as well as professional competence similar to any departmental candidate. There are currently four full-time pathology staff positions plus a consultant dermatopathologist. Three resident training positions in the Department's program are supported with funds from the Department of Veterans Affairs. All residents serve monthly rotations in Surgical Pathology, Autopsy Pathology, with access to special study programs in Surgical Pathology, Cytopathology and Digital Imaging. The VAAAHS laboratory retains full accreditation by the College of American Pathologists. The VAAAHS satellite laboratory at the Toledo Oupatient Clinic has been inspected by the Joint Commission and is currently fully accredited. The VHA Decentralized Hospital Computer System (***VistA***) is recognized as the most fully integrated medical information system in the nation. Data storage for all components of pathology and the clinical laboratories is available for patients from the nearly 4 decades since the inception of ***DHCP-VistA***. Digital images of selected patient surgical, cytopathology, and autopsy specimens are stored as part of the patient medical record and are accessible to clinicians.

In addition to the Toledo Outpatient clinic, there are additional community based outpatient clinics (CBOCs) in Flint and Jackson, Michigan. The VAAAHS PALMS provides specimen testing for these sites. The VAAAHS PALMS has successfully adapted to the shift to outpatient care and provides highest quality laboratory services in an environment of increasing demand. The VISN continues efforts toward an integrated health delivery system. Diagnostic Services will be a target for networking/consolidation among the current 8 independent facilities. This will result in additional sharing of service responsibilities, equipment standardization, VISN-wide reagent contracting, decreased cost of referred (send-out) testing to non-VA clinical labs and an increase in the workload in VAAAHS's anatomic pathology and clinical labs. Due to overall testing volume, laboratory equipment standardization with blanket contracting promises to allow for substantial savings in laboratory costs.

ANATOMICAL PATHOLOGY

Surgical Pathology

In addition to serving local hospital and clinics, the VAAAHS PALMS is currently performing all surgical pathology for the

VA Ann Arbor Health System Laboratories

- **Anatomic Pathology**
- **Clinical Pathology**
- **Facilities Integration**
- **Resident Training**

Battle Creek/Grand Rapid facilities. The Ann Arbor PALMS also performs all gynecologic cytopathology for Battle Creek, Detroit, Toledo, and affiliated CBOCs. Beginning FY13, the department will provide Anatomic Pathology services to the Aleda E. Lutz VA Medical Center, in Saginaw, MI. In addition, a significant expansion of surgical services will be implemented in FY13 that will increase workload.

Case load: 11,385 surgical cases were accessioned and reported during this reporting period, this represents a 4% increase over last year. This continues the trend of steadily increasing workload.

Quality Assurance: There is an extensive quality improvement program within Anatomical Pathology including regular consultations with colleagues at the University of Michigan as well as other outside consultants. There is a comprehensive quality assurance review with analyses of frozen section accuracy, amended diagnoses, surgical appropriateness, turnaround times, report quality, random retrospective review, and follow-up of positive cancer diagnoses. In addition, the VAAAHS PALMS has taken the lead with regard to patient safety by implementing pre-op second review of pathology for patients about to undergo major resections or excisions.

Surgical Pathology - 2011	
Surgical pathology diagnosis under 48 hr:	99.60%
Average surgical pathology report turn-around-time:	1.6 days
Case concordance (internal and external second reviews):	97.90%
Average frozen section turn-around-time:	9.0 min
Frozen section to permanent section concordance:	99.30%
Autopsy Service	
Autopsy completion turn-around-time average:	13.4 days
Percent less than 30 days:	100%
Cytology Service	
Non-gyn cytology diagnosis - Under 48 hours:	87.80%
Average non-gyn and gyn turn-around times:	2.96 days
Cytology PAP diagnostic concordance:	100%

Informatics, infrastructure and automation: In FY12 the VAAAHS PALMS continued expansion of standardized synoptic reporting and addition of state-of-the-art tissue processors. Future directions include efforts to institute digital telepathology consultation to further integrate VA facilities.

Autopsy Pathology

The Department of Veterans Affairs maintains a policy to recognize the value of the autopsy and to encourage increased utilization. Currently, VHA policy does not establish a target autopsy rate but rather encourages performing a maximum number sufficient to examine a variety of diseases and clinical circumstances. The VHA requires all autopsy reports to be finalized in under 30 days. Autopsies performed at the VAAAHS may also be presented at the Extended Gross and Clinical-Pathologic Correlation conferences.

Case load: 18 autopsies were performed during the reporting period.

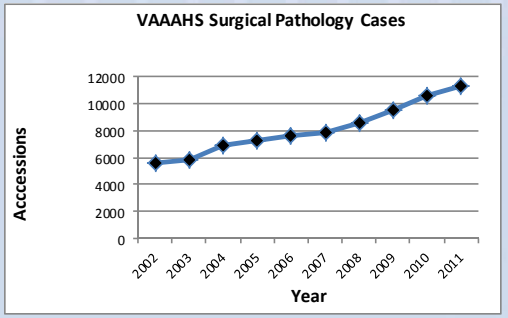
Quality Assurance: Autopsy protocols are submitted to clinical staff for comparison of anatomic diagnoses with to clinical findings. Each autopsy is also evaluated as to correlation of clinical and anatomic pathologic findings by review of the pathologist. Monthly reports are submitted to the VHA central office.

Cytology

Cytology specimens are of non-gynecologic diagnostic and gynecologic screening types. Due to the increasing population of women veterans, gynecologic pathology is becoming an important component of the VAAAHS workload. The VAAAHS performs all PAP screening cytologies for the northern tier of VISN 11. The Ann Arbor VA laboratory is rated a VA "Center of Excellence" in cytology.

Case load: 4,957 cases were examined and diagnosed during this period. This is a 3% increase over last year.

Quality Assurance: The VHA requires that its cytopathologists are enrolled in multiple proficiency testing programs encompassing both gynecologic and non-gynecologic diagnosis. In addition, several aspects of quality assurance are monitored.



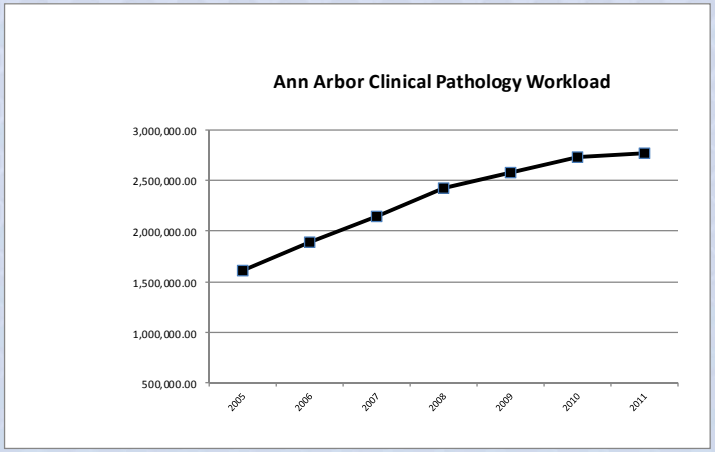
CLINICAL PATHOLOGY:

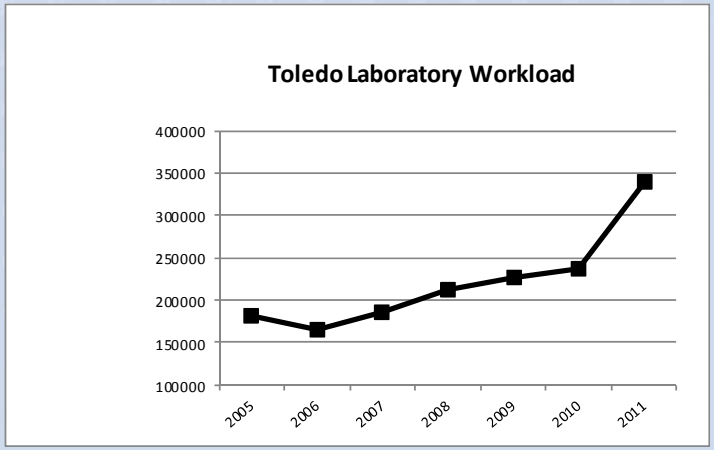
During the period of this report, 2,766,534 clinical pathology tests were performed in the Ann Arbor laboratory. Workload increases were observed in all areas (see chart). Our affiliated community-based outpatient clinic laboratory in Toledo performed 338,826 tests. Residents may participate or observe clinical pathology procedures when this activity is appropriate in relation to their rotations. Drs. Chensue, Utiger and Chamberlain oversee the clinical laboratory and make available interesting and pertinent clinical laboratory information available to residents as desired. Clinical Pathology and medical historical data is available to pathology residents via CPRS for their information in surgical pathology, autopsy pathology, and elective rotations.

Quality assurance: An extensive quality assurance program is in place monitoring all aspects of clinical laboratory activities, including proficiency testing, precision, turnaround-times, safety, education, and staff competency.

Informatics, infrastructure and automation: The VAAAHS clinical laboratories have continued to incorporate as much automation as possible employing state-of-the-art analyzers. In FY12 new chemistry analyzes were installed and the contract process was initiated to obtain an analyzer to perform automated urinalysis.

Clinical Pathology	
Chemistry	1,932,109
Hematology/ Coagulation/ Urinalysis	607,269
Microbiology	89,777
Blood Bank	50,184
Phlebotomy	113,870
Total Ann Arbor Cases	2,766,534
Toledo CP Cases	338,826
Total VAAAHS CP Cases	3,105,360





EDUCATION AND TEACHING:

In surgical pathology, the staff pathologists provide one-to-one mentoring during the surgical case sign out. The resident assigned to surgical pathology, usually a first year resident in training, has the opportunity to examine all of the specimens grossly and microscopically under close one-to-one mentoring by the staff pathologists. The resident interacts with the clinical teams. Weekly Urology Case Review Conference is held by Dr. Murphy. The residents assigned to autopsy and surgical pathology are primary presenters in clinical conferences. The residents obtain a broad educational experience and aid in providing high quality medical care. Residents are invited to join in continuing educational activities in histopathology and cytopathology from CAP and ASCP. Because of the closeness of various sections of the laboratory, there is frequent consultation among the pathologists and the residents are involved throughout. Since the VAAAHS is physically close to the University, the residents are expected to attend the appropriate teaching conferences at the University. VAAAHS pathologist staff contribute to teaching of medical and graduate students at the University of Michigan. Dr. Murphy designed and implemented pathology courses for graduate students (Path 581) which has since become a regular part of the Department graduate teaching program. Through his research program, Dr. Chensue also mentors post-doctoral fellows, graduate students and undergraduate students.

RESEARCH

The specific research efforts of the VA pathology staff are included on individual reports. Dr. Stephen Chensue has ongoing research programs funding by the NIH. He also participates in cooperative studies with other investigators at the University of Michigan. Dr. Chensue maintains research laboratories in Research Building 31 of the VAAAHS. All staff participates in various clinical studies and collaborates with a variety of investigators. The laboratory, in general, serves the VAAAHS research mission by providing considerable technical support for clinical research and, in some cases, for more basic research in both anatomic and clinical pathology.

ADMINISTRATION

Dr. Chensue has served as Chief of Service since March 2001. He serves on the VA/UM Affiliation Council as well as local and national VA oversight committees. Staff pathologists at the VA Ann Arbor Healthcare System serve in various capacities involving administrative tasks for the University of Michigan, such as the University Affiliation Council, Resident Selection Committee, the Medical Student Admissions Committee, Graduate student preliminary exam and thesis committees, teaching faculty for post graduate courses in the Medical School. At the VAAAHS, the pathology staff members serve on all major committees involved with institutional policies and procedures.

SUMMARY

The VAAAHS Pathology and Laboratory Medicine Service is the major provider of Anatomic Pathology services for the northern tier of VISN 11. The primary goal of the department is to provide high quality diagnostic services and appropriate care to the veteran patients. This is evidenced by continuing accreditation by external review agencies such as the College of American Pathologists (CAP), the Joint Commission (JC) for hospital accreditation and the Food and Drug Administration (FDA). There is close supervision of resident activities as they are involved with patient care. All staff members are privileged and evaluated in accordance with their training, experience, continuing education and participation in quality improvement activities. Within the service there is an extensive quality improvement program that integrates with that of the hospital as a whole. The affiliation with the University of Michigan serves to strengthen and improve the quality of patient care to our veterans. The teaching effort involving both residents and medical students is of benefit to the two institutions. The VAAAHS PALMS is positioned to continue delivery of high quality service to Veteran patients as demand for medical care continues to mount in the next decades.

Michigan Center for Translational Pathology

Arul M. Chinnaiyan, M.D., Ph.D.
S. P. Hicks Professor of Pathology
Professor of Pathology and Urology
Director, Michigan Center for Translational Pathology

The Michigan Center for Translational Pathology (MCTP) was formed in 2007 as a focused initiative to bring basic research discoveries from molecular medicine to clinical applications for the identification of biomarkers and therapeutic targets for cancer diagnosis and treatment. We have made several noteworthy discoveries that have driven cancer research forward and intend to develop these findings to advance cancer diagnostics and targeted therapies. It is our hope to explore avenues for the development of personalized medicine based upon an individual's specific genetic abnormalities underlying the development of his/her disease.

MCTP's overarching mission is to: 1) To establish the University of Michigan as the international leader in discovery and characterization of disease biomarkers and therapeutic targets using an integrated multi-disciplinary, systems biology approach. 2) Establish a new paradigm of bringing personalized medicine to routine clinical care through the use of high throughput sequencing. In parallel with the UM Health System, MCTP also has four core components to the mission: research, education, patient care and service. Our specific goals are to:

- Discover new disease biomarkers and candidate therapeutic targets using genomic, proteomic, and bioinformatics approaches.
- Employ a systems biology perspective in characterizing the molecular alterations in human disease.
- Translate and commercialize molecular discoveries for clinical utility.
- Train future translational cancer researchers.
- Ensure the long term scientific and funding success of the MCTP.
- Translate next generation sequencing based approaches (including associated bioinformatics) for clinical use in personalized medicine.
- Transform the practice of pathology and medicine.

During the past year, we have made tremendous progress toward our overarching goal of discovering the genetic lesions that initiate cancer development, dissecting the molecular mechanisms involved in cancer progression, and exploiting those findings to impact clinical diagnosis and treatment of cancers; we made advances on all those fronts. We identified novel non-coding RNAs that play a role in prostate cancer progression and are associated with aggressive disease (*Nat Biotechnol*. 2011) and discovered a group of microRNAs that coordinately regulate polycomb group complexes, components of which have oncogenic potential (*Cancer Cell*. 2011). We reported the exciting discovery and characterization of two

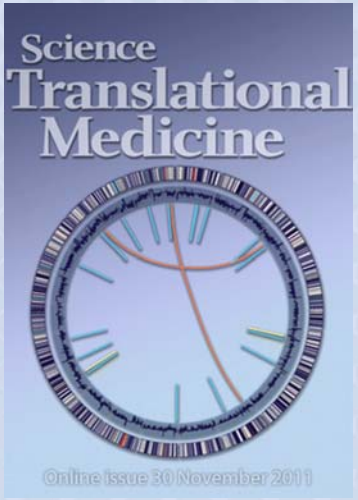
Michigan Center for Translational Pathology

- **Bioinformatics**
- **Cancer Biology**
- **Experimental Therapeutics**
- **Gene Fusion Discovery**
- **Genomics**
- **Immunomics**
- **Metabolomics**
- **Proteomics**
- **Tissue Core and Molecular Testing Laboratory**

novel recurrent and actionable gene fusions in our breast cancer cohort involving MAST and Notch genes (*Nat Med*. 2011). Our group developed a new urine test that supplements the prostate specific antigen (PSA) screen, designed to detect the gene fusion TMPRSS2:ERG as well as another prostate cancer biomarker PCA3. The combination was more predictive of cancer than either marker alone (*Sci Transl Med*. 2011). Our ambitious project, the clinical sequencing of cancer patients in order to identify actionable mutations that can be targeted with existing therapies continues to grow and we published the results from our pilot study (*Sci Transl Med*. 2011). We undertook the task of analyzing the global mutational landscape of metastatic castrate-resistant prostate cancer (CRPC) by sequencing the exomes of pre-treated and treatment naïve metastatic CRPC patients (*Nature*, 2012). Most recently, we developed a pseudogene expression pipeline to analyze a large compendium of paired-end next generation sequencing (RNASeq) data generated from 293 samples, comprising 13 different epithelial cancers (*Cell.* 2012).

The Center's research findings are continually being published in the scientific literature. Collectively, MCTP researchers published 76 journal articles in the 2012 fiscal year. Papers were published in high impact journals such as *Nature Medicine* (2), *Cancer Cell* (2), *Nature Biotechnology* (2), *Science Translational Medicine* (4), *Nature* (1) and *Cell* (1).

In addition to the scientific accomplishments, the Center further expanded its efforts toward the translation of scientific discoveries to the clinics. The MCTP Molecular Testing Laboratory, in association with MLabs, currently offers the PCA3 and CellSearch® CTC tests. We are working with Gen-Probe Inc., which has licensed the technology, to develop the assay designed to detect the gene fusion TMPRSS2:ERG for clinical use and we hope to offer the test to patients within the next few months. Other assays in early development are novel Immunohistochemistry-based automated methods for the simultaneous assessment of ERG/ PTEN and ERG/SPINK1 status in prostate cancer for clinical use. Collaborations have been established with industry partners such as GSK, Metabolon, Ventana, GenProbe, Armune BioScience and WaferGen to develop clinical testing platforms.



Personalized oncology through integrative high-throughput sequencing: A pilot study by Rowchowdhurry et al was the Cover Story in the November 2011 issue of Science Translational Medicine

Complementing our ongoing efforts in the discovery of novel molecular subtypes of cancer, we have launched a new initiative, Michigan Oncology Sequencing Center (MI-ONCOSEQ), to exploit the rapid advances in high throughput DNA sequencing technologies to realize the goals of "personalized medicine" for the treatment of cancer. We have begun to sequence patient genomes and transcriptomes to identify "actionable" driving mutations. We completed a pilot study where patients with advanced or refractory cancer who were eligible for clinical trials were enrolled. For each patient, we performed whole-genome sequencing of the tumor, targeted whole-exome sequencing of tumor and normal DNA, and transcriptome sequencing (RNA-Seq) of the tumor to identify potentially informative mutations in a clinically relevant time frame of 3 to 4 weeks. With this approach, we detected several classes of cancer mutations including structural rearrangements, copy number alterations, point mutations, and gene expression alterations. A multidisciplinary Sequencing Tumor Board (STB) deliberated on the clinical interpretation of the sequencing results obtained. The results of the pilot study of the initial MI-ONCOSEQ patients were recently published in Science Translational Medicine (*Sci Transl Med*. 2011 Nov 30;3(111):111ra121).

Since the pilot proof-of-principle study we have enrolled and analyzed sequence data of over 50 patients. We were recently awarded the Stand Up To Cancer-Prostate Cancer Foundation (SU2C-PCF) Dream Team Translational Cancer Research Grant for the project entitled, "Precision Therapy for Advanced Prostate Cancer". This study will enroll men with metastatic castrate-resistant prostate cancer to undergo sequencing analysis for the purposes of both therapeutic interventions as well as to investigate the underlying molecular basis of resistance. The international Team consists of scientists drawn from five leading prostate cancer clinical research centers in Ann Arbor, New York, Boston, Seattle and London.

In preparation for the SU2C-PCF project and to establish a clinically useful sequencing lab, we are in the process of obtaining CLIA certification for our sequencing facility. We hope to provide clinical-grade analysis to physicians so any actionable targets that are identified in patients can inform subsequent treatment options.

MCTP researchers are moving forward with their efforts to promote both national and international collaborations with other research groups and industry partners The Center continues to participate in research activities with the Early Detection Research Network (EDRN), caBIG, and Prostate SPORE. In association with Dr. Max Wicha's group at UMCCC, MCTP is working toward the creation of a National Center for Genetic Origins of Cancer (CGOC) at UM Medical School. This center will use new methodologies to enhance our current understanding of cancer development and metastasis. MCTP will lead the international SU2C-PCF Dream Team's research initiative to study and develop personalized treatment for castrate resistant prostate cancer.

Accompanying our publications, the Center's visibility and reputation, both nationally and internationally, continues to grow as well. This past year, MCTP's research gained much press attention, appearing in media outlets such as *The Los Angeles Times*, MSNBC, *Science Daily*, and *Detroit Free Press*, among others. Jyoti Athanikar (MCTP science communication specialist) and Radhika Varambally (web programmer) maintain and update the MCTP website (http://mctp.path.med.umich.edu/mctp/main/index.jsp). The website is consistently visited by approximately 53 users each day, with visitors coming from a diversity of domains, both nationally and internationally. Plans are currently underway to overhaul the website platform and design by working with a web design company.

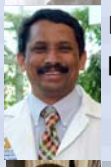
Our publications in high impact journals and increased exposure were coupled with the recognition of MCTP scientists by their scientific peers.

Dr. Arul Chinnaiyan, an Investigator, Howard Hughes Medical Institute and an American Cancer Society Research Professor, was recently named the SU2C-PCF Dream Team leader of an international team focused on the personalized treatment of metastatic castrate-resistant prostate cancer. The SU2C-PCF Prostate Dream Team Translational Cancer Research Grant will provide $10 million over a three-year period to fund the project; the international Team consists of scientists drawn from five leading prostate cancer clinical research centers in Ann Arbor, New York, Boston, Seattle and London.

Many of MCTP's young emergent researchers were also recognized for their achievements this past year:

Brendan Veeneman received a two-year IGERT grant in September, 2011.

Alejandro Balbin was awarded the FASEV MARC Poster/Platform Presenter Travel Award to attend the 2011 ISMB meeting in Vienna.

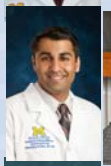


Dr. Nalla Palanisamy received the Department of Pathology's Employee Recognition award for Professional Development.

Chad Brenner (CMB candidate) and John Prensner (MSTP candidate) were awarded the 2011 Programs in Biomedical Sciences (PIBS) Excellence in Research Award.

Dr. T.M. Rajendiran received a grant ($430,000) from Metabolon.

Dr. Chandan Kumar received a Career Development award from the UM GI SPORE and the American Pancreatic Association Young Investigator Travel Award.



Drs. Sameek Roychowdhury and Chad Brenner were awarded the Prostate Cancer Foundation (PCF) Young Investigator award.

Dr. Ken Pienta was appointed the new Associate Vice President of Research, Health Sciences.

Dr. Scott Tomlins will join the Department of Pathology with a joint appointment in the Department of Urology as an Assistant Professor.

Dr. Soory Varambally received his second NIH R01 grant.

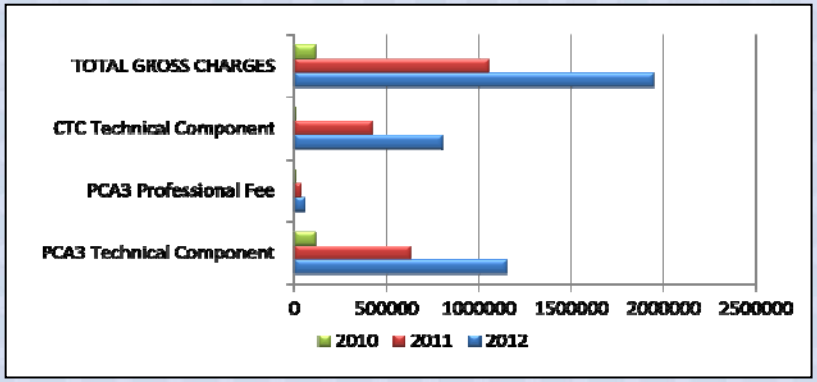
Dr. Ram Mani was awarded the highly competitive NIH Pathway to Independence Award (K99/R00).

MCTP continues to support the training and career development of the next generation of translational cancer biologists. MCTP faculty, Dr. Sooryanarayana Varambally received his second NIH R01 and Dr. Nalla Palanisamy's promotion to Associate Research Professor in the Department of Pathology, effective September 1, 2012, was approved by the Regents. In addition, MCTP students continue to make progress towards their educational goals as evidenced by their authorship on papers and recognition they have received for their accomplishments. Two graduate students defended their dissertation this year. J. Chad Brenner, a Cellular and Molecular Biology graduate student presented his dissertation entitled "Therapeutic targeting of ETS rearranged cancers" on March 21, 2012. He is continuing his research in the lab as a postdoctoral fellow, supported by the PCF Young Investigator Award. John Prensner, a MSTP student defended his thesis entitled "Discovery and characterization of long noncoding RNAs in prostate cancer" on May 14, 2012. He has returned to the clinics to complete his MSTP program.

Students, postdoctoral and clinical fellows that trained at MCTP have gone on to obtain independent faculty positions. Dr. Chris Maher was successfully recruited as a faculty member last fall at Washington University in St. Louis, MO as an Assistant Professor. He also serves as an Assistant Director of the Washington University Genome Institute. Dr. Scott Tomlins, whose dissertation work at MCTP led to the landmark discovery of the TMPRSS-ETS gene fusions in a majority of prostate cancer cases, has accepted an offer to join the Department of Pathology with a joint appointment in the Department of Urology. Dr. Tomlins will be a member of the Michigan Center for Translational Pathology and pursue research in the molecular genetics of bladder cancer and the application of sequencing-base diagnostics to cancer care. Dr. Rohit Mehra, a former clinical fellow at MCTP, will return to University of Michigan as an Assistant Professor in the Department of Pathology with a joint appointment at MCTP.

This past fiscal year, the Center obtained $5,308,559 in committed awards. In addition, we received $1.5M in funding from Howard Hughes Medical Institute Award. Fundraising efforts for MCTP resulted in a total production of $1,606,591 including PCF matching funds. The majority of the gifts received were from foundations and corporations.

The total gross charges continue to increase each fiscal year for our CLIA testing. Fiscal year 2012 saw total gross charges of $1,946,557, an increase from $1,050,661 in 2011 and 112,652 in 2010. Net collection of the invoices is approximately 35%. We will be introducing a combined T2ERG/PCA3 test in fiscal year



The highlights of the Center's activities this past year are summarized in greater detail in the *Michigan Center for Translational Pathology Annual Report for 2012*, which is a separate, comprehensive review of the Center.

Michigan Center for Translational Pathology

Division of Finance And Administration

Martin Lawlor
Director, Division of Finance and Administration

The Division of Finance and Administration, which is under the auspices of the Office of the Chairman and directed by Mr. Martin A. Lawlor, Department Administrator, is responsible for the business, operational, and fiscal affairs of the Department of Pathology as mandated by the policies of the Chairman, University of Michigan Health System (Medical School and Hospitals), and the University. In addition to directing this Division, Mr. Lawlor serves on various departmental, Health System and University committees including the Financial Advisory Committee, Clinical Research Billing Committee, Revenue Cycle Advisory Committee and the Executive Committee for the Joint Venture Hospital Laboratories. Mr. Lawlor also serves as Chair of the Administrative Modernization Research Subcommittee, which is charged with improving quality and finding cost efficiencies in Research Administration across the School of Medicine.

Some key Divisional highlights orchestrated by Mr. Lawlor this academic year include:

- Finalizing the Medical Examiner contracts with Wayne County (through September 2014) and Washtenaw County (through September 2015), resulting in 8 new faculty positions and the ability to add 2 new fellowships.

- Shepherding Paradigm through the MHC process and drafting the Purchased Services Agreement.

- Serving as a liaison between Tsoi Kobus and Hospital Administration in the conceptual design of the new Pathology Building and developing an ROI based on assumptions provided by Finance.

- Ensuring the Department was adequately staffed for the opening of the new Children's and Women's Hospital as well as two MiChart go-lives.

We saw our professional revenues increase once again this year. Pathology began professional component billing for Clinical Pathology outpatient services in 4th quarter of 2010, resulting in a new revenue stream of $1,029,683. UMHS Department of Pathology is the first group to institute professional component billing in the state of Michigan. We have also seen the benefit of three years of work on blood product negotiations with the Red Cross and utilization reductions that resulted in a savings of over $2 million from FY 2010.

ADMINISTRATIVE SUPPORT CENTER

Administrative Support Center/Pathology Laboratories

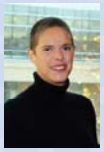
The Administrative Support Center for Pathology Laboratories is responsible for the preparation and monitoring of all Hospital laboratories' revenue, expense and capital budgets, and personnel and payroll systems. Gross revenue for FY2012 was $516,458,041, compared to $483,619,311 in FY2011, an in-

Finance and Administration

- **Administrative Support Center—Pathology Labs**
- **Human Resources, Faculty Affairs and Education**
- **Office of Academic and Business Affairs—Medical School**
- **Office of the Chair**
- **Professional Fee Billing Office**
- **Financial Data**

crease of 6.8%. During this period, total laboratory expenditures were $93,403,866. Pathology is responsible for 11.4% of total Hospital Gross Revenue and 4.8% of total expense. As detailed below, Mr. Thomas Morrow is responsible for administration of the Clinical Pathology Laboratories, Ms. Christine Rigney for the administration of the Anatomic Pathology Laboratories, and Ms. Brenda Schroeder for maintaining licensure and accreditation for our laboratories.

Mr. Thomas Morrow oversaw the Clinical Pathology Laboratories. During this challenging year in which major Hospital Patient Management and Patient Accounting systems were replaced, we still experienced positive results. Clinical pathology laboratory activity was 2.2% above last fiscal year's levels, and Clinical Pathology revenue was 7.0 % over last fiscal year's levels. In February 2012, the institution converted to a new Patient Management and Patient Accounting system called MiChart. Mr. Morrow served as the Administrative lead for this change that required a complete revision of our technical and professional billing applications and databases, including the generation of our MLabs client billing. Concurrent with the implementation of MiChart, he also assisted with the planning and conversion of our LIS from Cerner Pathnet to Soft Computer Corporation. Mr. Morrow was instrumental in putting together submissions and ROI's to get our capital needs met, as well as leading Lean workflow improvements.



Ms. Christine Rigney, Anatomic Pathology Operations Administrator, oversaw the Anatomic Pathology Labs. Ms. Rigney is the department lead for many building and renovation projects which include the new Children and Women's Hospital space planning, upgrades for the grossing room in the CVC, and the NIB forensics center integrated autopsy service with the Washtenaw County ME Office and Wayne County ME Office, which potentially may expand services to other counties. Ms. Rigney is also involved in the development of the new Laboratory Information System.

Ms. Brenda Schroeder, Administrative Coordinator, is responsible for maintenance of all department and hospital laboratory licensure and accreditation for JCAH, CAP, CLIA, COLA and MDPH including coordination of external CAP inspection training and survey teams. She is a member of the UM Accreditation and Regulatory Readiness Council, serves as a liaison to the Quality Improvement Team, and is a member of Infection Control, Waste Management, and Disaster Committees for UMHS. She is responsible for safety programs and serves as Chair for the department's Safety Committee.

Office of Academic and Business Affairs–Medical School

Mr. David Golden is responsible for all administrative operations associated with the academic side of the department, including management of department finances (budgets, contracts, research grants, forecasts and analysis), as well as clinical billing (professional and technical front end operations), in collaboration with the Chair and Administrative Director. He also implements and directs strategic goals for Medical School operations including development of policy and business plans, management of faculty compensation and departmental funds, and use of departmental facilities, including modifications, renovations and reassignment of department space.

During the past year, Mr. Golden refined the component billing system that generated $2,391,740 in gross charges and $1,029,683.29 in incremental net revenue, and managed the UMHS and All Funds expenditures and forecast processes. Total All Funds expenditures for FY 2012 (Pathology and MCTP) were $55,384,615 and Hospital expenditures were $93,403,866. He also developed the 2013 forecast for the Hospital, Pathology and the MCTP. Mr. Golden managed the pre- and post-award research enterprise for both Pathology and the MCTP. There were 175 research proposals submitted to external sponsors this year. 54 of these proposals were submitted to the NIH. Committed awards were up 2.5% to $277,442,203. Actual sponsored research revenue is up this year by 4% to $30,112,899. Overall, the academic side of the Department saw a 4.81% increase ($2.32M) in the following revenue components: component billing, federal and non-federal research and other revenue (Washtenaw and Wayne County contracts, Royalties, rebill activities, operating transfers) from FY 2011 to FY 2012. FGP Net Patient Care was up year-to-year (8.74%). Overall gross charges for Pathology's group practice were up 6.53% ($3.08M). Mr. Golden continues to manage and mentor Karen Giles, John Harris, Laura Labut, Nancy Parker, Thad Schork and Christine Shaneyfelt in their analytic and managerial roles.

Mrs. Nancy Parker is responsible for all front-end billing operations. This includes laboratory gross charges of $516,458,041 and professional fee gross charges of $50,178,179. Mrs. Parker is responsible for Send-out billing, component billing, MLabs client statements, ensuring the accuracy of the daily billing files, correction of all errors with the appropriate Hospital department and responding to all questions regarding interdepartmental, MLabs or Hospital patient billings. MiChart implementation this year had a profound effect on front-end billing with the addition of many new tasks. This implementation resulted in a new internal Oracle billing system as well as a number of MiChart work queues that require constant management by Mrs. Parker's team.

Mr. John Harris is responsible for oversight of the accounting and financial staff supporting our research programs, and the daily management of post awards. Extramural sponsored expenditures for FY2012 amounted to $30,112,899. Mr. Harris manages a staff of three accountants and two procurement specialists. He also provides many *ad hoc* financial reports related to Medical School and clinical operations.

Mr. Thad Schork is responsible for pre-award activities for our pathology research program and serves as Development Coordinator for the Department of Pathology. In addition, he also serves as the lead administrative staff member for facilities (building maintenance and renovation), including major renovation projects initiated in the University Hospital and other buildings occupied by Pathology.

Ms. Christine Shaneyfelt serves as the primary contact for UHHC finance. This includes completing the Hospital budget and developing and managing the departmental capital equipment process. In addition, Ms. Shaneyfelt has prepared a number of financial analyses including profit and loss statements, faculty incentive analysis and financial performance reports for both Anatomic and Clinical Pathology divisions.

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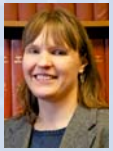
Human Resources, Faculty Affairs and Education

The non-instructional human resource function in the Department of Pathology is part of a larger Human Resource Team entitled Diagnostic Services, which includes Radiology and Pathology. The team lead for this area is Ms. Katie Adams with support from Ms. Beverly Smith and Ms. Cathy Bearman. Our Staff Human Resources Office provides support for Pathology's hospital laboratories (approximately 650 FTEs) and Medical School support staff, including our research programs (approximately 218 FTEs). Both Ms. Smith and Ms. Bearman coordinate the department's orientation program and participate in the department's Service Excellence Committee. Ms. Smith coordinates the Medical Technology Internship Program, and actively participates in the Foundations for Supervision training program as a facilitator. Ms. Bearman is the department's Wellness Champion and has led a group in developing wellness initiatives within Pathology.

Faculty Affairs is the responsibility of Ms. Laura Blythe, who coordinates appointments and promotions for our faculty (approximately 117 FTEs) as well as serving as the Department of Pathology's effort certification specialist. Ms. Blythe serves as a member of UMHS M-ACE (appointments, credentialing and enrollment) Advisory Committee and the Medical School's Effort Certification Committee. Ms. Blythe is also responsible for the Education Office activities including the Residency and Fellowship Training Programs (28 residents and 18 fellows in 7 ACGME and 7 non-ACGME programs) and the Medical Student Teaching Programs for the M1 and M2 laboratories and the M4 Clerkship Program. Ms. Blythe has developed a web-based human resources management system for all faculty, residents and fellows. Her efforts were recognized with the Dean's Staff Award for Outstanding Service.



Mrs. Laura Labut is responsible for administration of the Molecular and Cellular Pathology PhD program with 26 students actively pursuing their doctorates. Management responsibilities are fo-

cused around curriculum management (including the Research Seminar Series), academic records, budget planning and financial operations, recruitment, and program activities such as the annual departmental research symposium. Mrs. Labut is the administrator for the department's two NIH training grants (PIs Steven Kunkel, Ph.D. and Nicholas Lukacs, Ph.D.) which support 6 pre- and 8 post-doctoral trainees and two active seminar series. Mrs. Labut performs the human resource functions for the department's graduate students (43 including 20 non-MCP students with Pathology mentors) and training grant trainees (14).

Office of the Chairman

Ms. Lynn McCain provides support to the Chair of the Department including management of his calendar, completing travel arrangements and preparation of manuscripts, grants, abstracts, correspondence, and all materials related to the many committees chaired by Dr. Hess. In addition, Ms. McCain continues in her managerial responsibilities for our faculty support group, and continues to lead the monthly mentoring series for our administrative support staff. This year, she also initiated and led an interdepartmental committee to develop a comprehensive orientation manual for Administrative Support staff, which has been distributed throughout the Medical School. This Committee was recognized with a Team Service Award for their efforts. In addition, Ms. McCain provided instrumental support in the establishment of Paradigm, a joint-venture non-profit organization chaired by Dr. Hess, with continuing board support responsibilities. Ms. McCain is currently working as the project manager with Dr. David Keren, the Medical Director, on establishing a Genetic Testing Resource Center in the Department of Pathology in conjunction with Blue Cross Blue Shield of Michigan.

Ms. Angela Suliman provides support to the Administrator, Mr. Martin Lawlor, including scheduling, travel arrangements, data collection, and event planning. She has been the facilitator for the Administrative Modernization Research Subcommittee, the Post-Award Grant Administration Workgroup, the Service Excellence Steering Committee and the Lab Formulary Committee. She oversees the reconciliation of the department P-cards, the renewal of medical licenses and payment of honoraria for visiting professors, as well as all CME requests for faculty and house officers. She has also taken part in the planning and implementation of the Advances in Forensic Medicine and Pathology Conference.

Pathology Professional Fee Billing Office

Ms. Holly Daul continues in her role as Revenue Cycle Director of Professional Billing for the specialties of Pathology, Radiology, Radiation Oncology, Physical Medicine, and Neurology. She supervises 35 FTE staff and is responsible for accounts receivable management and collections of professional fees for services provided by Department of Pathology faculty. Ms. Daul serves on several physician professional fee committees and is one of the Process Owners for MiChart.

SUMMARY OF FINANCIAL DATA FOR FY2010