



Department of Pathology Annual Report 2012-2013



Department of Pathology 2013



University of Michigan Medical School Department of Pathology

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



This has been a particularly eventful year for the Department of Pathology and the University of Michigan Health Care System (UMHS). As I will be transitioning to become the Vice President of University Clinical Affairs and Dean of the Indiana University in September 2013, leadership of the Department is now in the extremely capable hands of Interim Chair **Dr. Kathleen Cho**.

Our faculty continue to be called upon to fill important leadership positions. **Dr. Jeffrey Myers** currently serves as President of the United States and Canadian Society of Pathology. Our faculty also garnered a number of important awards. **Dr. Donald Giacherio** Director of Chemical Pathology, was selected for the 2013 Board of Directors Recognition award for his contributions and support of *ASCLS-Michigan* at the annual meeting held in East Lansing. **Dr. Celina Kleer**, Harold Oberman Professor of Pathology, received the United States and Canadian



KATHLEEN R. CHO, M.D.

Peter A. Ward Professor
and Interim Chair

Academy of Pathology Ramzi Cotran Young Investigator Award (the third faculty in the Department to receive this award). **Dr. Lori Lowe**, Professor of Pathology and Dermatology and former Director of Dermatopathology, was awarded the **2013 Walter Nickel Teaching Award** by the **American Society of Dermatopathology (ASDP)**. **Dr. Lowe** also received the University of Michigan Medical School Outstanding Clinician Award.

Scott Tomlins was named the inaugural winner of the **Martin and Rose Wachtel Cancer Research Award** presented by the American Association for the Advancement of Science and Science Translational Medicine. **Dr. Arul Chinnaiyan**, S.P. Hicks Professor of Pathology and Director of the Michigan Center for Translational Pathology received the 2013 Distinguished University Innovator Award and was also quoted in an article about prostate cancer screening written by Andrew Pollack in the March 27, 2003 edition of the New York Times.

Our faculty continues to grow with recruitment of outstanding individuals both junior and senior. The newest additions to our faculty, arriving early in FY2014, include:



Daniel Boyer, M.D. Ph.D., who completed both his residency and fellowship training at Massachusetts General Hospital (MGH) will join the faculty in hematopathology.



Evan Farkash, M.D. will join the faculty as Clinical Lecturer with a focus in renal pathology. Dr. Farkash is currently a research fellow in renal pathology and transplantation tolerance at MGH.



Madelyn Lew M.D. will join the faculty in cytopathology. Dr. Lew did her residency training in anatomic and clinical pathology at MGH before moving across town to Brigham and Women's

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

Hospital (also a Harvard Medical School teaching hospital) where she is currently a fellow in cytopathology.

This was another extremely busy year for our clinical services, with work RVUs up over 5.3% for the fiscal year. We experienced especially strong growth in our consultation practice department-wide. Under the strong leadership of **Dr. Jeff Warren** and **Suzanne Butch**, we prepared well and had an exemplary CAP inspection with remarkably few citations. We implemented electronic document control and went live with the new SOFT LIS in June, all on the heels of going live with MiChart. Needless to say, **Dr. Ulysses Balis**, **Kathy Davis** and colleagues did a phenomenal job meeting a number of crucial deadlines and milestones very effectively. With these challenges behind us we are well poised for increased productivity in the years ahead.



Dr. Ul Balis &
Kathy Davis

Dr. Jeffrey Myers in his role as Director of MLabs outreach services has been very actively focusing our efforts in support of UMHS patients and expanding our capabilities and client base in molecular diagnostics. One major initiative in the coming year is to continue to develop our capabilities in high throughput sequencing. As part of this initiative, we launched Paradigm, which will position the Department to be a leader in diagnostic molecular pathology well into the 21st century.

With the Medical School FastForward initiative lead by **Senior Associate Dean for Research Steven Kunkel**, this was an important year for institutional strategic planning. Meanwhile, the Department's research programs continue to thrive with many faculty members in the Department publishing a number of papers in high impact journals. Of note, the University of Michigan was among the top ten departments in the country at the USCAP meeting for the number of abstracts submitted. The Michigan Center for Translational Pathology's MI-ONCOSEQ continued to identify molecular drivers and potential therapeutic targets in human cancers. Overall,



despite a challenging funding environment, our total research funding held constant at approximately \$30 million.

Our Education Division continues to thrive under the leadership of **Dr. Barbara McKenna**. We achieved outstanding results in the match, attracting a highly qualified group of residents. In addition, we are experiencing strong interest in our clinical fellowships, so much so that we are attracting an increasingly competitive pool of candidates. We are continuing to emphasize active learning, maximizing the educational value of resident rotations and better preparing our learners for future management responsibilities. Another important development is that after eight years of dedicated and highly capable service, **Dr. Nicholas Lukacs** stepped down as Director of the Molecular and Cellular Pathology Graduate Program, a role that will be assumed by **Dr. Zaneta Nikolovska-Coleska**. This year, under Dr. Nikolovska-Coleska's leadership, we will be launching an innovative initiative to bring together residents and Ph.D. students in a new course in Translational Pathology.



ZANETA NIKOLOVSKA-
COLESKA, PH.D.

Director
MCP Graduate Program

After a challenging year financially, the Hospitals and Health Centers will end the year at near breakeven and the Medical School with an approximately \$18 million loss. Some of the contributing factors included the loss of productivity related to the MiChart implementation, rising salary and supply expenses and a down turn in research productivity. Fortunately, with some budgetary adjustments, the Department of Pathology closed the fiscal year with a strongly positive operating margin. Together with strong market gains, the Department ended the year with all time high levels of assets. This financial strength is essential for the Department to continue to grow its academic programs as well as weather the storms that lie ahead in terms of reduced clinical reimbursement and flat external funding.

The financial setbacks for UMHS contributed to an institutional decision to put a number of major capital projects, including the clinical laboratories, on hold. The Department requires additional clinical laboratory space. This is an issue that we have worked on diligently, even before the eight years of my tenure, and which must be resolved. While a new laboratory build-

ing appears to be unfeasible in the current financial climate, we are now working with the Hospital and Medical School leadership planning a new space solution involving renovation of existing space (Buildings 35 and 36) at the North Campus Research Complex that is much more cost-effective. While we don't have an ironclad commitment, obviously a space solution will be crucial for recruitment of the Department's next Chair. I am confident about this plan and know that it has broad support amongst the health center leadership.

In closing, we are in an enviable position and have every reason to be optimistic about the Department's future. It has truly been a joy to work with all of you. I am immensely proud of your accomplishments and will miss having every one of you as colleagues.

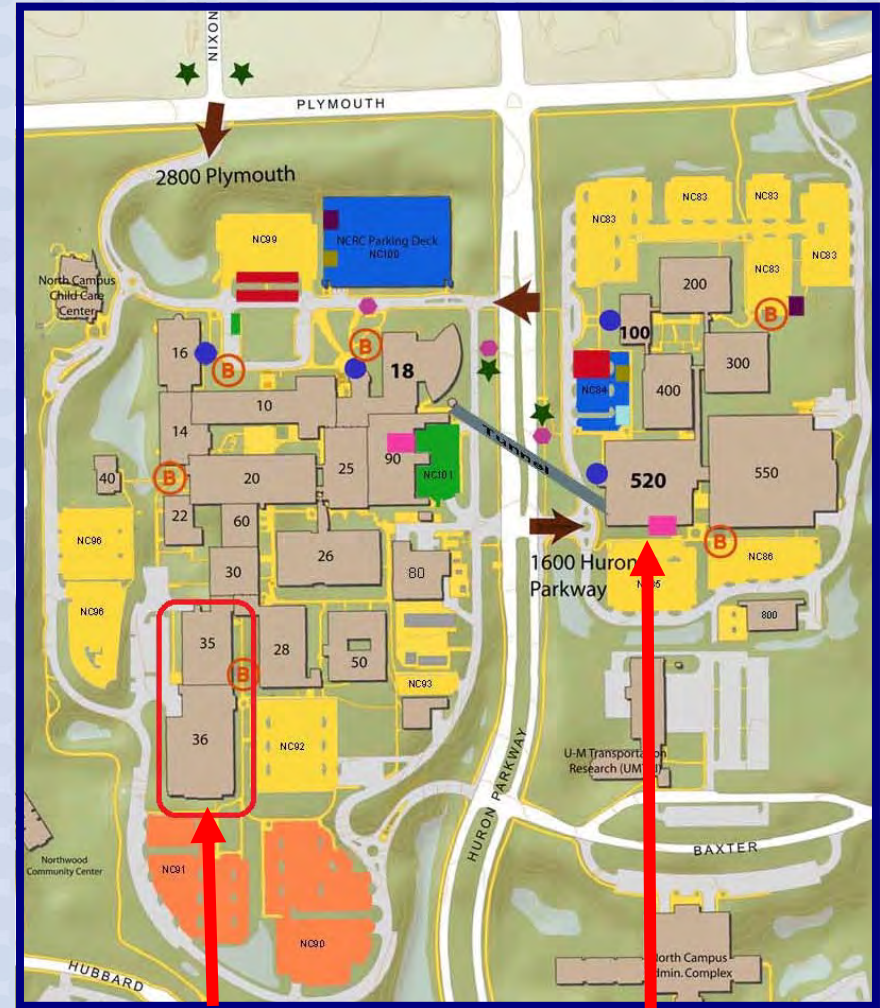
Jay L. Hess M.D., Ph.D., M.H.S.A.



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July 1, 2008—August 30, 2013



Buildings 35 and 36 in the North Campus Research Complex is the proposed site for the expanded Pathology Laboratories with additional office space for faculty offices and Pathology administration being housed in Building 520.

Farewell, Dr. Abrams!

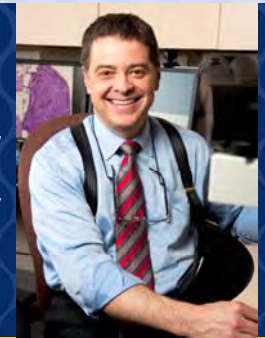


The Department celebrated Dr. Gerald Abrams' final lecture on April 18, 2013, after a career spanning over 60 years at the University of Michigan —beginning in Medical School in 1951!

A collegiate professorship will be endowed in his honor in FY 2014.

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 be successful in all missions. Demand for clinical services remains strong despite downward national trends. SoftPathDx, the anatomic pathology module in the integrated laboratory information system (LIS) by Soft computers, was successfully implemented in June 2013 but prevented acquisition of a complete data set for preparation of this report (May YTD and annualized projections are identified throughout).

Integration of the Wayne County Medical Examiners Office (WaynCME) with our forensics and autopsy service continued to drive faculty recruitment. **Drs. Avneesh Gupta** (Assistant Professor), **Kilak Kesha** (Assistant Professor), **Chantel Njiwaji** (Assistant Professor), and **Allecia Wilson** (Assistant Professor) joined our faculty in July and August of 2012 with primary service responsibilities at WaynCME.



Drs. Avneesh Gupta, Kilak Kesha, Chantel Njiwaji and Allecia Wilson supporting the Wayne County Medical Examiner's Office.

Drs. Rohit Mehra (Assistant Professor) and **Scott Tomlins** (Assistant Professor) joined the faculty in July 2012, both with a focus in genitourinary pathology. And **Paul Harms** (Clinical Lecturer) joined anatomic pathology as a member of our dermatopathology group, also in July 2012.

Additional faculty were recruited in the last two quarters of FY2013 and will join the faculty in the first quarter of FY2014 as listed below.

Madeline Lew (cytopathology) July 2013

Evan Farkash (renal pathology) September 2013

Success and vitality in our research activities remains very strong as evidenced by continued visibility in peer-reviewed journals considered high impact by the academic anatomic pathology community. The number of published abstracts and invited lectures were at all time highs. Intramural funding allocated by our AP Projects Funding Committee under the leadership of **Dr. Kathleen Cho** rose to the second highest level in the seven year



Drs. Paul Harms (top), Rohit Mehra (left) and Scott Tomlins (right) joined Anatomic Pathology in FY 13.



Anatomic Pathology

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

history of the program. Extramural funding has diminished reflecting the loss of **Peter Lucas**, a productive clinician scientist who accounted for nearly \$700,000 in research expenditures in FY2012, and the increasingly challenging funding climate.

Education programs remain strong as demonstrated by ongoing successes in existing fellowships, reaccreditation of our dermatopathology and pediatric pathology fellowships for 5 years, and accreditation of our forensic pathology fellowship for 3 years. Our neuropathology fellowship successfully completed its first internal review and recruited an internal candidate to the 2014-2015 academic year. AP faculty continue to play key roles in supporting our residency program and in medical school teaching, serving the needs, interests and desires of 1st, 2nd, and 4th year students. Division faculty served as directors of two successful, ongoing seminars that offer continuing medical education to a regional and national audience: New Frontiers in Pathology and Advances in Forensic Medicine and Pathology.

CLINICAL ACTIVITIES



David Lucas, M.D.

Surgical Pathology

We are projected to finish FY13 with a total of 90,220 non-cytology specimens, including a combination of intramural and extramural cases, compared to 88,940 in FY12, 89,785 in 2011, and 80,690 in 2010. This represents a 1.4% increase compared to FY12 and a 11.8% increase compared to FY10. Among our “inside” surgical pathology practices all but a single service (GU) were projected to see year-over-year growth including breast (5.5%), gastrointestinal (3.5%), gynecologic (2.6%), general surgical (3.9%), pediatric surgicals (1.0%), and placentas (13.4%). The total number of specimens acquired from procedural areas within the UMHHC grew at an annual rate of 1.9% and accounted for 67% of our patients. In contrast, outside (“transfer”) cases reviewed for patients referred to UMHS grew at an annual rate of 7.4% and accounted for 12.8% of cases. The number of extramural consultation cases was projected to total 10,724 compared to 10,976 in FY12, reflecting a 2.3% drop but a 25.1% increase compared to the 8,574 consultations signed out in FY10.

Our frozen section coverage expanded to include adult patients having surgery at Mott Hospital. Surgical Pathology now covers four separate frozen section labs: University Hospital, Cardiovascular Center, East Ann Arbor, and Mott Hospital. A newly developed Surgical Pathology Officer posi-

tion was created not only to cover the expanding frozen section needs, but also to ensure quality of tissues and/or slides selected for molecular diagnostics testing as well as out-going review and clinical trials. In conjunction with Pathology Informatics, telepathology was upgraded and improved to high-definition Olympus cameras and Glance conferencing software, enabling high-quality, real-time images that can be viewed from anywhere over the web in support of both frozen section and individual case consultations.

Faculty productivity was relatively level. Expressed as a 12 month rolling average, faculty generated an average of 808 RVUs/FTE/month in May 2013 compared to 861 RVUs/FTE/month in May 2012. This reflects the impact of new faculty who joined us in FY13 boosting available clinical FTEs to an average of 32.5 compared to 28.0 in the previous year. Despite growth in the size of our faculty, however, the average number of RVUs generated by those actively engaged in our surgical and cytopathology practices increased by 6.2% from 5,017 RVUs/FTE in FY12 to 5,328 RVUs/FTE in FY13.



Raja Rabah, M.D.

Pediatric and Perinatal Pathology

The pediatric and perinatal pathology service continued to flourish in FY2013 under the leadership of **Dr. Raja Rabah**. As summarized in Table 1, the pediatric surgical service grew at an annual rate of 1.0%, with 2,199 cases from the C. S. Mott Hospital ORs, as well as over 200 transfer cases and 70 extramural consultation cases. In addition, a total of 1,651 placentas were examined from the Von Voigtlander Women’s Hospital reflecting a 13.4% annual increase.

Table 1: Pediatric Pathology Clinical Activity FY10-FY13

	FY10	FY11	FY12	FY13	% CHANGE
Peds (IP)	1655	1820	2177	2199*	1.0%
Placentas (PL)	1166	1478	1456	1651*	13.4%
Pediatric autopsies			29	25*	(13.7%)
Fetal examinations			36	107+	197%

*projected year-end based on MAY YTD data

†May YTD data

In addition to surgical cases and placentas, the pediatric team covers all pediatric autopsy cases from Mott Hospital. Twenty-five autopsies were performed through May of this year and most of them were reviewed in grand rounds and morbidity/mortality meetings with different pediatric/perinatal subspecialties.

All cases of intrauterine fetal demise and terminations at the Women’s Hospital are examined by the pediatric/perinatal pathologists. Over 107 exams were done by end of May 2013, triple the number of examinations performed in FY12. Effective April 2013, the pediatric team provides consultation services for the pediatric and perinatal autopsy cases from St Joseph Mercy Health System, Ann Arbor.

Fig.1: Pediatric surgical case volume and TAT, FY12-FY13 May YTD

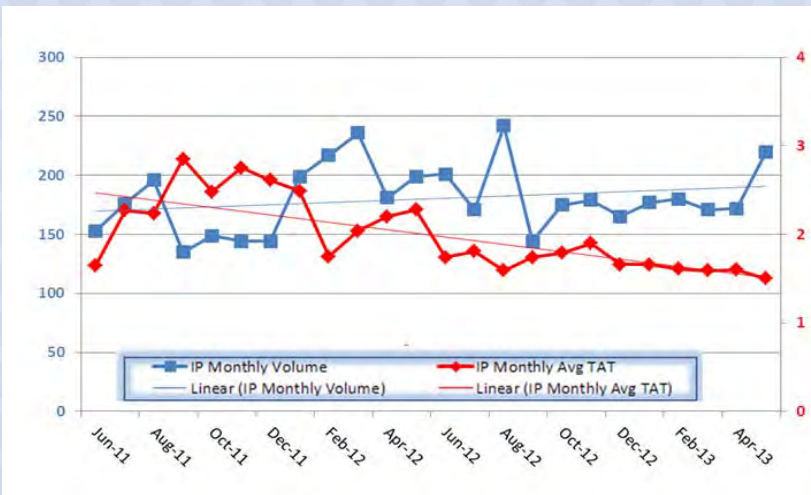
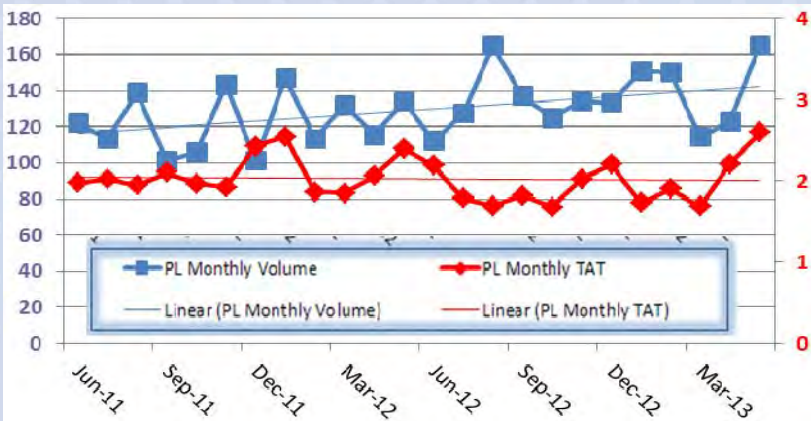


Fig. 2: Placenta case volume and TAT, FY13 May YTD



The team participated in over 126 multidisciplinary and teaching conferences at Mott and Women’s Hospital and over 785 patients’ cases were discussed.

Volume, quality and turn-around time are continuously improving as depicted in Figures 1-4.

Fig. 3: Fetal examination case volume and TAT FY13 MAY YTD

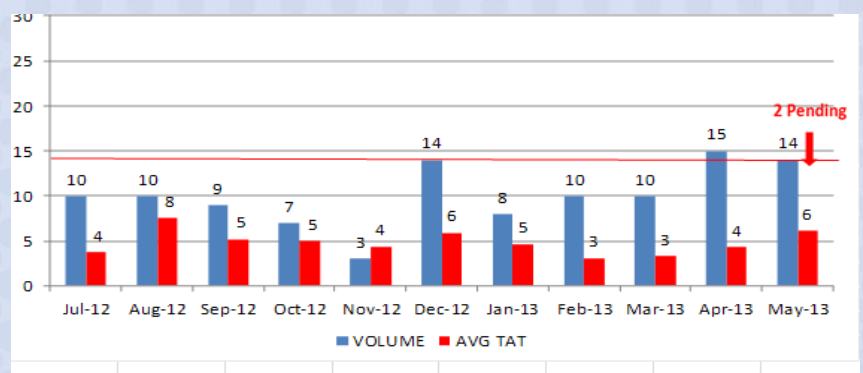
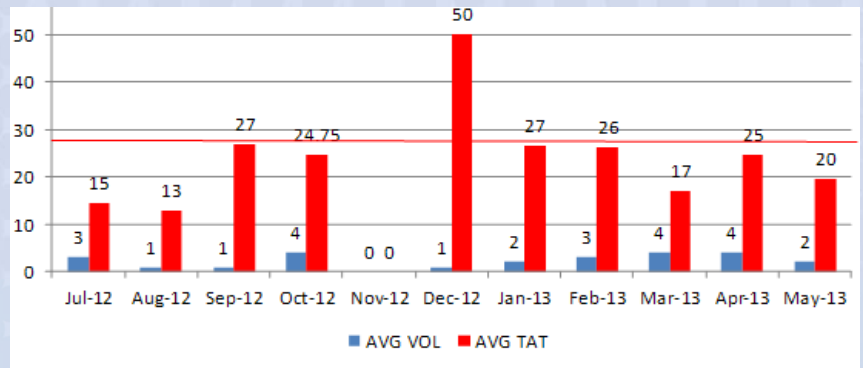


Fig. 4: Pediatric autopsy volume and TAT FY13 MAY YTD



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

Table 2: Dermatopathology Clinical Activity, FY11-FY13

	FY11	FY12	FY13*	% change (FY12 - FY13)	% change (FY11 - FY13)
ID	13,441	13,716	13,491	(1.6%)	0.4%
MD	9,691	7,412	7,335	(1.0%)	(24.3%)
TD	2,828	3,566	3,708	4.0%	31.1%
Consults	2,106	2,263	2,154	(4.8%)	2.3%
TOTALS	28,066	26,957	26,688	(1.0%)	(4.9%)

volume service (see Table 2) and realized substantial growth in transfer cases to nearly offset minor declines in the other services. Volumes in the internal UMMC practice (ID) dropped in the second quarter coincident with implementation of MI-Chart but showed strong recovery in the last quarter. Biopsies processed through MLabs (MD) also showed strong growth in the last half of the fiscal year and were up 11.0% in January through May of 2013 compared to the same period a year ago.

Dr. Doug Fullen assumed responsibilities as **Director of Dermatopathology** in July 2012 after a long period of success under the leadership of **Dr. Lori Lowe**. **Dr. Aleodor Andea** joined the faculty in July 2012 from the University of Alabama at Birmingham and has been actively engaged in clinical service and development of a **Dermatopathology Molecular Research Laboratory (DMRL)** aimed at integrating molecular diagnostics into the diagnosis of cutaneous malignancies and supporting research in cutaneous oncology. In addition to their primary role in the dermatopathology service, **Drs. Rajiv Patel** and **May Chan** continue to participate in the soft tissue and orthopedic pathology and general surgical pathology (Room I) services, respectively.

Dr. Alexandra Hristov has transitioned to a part-time position and continues to participate in the full breadth of dermatopathology diagnostic services while lending invaluable hematopathology expertise for cutaneous hematolymphoid disorders. Upon completion of our dermatopathology fellowship training program, **Dr. Paul Harms** was appointed Clinical Lecturer effective July 1, 2012. Dr. Harms provides 25% effort to the dermatopathology diagnostic services and his remaining effort to pursuing research projects in the laboratory of Dr. Arul Chinnaiyan.



Lori Lowe, M.D.

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.

This was a particularly productive academic year for the dermatopathology faculty with high visibility of our faculty at national meetings. **Dr. Lowe** was selected the prestigious **Walter Nickel Award** recipient for teaching from a highly competitive pool of national candidates and will receive her award at the upcoming American Society of Dermatopathology meeting in Washington, D.C.. Under the mentorship of Drs. Arul Chinnaiyan (pathology) and Andrzej Dlugosz (dermatology), **Dr. Harms** received the **Dermatopathology Research Career Development Award** (7/13-7/16) from the Dermatology Foundation. **Drs. Patel, Hristov** and **Chan** participated in a short course entitled *Dermatopathology greatest hits: top ten lessons learned (so far) from academic consultative practice* presented at the annual meeting of the United States and Canadian Academy of Pathologists in March 2013. Collectively, the dermatopathology faculty had 28 abstracts presented at national or international meetings and 41 peer reviewed publications, either published or currently in press over the past academic year.

Neuropathology



Sandra Camelo-Piragua, M.D.

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

There were just over 1300 neurosurgical cases examined this year (see Figure 5). UMHS surgical patients accounted for about half of the accessioned cases and included over 200 intraoperative consultations. The nerve and muscle biopsy service is staffed by Drs. McKeever and Camelo-Piragua and saw substantial year-over-year growth in both UMHS (11.3%) and extramural MLabs (4.4%) patients, accounting for 29% of accessioned cases. Consultation cases increased to 263 compared to 230 in FY12. Neuropathology faculty staffed the following conferences: twice weekly neuropathology case conference; monthly neurosurgery CPC; weekly brain cutting conference; weekly nerve and muscle conference; weekly brain tumor board. The Neuropathology Case Conference was ex-

panded from once to twice weekly to share difficult and interesting cases. Sixty cases were examined at brain cutting conference. Of these, 41 were UH hospital cases and 19 were acquired through the UM Alzheimer's Center and required a more extensive evaluation.

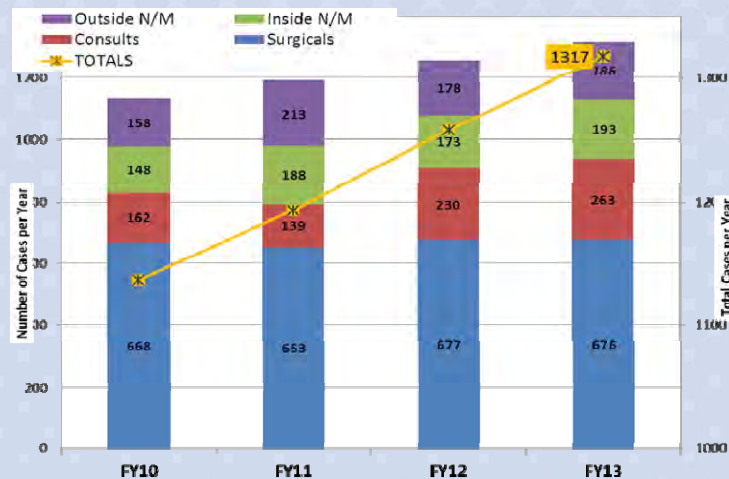
Medical Renal Pathology



Drs. Paul Killen (Director) and **Jeffrey Hodgin** supported our renal biopsy service in FY2013. **Dr. Kent Johnson**, transitioned to Active Emeritus status at the end of FY12. A search committee under the leadership of **Dr. Killen** successfully recruited **Dr. Evan Farkash** from Massachusetts General Hospital who will join our faculty as a Clinical Lecturer in September 2013.

Paul Killen, M.D. Our renal biopsy practice continued to show strong growth, accessioning 1,370 cases in FY13 compared to 1,166 in FY12 (see Table 3 and Figure 6). This is the third consecutive year in which a change in protocol for managing UMHS renal transplant patients combined with growth of the transplant program has more than doubled the size of our renal biopsy practice. Whole slide scanning remains an aspirational goal as a method for archiving and virtual review of biopsies from renal transplant patients.

Fig. 5: Neuropathology Case Volumes, FY10-FY13

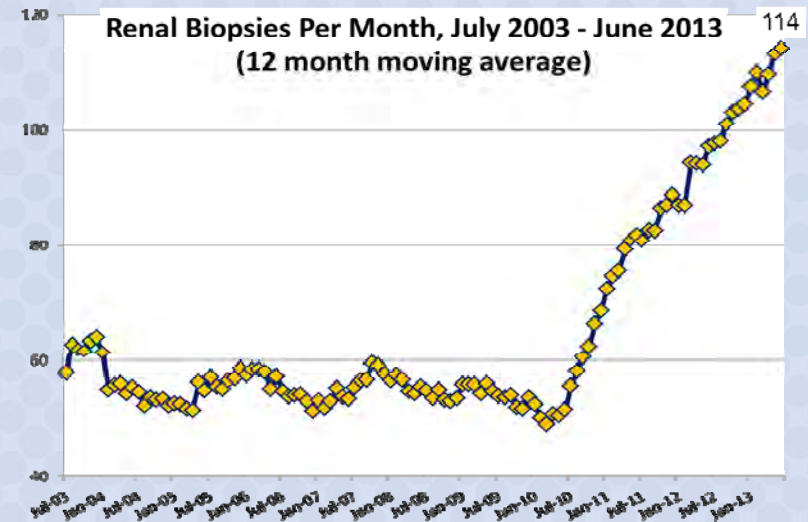


Neuropathology case volumes grew at an annual rate of just under 5%

Table 3: Renal Biopsy Case Volumes, FY10-FY13

FY10	FY11	FY12	FY13	% change (FY12 – 13)	% change (FY10 – 13)
618	984	1,166	1,370	17.5%	121.7%

Fig. 6: Renal Biopsies Per Month, FY04-FY14



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 115 cases monthly.



Michael Roh, M.D.

Cytopathology

Our cytology service and cytopathology continued to thrive under new leadership in FY13. **Dr. Michael Roh** assumed the roles of Director of Cytopathology, Medical Director of the Cytopathology Laboratory, and Program Director for the Cytopathology Fellowship effective July 1, 2012. **Dr. Judy Pang** redirected her effort away from our East Ann Arbor ambulatory surgery and breast practice to serve as a core member of our cytopathology service. In the third quarter, a search committee chaired by Dr. Roh successfully recruited **Madelyn Lew** from the cytopathology fellow-

ship program at Brigham and Women’s Hospital and Harvard Medical School with a July 2013 start date. In FY14, responsibility for the cytopathology fellowship will transition to **Dr. Xin Jing** as our new **Program Director**.

Brian Smola continues to serve as interim supervisor while **Kalyani Naik** remains on temporary leave to play a lead role in implementing SoftPath, a new laboratory information system (LIS) that went live on June 1, 2013. Brian also served as a member of the SoftPath build team and was actively involved in building and implementing the new LIS.

Total gynecologic specimens for the year were 26,928; an 18.1% decrease from last year (see Table 4). This is in line with national trends as a result of changes in follow-up Pap test recommendations for women with negative HPV.

Non-gynecologic specimens numbered 10,319, a 6.3% increase from last year. Exfoliative non-gyn specimens totaled 7,357, a 4.4% increase from last year. Fine needle aspirations (FNAs) totaled 2,962, an 11.2% increase from last year. FNAs performed at the Cancer Center (ASP3) numbered 208, representing a 14% decrease from last year. Assisted FNAs (ASP2) increased 15.3% to a total of 1,802 while aspirates performed by clinicians without our assistance (ASP1) declined by 4.2%, falling to 826. 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 drives increased demand on laboratory personnel, cytotechnologists, fellows and faculty to provide the needed service.

Table 4: Cytopathology Clinical Activity, FY 11-FY13

	FY2011	FY2012	FY2013	% change
Gyn Total	34014	32866	26928	(18.1%)
Non-Gyn Total	9812	9664	10319	6.3%
Non-Gyn Exfoliative	7123	7034	7357	4.4%
ASP Total	2604	2630	2962	11.2%
ASP 1	962	862	826	(4.2%)
ASP 2	1423	1526	1802	15.3%
ASP 3	219	242	208	(14%)

Table 5:
Cytopathology
Turnarount Time
(7 day week)

	FY10	FY11	FY12
GYN	4.0	5.1	2.7
NGYN/FNA	1.7	1.5	1.5

Cytology continued to focus on maintaining high service delivery levels as summarized in Table 5 and continued to employ Lean principles and tools in laboratory management.

Summary of Quality and Lean Initiatives in Cytopathology

- A monthly cytology dash board is published.
- Given the recent implementation of the SOFT Pathology LIS, efforts are under way to ensure that LEAN workflow is preserved and opportunities are seized to improve LEAN workflow.
- Cytopathology staff actively participated and presented at AP QA meetings.
- A wireless temperature monitoring system (TempTrak) was installed on all (4) cytopathology refrigerators. This reduced waste by eliminating the need for daily monitoring by hand with a thermometer as well as paper logs. The system tracks the temperature of all refrigerators every 15 min as opposed to once daily and immediately notifies us of a problem by both pager and email, protecting patient specimens.
- A hand-held wireless printer is currently being piloted at the Domino's Farms Thyroid FNA clinic to allow printing of FNA slide labels rather than hand labeling. So far it has performed without incident and will be subsequently installed at our other FNA locations as well as on our mobile cart.

Summary of Service Initiatives in Cytopathology

- Continued Expansion of Domino's Farms Thyroid FNA Service: June marks the four-year anniversary for the implementation of the telecytology program designed to cover the endocrinology/thyroid fine needle aspiration program from Domino's Farms. The onsite adequacy assessment via the web was successfully implemented with no major difficulties and continues to grow 4 years later. The service has grown to involve two procedure rooms at Domino's Farms which operates two days per week. Starting in July, these operations will expand to

three days per week. Cytopathology will continue to play a supportive role in this endeavor.

- Expansion and Advancement of the MPU FNA Service: MPU-G has been remodeled to include a telecytology set up modeling after the successful implementation of telecytology at Domino's Farms. This addition has the potential of increasing the efficiency of our FNA service in MPU.
- ER/PR scoring (VIAS) by Cytotechnologists: 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, Mr. Brian Smola and Dr. Julie Jorns led the training of our cytotechnologists. A total of 3 cytotechnologists are currently trained (Binita Naylor, Kim Lockett, Brian Smola) and are performing scoring on approximately 900 breast biopsies annually. The VIAS system has been approved to be upgraded to Ventana's new iScan Coreo system.
- Cytopathology has established a system for sendouts of thyroid aspirate material to Veracyte for Afirma testing. Cytopathology renders diagnoses for these aspirates and determines when to send out material for molecular testing.
- Initiatives are under way to implement pathologist-performed ultrasound-guided FNAs. Anticipated GO-LIVE is August 1. Drs. Pang, Roh, and Heider have already completed CAP training in ultrasound-guided FNAs. Cytopathology faculty and fellows will receive additional training prior to GO-LIVE in collaboration with Dr. Barbra Miller from the surgery department.
- Implementation of SOFT in cytopathology was smooth during the month of June.

Other initiatives in Cytopathology

The laboratory continues to participate in departmental activities including the School Job Shadow Program (Brian Smola and Kim Lockett), UMHS Safety Liaison (Linda Dawson and Lana Jajko), and the Pathology Service Excellence Committee (Linda Luchansky).

Autopsy and Forensic Services



The autopsy section provides faculty and resident coverage for hospital autopsies at the UMHS and VA hospitals as well as medical examiner cases for the offices of the Washtenaw County Medical Examiner (**WashCME**) and the Wayne County Medical Examiner (**WaynCME**). Residents complete three-month rotations on the autopsy service in order to comply with ACGME requirements.

Medical students actively participate in the autopsy service. Educational conferences include a weekly gross autopsy conference, monthly forensic conference and multidisciplinary clinical conferences on request. The autopsy staff consists of a full-time Director at the UM campus with contracted weekend coverage and eight (8) full-time positions stationed at the Wayne County medical examiner office.

A total of **579 autopsies** were performed in FY2013 in the **UM morgue**, an 11.3% increase compared to 520 cases in FY2012. Three hundred twenty eight (57%) of the total were **WashCME cases**. Of the medical examiner cases, there were 316 full autopsies, 12 limited autopsies, and 25 external examinations. The combined hospital and medical examiner cases accounted for approximately 30% of hospital deaths. Overall average turn-around-times were: hospital cases 49 days, brain only cases 41 days and WashCME cases 23 days.

Dr. Jentzen provides autopsy coverage for approximately 40% of hospital as well as Washtenaw and Wayne County cases. Eight pathologists assisted by two fellows provide coverage for WaynCME. In addition to the coordinator of autopsy services, there are two full-time death investigators/autopsy assistants who provide autopsy support and investigation from 7:00 am—11:00 pm daily. A group of five part-time investigators provide third-shift coverage from 11:00 pm—7:00 am. A dedicated administrative assistant provides clerical, computer, and administrative support, while another focuses on providing death certificates, cremation certificates, and maintains the death investigation software.

Effective in the second quarter of FY2012, the autopsy section contracted with the WaynCME 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. **Dr. Carl Schmidt**, Associate Professor of Pathology, serves as the Chief Medical Examiner for Wayne County. In FY13, the fac-

ulty, staff and trainees at **WaynCME** performed **1,975 full autopsies, 32 limited autopsies**, and **759 external examinations**.

For the fourth year, the Department sponsored **Advances in Forensic Medicine and Pathology**, a two-day conference on topics related to advances in death investigation, supported by the staff. The conference was well attended and received superior evaluations from the participants.

Current initiatives for the section revolve around improved turnaround time for hospital and WaynCME autopsies, directing the newly approved and filled forensic pathology fellowship, expanded coverage for WashCME, and integrating the WaynCME case volume and pathologists into section activities.

RESEARCH ACTIVITIES

The Anatomic Pathology faculty remains remarkably productive despite the demands of patient care (see Table 6). Despite an incomplete dataset, twenty-nine faculty reported an average of 6.9 (median 5) peer-reviewed publications for a total of 218 papers either in print or in press at the end of FY2013 compared to 188 in FY2012. This reflects a substantial 16% increase compared to a year ago. In addition, faculty reported the results of their work in abstract form on 120 occasions, a 14% increase over last year. Twenty-six faculty served as invited lecturers, speakers or visiting professors on 144 occasions, for an overall average of 5.5 (median 4) per participant. This is a nearly 43% increase over FY12 and, like the number of peer reviewed publications and abstracts, is a record level of productivity in the eight years for which data is available. Clearly, our faculty remain top-of-mind when looking for cutting edge speakers in anatomic pathology. In addition, seventeen different faculty reported being members of 36 editorial boards, including an Associate Editor for BMC Cancer (**Dr. Celina Kleer**).

Table 6: Academic Productivity in AP, FY 11-FY13

	FY2011	FY2012	FY2013	% change
publications	157	188	218	16%
abstracts	90	105	120	14.3%
invited lectures	120	101	144	42.6%
editorial boards	29	32	36	12.5
FTEs funded	4.9	4.5	4.0	(10.6%)
research expenditures	\$4,125,489	\$4,167,734	\$3,235,470	(22.4%)

Research expenditures dropped by just over \$900,000, reflecting a year-over-year decrease of 22.4% compared to FY2012 (see Figure 7). Nearly two thirds of that drop was the result of **Dr. Peter Lucas'** departure for the University of Pittsburgh at the end of the second quarter. Two additional clinician scientists lost large grants but are engaged in the process of competitive renewal. Despite the challenges of the extramural funding climate, research expenditures in FY13 exceeded funding in FY06-FY08 and was only 6.9% lower than FY10. The total number of funded FTEs showed minor downward fluctuation, dropping from 4.5 to 4.0, but sustaining the gains realized in FY2009 (3.9 FTEs) compared to FY2008 (3.6 FTEs). Maintaining current levels of funding in today's environment reflects the re-

Fig. 7: AP Research Expenditures, FY06-FY13

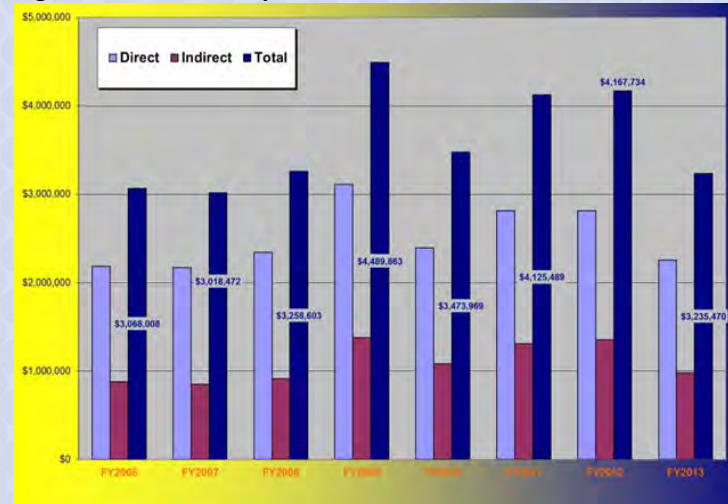
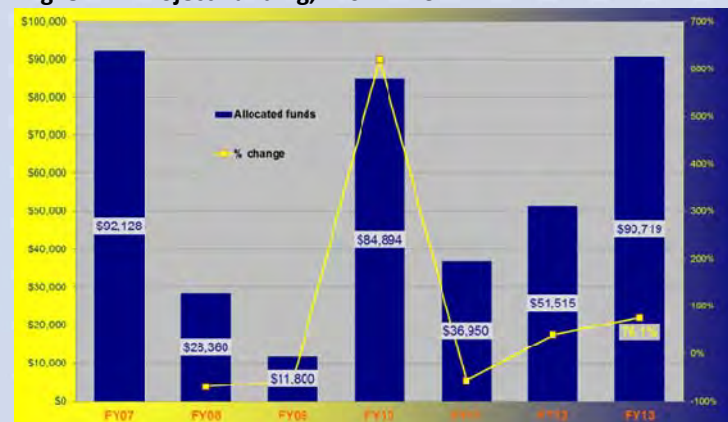


Fig. 8: AP Project Funding, FY07-FY13



markable success of our laboratory investigators, all of whom also have substantial commitments to patient care. Addition of young clinician scientists like **Evan Farkash, Paul Harms, Jeff Hodgins** and **Scott Tomlins** is an important part of our strategy to maintain the vitality of our laboratory-based discovery programs but hinges on continued attention to the infrastructure required for success.

AP funding accounted for an additional \$90,719 allocated in support of projects in which AP faculty and trainees served as Primary Investigators (see **Figure 8**). This reflects a 76.1% increase compared to FY12 and nearly two and a half times the budget allocated in FY11.

We hosted our **4th Annual Research Day** on January 19, 2013 in collaboration with Hematopathology and Molecular Pathology. The day included 30 abstracts presented as posters (22) and platforms (8). Our Keynote Speaker was **Dr. Jonathan Fletcher** from Brigham and Women's Hospital and Harvard Medical School. 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 2013 Annual Meeting of the USCAP as well as manuscripts in press or in print in peer-reviewed journals.

Dr. Doug Fullen was promoted to Professor, and **Drs. Lakshmi (Priya) Kunju** and **Jonathan McHugh** to Associate Professor effective in the first quarter (September 2012) of FY2013. **Drs. Scott Owens** and **Rajiv Patel** were approved for promotion to Associate Professor effective in the first quarter (September 2013) of FY2014.

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. Trainees continued to actively participate in various research projects during the course of the year. Thirteen residents and 6 fellows served as authors or co-authors for **23** different **abstracts** presented at the **2013 annual meeting** of the **USCAP**

in Baltimore.

Fellowships in breast pathology (1), cytopathology (2), gastrointestinal pathology (1), dermatopathology (2), genitourinary (1), gynecologic (1), pulmonary (1) and surgical pathology (3) were filled by competitive candidates in the 2012-2013 academic year. The **pediatric pathology fellowship** program, under the direction of **Dr. Raja Rabah**, underwent its first Accreditation Council for Graduate Medical Education (ACGME) site visit February 2013 and received continuous full accreditation for 5 years. Our second pediatric pathology fellow (Allecia Wilson) was recruited to matriculate in July 2013. The **dermatopathology fellowship**, under the directorship of **Dr. Doug Fullen**, had a site visit from the ACGME in October 2012 and received preliminary notification of renewed accreditation for a full 5-year cycle. It again recruited highly competitive fellows (Thanh Ha and Jeremy Vincent) for the 2013-2014 academic year. In FY14, responsibility for the dermatopathology fellowship will transition to a new Program Director, **Dr. Aleodor Andea**.

A **fellowship in neuropathology**, under the direction of **Dr. Andrew Lieberman**, was accredited for 3 years in December 2011 and successfully completed its first internal review in the 3rd quarter of FY13. The first neuropathology fellow (Amanda Fisher-Hubbard) was recruited to matriculate in July 2014. Our fellowship complements a rich history of education in our neuropathology section. This year the neuropathology faculty taught in the Neuroscience Sequence for M2 students. Two one-hour lectures were presented by Dr. Lieberman on dementia and CNS tumors, one half-hour lecture was presented by Ms. D'Amato reviewing neuroanatomy, neurohistology, and basic neuropathology. Three laboratory sessions, two hours each, were also taught by Dr. Lieberman and Ms. D'Amato. Nine pathology residents completed 2-week rotations on the neuropathology service and were provided training in surgical and autopsy neuropathology (including frozen sections) and in the evaluation of nerve and muscle biopsies. Residents were given the opportunity to present their cases at the conferences noted above. The neuropathology service also hosted a rotating resident in pediatric neurology for 4 weeks and three M4 student on their pathology electives. Neuropathology 858, an evening course, given in the Fall, was taught by Dr. Lieberman and Ms. D'Amato. This overview of microscopic neuropathology course was attended by 16 residents/fellows in pathology, neurology, neurosurgery and neuroradiology.



*Congratulations
on your
promotions!*

A **fellowship in forensic pathology**, under the direction of **Dr. Jeffrey Jentzen**, received preliminary notification of accreditation for 3 years and matriculated two fellows (Amanda Fisher-Hubbard and Jeffrey Hudson) in July 2013. 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. 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 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 1,606 contact hours. AP faculty had primary responsibility for first and second year courses in pathology as lecturers, laboratory instructors, advisers and mentors. **Drs. Scott Owens** and **Michael Roh** assumed primary responsibility as directors of the pathology curriculum for the 1st year medical students (including histopathology), and together with other faculty members who lectured and led laboratory sessions accounted for over 730 contact hours recorded by the University of Michigan Medical School! Multiple additional faculty participated in laboratory-based educational experiences for 2nd year students and in teaching dental and graduate 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, head and neck pathology, 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.

Three invited speakers visited our department through the **A. James French Visiting Professorship**, each presenting a lecture and slide seminar,

including **Drs. Arie Perry** (University of California at San Francisco), **Steven Tahan** (Beth Israel Deaconess Hospital and Harvard Medical School), and



Arie Perry, MD Steven Tahan, MD Mark Stoler, MD

Mark Stoler (University of Virginia).

Multiple faculty participated in our sixth CME workshop, **New Frontiers in Pathology**, presented in collaboration with the A. James French Society. The 2012 course was held off campus in northern Michigan and saw a decrease in attendance despite very strong evaluations for the quality and content of the program. **Dr. John Hart** from the University of Chicago served as guest faculty and the A. James French Lecturer. In FY2014 New Frontiers will return to Ann Arbor.

Our CME offerings included the fourth year of **Advances in Forensic Medicine and Pathology**, hosted in collaboration with the Washtenaw County Medical Examiner's Office in May 2013 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.



*John Hart, MD
2012 A. James French Lecturer*



Back: Deputy Edwin Moore, Dr. Jeffrey Jentzen, Dr. Joseph Prahlow

Front: Investigator Richard Cruz, Judge Stephanie Domitrovich, Ph.D., Dr. Yi-Li Wu, Dr. Michael S. Pollanen

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Division of Clinical Pathology

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



Staff, trainees, administration and faculty from the Department of Pathology Division of Clinical Pathology and Clinical Laboratories overcame unprecedented challenges in 2012-2013. Major laboratory-wide accomplishments included successful implementation of the first phase of the University of Michigan Health System (UMHS) MiChart clinical order entry system; selection and installation of Master Control, a new laboratory document management system; passage of our biannual unannounced College of American Pathologists (CAP) laboratory inspection; and completion of intensive preparations that led to successful “go live” activation of the new SCC/Soft laboratory information system (LIS) in June, 2013. Superimposed upon these activities was a UMHS-wide 2.5% margin improvement program, planned and executed within a six month time frame! Literally hundreds of individuals worked tirelessly to accomplish these goals. UMHS MiChart implementation created numerous work flow disruptions and the need for hundreds of real time *ad hoc* corrective actions. While many processes remain to be refined, equilibrium was reached within weeks of initiation. Adaptation to MiChart within the Clinical Laboratories was made possible by medical technologists, laboratory supervisors and managers, Pathology administration and faculty, and the extraordinary efforts of Pathology Informatics (**Ul Balis, M.D., Ph.D.**, Director; **Kathy Davis**, Manager; **Cybil Rowerdink**; **Bill Hubbard**; and many, many others). Selection and installation of Master Control was ably led by **David Keren, M.D.** (Associate Director of Clinical

Laboratories); **Kristina Martin** (CP), and **Brian Smola** (AP).

Master Control greatly facilitated preparations for both the CAP inspection and SCC/Soft “go live”. The “fully loaded” document management system will encompass more than 5,000 configurable documents! **Suzanne Butch** (Chief Technologist, Blood Bank/ Transfusion Medicine Service), accepted an incremental departmental administrative role as lead for compliance, accreditation and out-of-state laboratory licenses. Her outstanding leadership was validated by our “most successful ever” CAP inspection (only 14 citations) in April, 2013. Thousands of hours of work, much of it during weekends and nights, by laboratory staff, supervisors, faculty and Pathology Informatics personnel, led to the successful conversion from our legacy LIS to SCC/Soft in June, 2013. This conversion, after more than 30 years of the legacy system, succeeded in the face of an unyielding timeline and the other aforementioned challenges.

THE LABORATORIES

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 He-

Clinical Pathology Sections

- ◆ Blood Bank/Transfusion Medicine
- ◆ Chemistry
- ◆ Microbiology—Virology
- ◆ Hematology
- ◆ Specimen Processing
- ◆ Phlebotomy
- ◆ Cytogenetics
- ◆ Molecular Diagnostics
- ◆ Histocompatibility
- ◆ Immunology

matology, Automated Hematology, Flow Cytometry, and Coagulation); Chemical Pathology (which encompasses Special Chemistry, Automated Chemistry, Immunology, Toxicology-Therapeutic Drug Monitoring, 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. Clinical Laboratory 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, Pediatrics Pulmonary Laboratory, Adult Blood Gas Laboratories, and the CLIA laboratory component of the Michigan Center for Translational Pathology (MCTP) and Paradigm, an advanced cancer diagnostics company, jointly formed by the University of Michigan Department of Pathology, the International Genomics Consortium (Phoenix, AZ) and the UMHS.

GREAT PATIENT CARE: A VERY BUSY YEAR!

While “major challenges” was the overarching theme for 2012-2013, the Clinical Laboratories continued to provide outstanding service in support of patient care! Key indicators of these efforts included nearly 11,000,000 discrete laboratory test results (5.69M billed tests), more than 250,000 blood draws, \$543.8M gross charges, an expense budget of \$94.7M, dispensation of 108,000 units of blood product, and 1,900 therapeutic apheresis and hematopoietic stem cell harvests.

This work, produced by more than 500 laboratory personnel, served UMHS and MLabs patients cared for via 45,000 hospital admissions

and 1.9M outpatient visits (93,000 adjusted discharges). Outstanding administrative leadership was provided by the laboratory supervisors and chief technologists, faculty laboratory directors and by Pathology administration. As noted above, **Suzanne Butch** led compliance, accreditation and licensing efforts; **Kristina Martin** led Clinical Pathology operations and ably served as Pathology lead for all Southeastern Michigan American Red Cross blood drives at the UMHS; **John Perrin** led the Clinical Pathology Quality Assurance program; **Maegen Weighman** took over leadership of the 33-member (every laboratory domain) Laboratory Safety Committee; **Christine Shaneyfelt** led capital equipment tracking and acquisition, as well as financial and utilization data procurement and analysis.

EDUCATION, RESEARCH AND INNOVATION

Despite the challenges posed by the major initiatives and the ongoing provision of high quality, high volume and broadly scoped patient care, the year was also marked by very successful educational programs, research and innovations. Among the many educational highlights of 2012-2013 were the well-attended October, 2012 Clinical Pathology Symposium which encompassed two half-day groupings of laboratory medicine presentations; a national expert panel symposium entitled “Thrombotic Thrombocytopenic Purpura and Atypical Hemolytic Uremic Syndrome” organized and hosted by **Dr. Chisa Yamada**; ongoing quarterly joint Hematopathology-Anatomic Pathology case review evenings; visiting professors (Bobbi Pritt, MD; Mayo Clinic Microbiology; October 14-15, 2012 – organized and hosted by **Dr. Duane Newton**); and ongoing participation of clinical laboratory staff, trainees and faculty in standing departmental educational programs as well as in dozens of extra departmental conferences, tumor boards and seminars.

The 2013 Current Topics in Blood Banking Conference (April, 2013) was highlighted by guest speaker, Mark Popovsky, MD, Harvard Medical School and Chief Medical Officer, Haemonetics Corporation. In addition to Dr. Popovsky, University of Michigan faculty presented a wide range of talks encompassing aspects of current transfusion medicine



**Suzanne Butch, MLS(ASCP)^{CM},
SBB^{CM}, DLM^{CM}**

Overseeing compliance, Suzanne led us through our best-ever CAP Inspection in 2013.

practice. “Current Topics in Blood Banking” has run for 31 consecutive years! Finally, the University of Michigan was very well-represented in terms of presentations, recognition and leadership at the annual American Society of Clinical Laboratory Science meeting in East Lansing in April, 2013. Leading edge medical practice is marked by innovation! Outstanding examples occur on a daily, even shift-by-shift basis, in the Clinical Laboratories – whether in solving workflow problems, creating informatics “hot fixes” or finding an alternative to a “short sample.” Noteworthy 2012-2013 examples of innovation included development and implementation of a new massive transfusion protocol, of the UM Pathology “Virtual Slide Box” public portal for Pathology Education – an application that allows access from PCs, Macs and iPads from any location to view more than 600 virtual histology slides (5,000 to be added). Slides can be viewed at varied magnifications as unknowns if desired, and are annotated with educational content. **Sheridan Mattson** (Chemistry) and **Dr. Matt Elkins** (Transfusion Medicine Fellow) developed and promulgated the “Drug 6 Card” which led to a remarkable improvement in UMHS-wide test utilization related to urine drug screens.

Finally, **Dr. Duane Newton**, **Bill LeBar**, and colleagues in Microbiology launched rapid organism identification via matrix-assisted laser desorption ionization – time of flight (MALDI – TOF) which, in conjunction with the UMHS Antimicrobial Stewardship Team, led to dramatic improvements in outcomes in patients with bacteremia and fungemia. Again, these are just a few examples among many! (Of particular note, at the close of 2012-2013, Clinical Laboratory staff had submitted twenty UMHS Quality Month project posters for the Fall 2013 program.)

2012-2013 was an outstanding year! Faculty, trainees and laboratory staff published nearly 100 peer-reviewed papers, many in high impact journals (e.g., *Journal of Experimental Medicine*, *Journal of Clinical Investigation*, *Blood*, *Proceedings of the National Academy of Science*, *Cancer Cell*, *PLoS*, *American Journal of Medical Genetics*, *Genome Biology*, *American Journal of Clinical Pathology*, and others). In addition, these Section and Laboratory reports are highlighted by many examples of leadership by both faculty and laboratory staff in national organizations, on editorial boards, and through participation in national and international panels and symposia.

Combined Hematology Laboratory (Hematology, Bone Marrow, Flow Cytometry, Coagulation)



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 2013.

- The volume of complete blood count (CBC) testing—a key benchmark of laboratory activity-- was increased from 500,000 CBCs performed to over 570,000.
- The volume of HP specimens in flow cytometry and smears and fluids increased in FY 2013, while TH and HR remained stable .
- The total RVU for the section increased by 2.4% over FY 2012.

Major efforts have been deployed in the development and transition to the new LIS and optimizing manpower needs to meet the changing clinical needs of the Children’s Hospital and the Cancer Center in the face of budget cuts. The hematopathology section has taken on the additional clinical work of evaluating all of the pediatric bone marrow aspirate biopsies which represents a significant patient safety and laboratory quality improvement.

Clinical Hematology Laboratory



Dr. Jo-Ann Vergilio joined the HP section in January 2012 to assume the position of Directory of Clinical Hematology Laboratory.

The Hematology laboratory continues to offer a wide-spectrum of testing that encompasses the high volume complete blood count (~570,000 per fiscal year) with manual differential enumerations (~17,000 per fiscal year) as well as the specialized preparation and assessment of bone marrow studies (~2000 per fiscal year) . Additionally, pathologist reviewed peripheral blood smears, body fluids and crystal examinations have increased 25%, 18%, and 11%, respectively, as compared to FY 12.

This past year, the laboratory experienced significant change in its most senior technical management with both a new Administrative Manager

(Usha Kota) and a new Daytime Supervisor (Sara Gay). Additionally, four full-time staff have retired with only two formal replacements, thereby leaving vacancies in a senior technologist and a medical technologist position. Given increasing workloads superimposed upon implementation of various major departmental initiatives (e.g., SOFT, Master Control), staff have been overburdened, but have risen to each of the many challenges.

In order to improve communication throughout the lab, regular meetings have been established with medical and technical leadership (Manager, Supervisors, Senior Technologists) in order to better communicate ideas, identify problems, and formulate action plans. Daily huddles have also been established to improve communication of issues within and between technical shifts. Additionally, a formal continuing education program was introduced for Hematology technologists in order to encourage and foster ongoing education and professional development for technical staff. This program outlines annual mandatory requirements that each technologist must fulfill (e.g. attendance at internal or external conferences, microscope sign-out sessions, teleconferences/online educational opportunities, etc.).

Five individuals received Pathology recognition awards for their outstanding service and commitment to patient care during 2012-13: Susan Clark, Gerald Davis, Sara Gay, Usha Kota, and Onike Mnzava. Their dedicated efforts are recognized both within and outside of the department.

Having just completed the SOFT GO-LIVE transition on June 1st, the laboratory continues to work to resolve outstanding issues and streamline operations. Unlike other laboratories, the complex and multidisciplinary nature of hematopathology necessitates training and facility in all three of the SOFT modules (LabMic, Flow, and GeneDx), not just one. Staff participated in numerous weekday and weekend training sessions and their efforts have greatly helped to optimize this transition phase.

In an effort to increase efficiency and quality, the laboratory undertook LEAN initiatives, two of which will be continuing on into the next fiscal year:

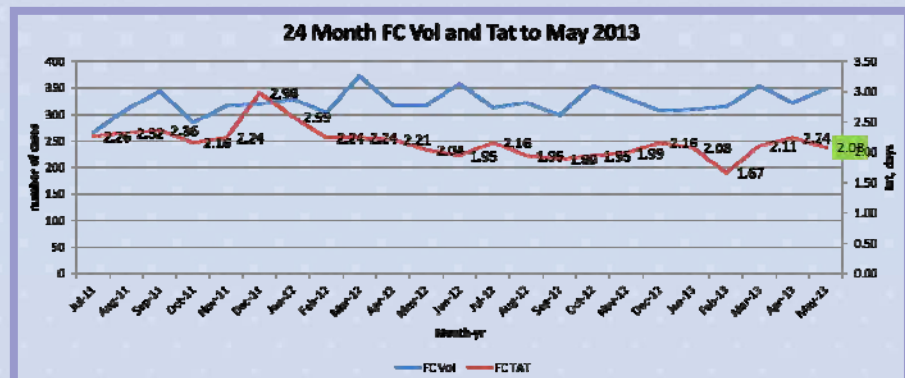
- ◆ Acquisition and implementation of Cellvision, a digital imaging device, to be used in peripheral smear manual differential count and reviews.

- ◆ Restructuring of bone marrow procurement process in order to eliminate the presence of the medical technologist at the bedside, saving 1 FTE of “non-value-added” effort.

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, which has been highly-productive in establishing a full complement of Clinical Practice Guidelines for UMHS. The laboratory was able to validate the Siemens Control N & P for several assays, for which four controls were previously required. This significantly reduced costs and technician preparation time. In addition, by switching to a better and more automated reagent for Protein S Antigen Free, approximately 90 minutes were saved per assay, with much improved precision and separate reference ranges for males and females. The lab was also able to bi-directionally interface a number of assays, which eliminated any data entry errors in the input of data, further improving the efficiency and quality of the laboratory’s services. The Coagulation laboratory is actively involved in the educational mission with a coagulation rotation for Hematopathology and Hematology/Oncology Fellows, and special Coag Lab themed seminars for Pharmacy students. Dr. Pipe’s work on a research committee tracking compliance and complications related to anticoagulation within UMHS has led to abstracts and publications in process.



Clinical Flow Cytometry Laboratory



The Clinical Flow Cytometry Laboratory, under the leadership of **Dr. Lloyd Stooman**, experienced overall test volumes in the Clinical Flow Cytometry Laboratory remained relatively stable with a 1.5% increase over FY 2012, while turn-around times decreased another 11.9% on top of the 12% decrease in the prior year's performance despite retirements of several senior technologists and a Hospital-wide hiring freeze. This was accomplished through enhanced screening for medically unnecessary orders, adherence to standard panels where possible and reduced ordering of custom antibody cocktails. It is anticipated that the move to 8-10 color cocktails for all standard panels and the purchase of robotic prep assistants will increase capacity and decrease turn-around time thus helping our reduced workforce maintain service excellence in economically challenging times. The laboratory also completed its CAP inspection with zero defects while simultaneously validating the Flow Cytometry Software Module (Soft Flow, Soft Gene Suite) for the first major LIS upgrade in 20 years. This latter activity culminated in go-live with the new LIS on June 1st. As anticipated, the accelerated timeline for LIS deployment resulted in reduced productivity and forced the laboratory staff to troubleshoot deficiencies and develop workarounds while delivering uninterrupted service. The extraordinary dedication and effort of our technologists, led by the Hematology Laboratory Manager Usha Kota, and the perseverance of our trainees and staff are carrying the laboratory through this challenging period. We are exploring a co-development agreement with Soft Systems that would incorporate the custom Flow Cytometry sign-out, management and educational tools developed by Joshua Jacques, Programmer Senior, and Dr. Stoolman to the Soft Flow Module.

IMPROVEMENTS IN SERVICE ORGANIZATION AND QUALITY ASSURANCE/CONTROL

The Hematopathology section is continues to explore opportunities for improvement in their services. One area that has been in long-standing need of improvements is the Hematopathology Sign-Out areas. In FY 2013, new ergonomic tables were added to both the Medical Science and Hospital sign-out areas and telepathology functionality was added in the

Hospital sign-out room. Additional monitors were also added to accommodate additional observers. These changes have improved the working conditions and efficiency of the sign-out process for our attendings and trainees.

In addition, the Hematopathology section and the Pediatric Hematology/Oncology section have worked together in a QA/QC effort to ensure all pediatric bone marrow aspirates are being evaluated and reported by hematopathologists, with the aim of improving patient care and outcomes.

HEMATOPATHOLOGY EDUCATION – FELLOWS/ HOUSE OFFICERS/ TECHNOLOGISTS

Dr. Megan Lim, Director of the Hematopathology Fellowship Program decided to step down from this role and our Assistant Director, Dr. Lauren Smith, will be the new Director of the Hematopathology Fellowship Program, effective July 1, 2013.



To enhance our trainees' experiences, additional reference manuals have been added to the fellows' room and all lectures given at the weekly HP Educational Conference are now archived on Camtasia for viewing in case they were missed or if our trainees wish to review the information presented. In addition, an on-line didactic repository is currently being built.

In FYI 2013, our fellows and house officers presented over 10 scientific abstracts at national meetings and Dr. Carlos Murga (House Officer) received recognition for his research abstract presented at the Department of Pathology AP/HP/MP Research Symposium.



LAUREN SMITH, MD

Director, HP Fellowship

Chemical and Clinical Immunology Pathology Laboratory

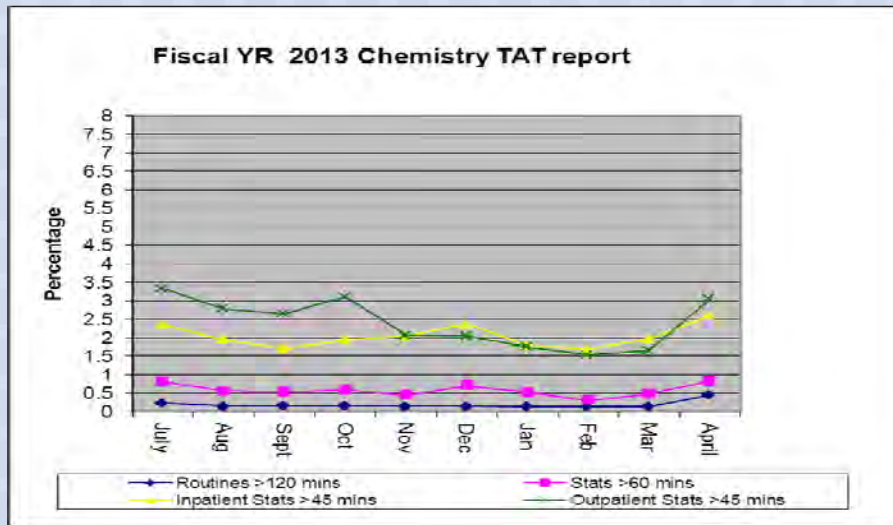


The Chemistry Section, under the leadership of **Donald Giacherio, Ph.D.** and the administrative management of Sue Stern, experienced an approximate 1.8 % increase in overall testing volume this year. The lab produced nearly 8.45 million individual patient test results. In addition, the lab serves as 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 preparation for the go-live of the new SOFT lab information system. The outstanding efforts of Sue Stern, Merry Muilenberg, and all the lab supervisors and staff on this project 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 con-

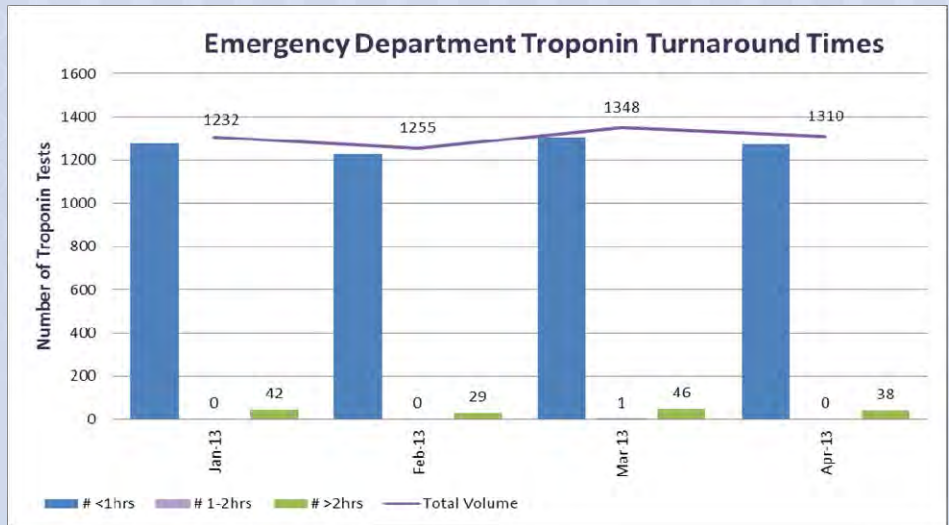
of lean team groups in chemistry and the suggestions from weekly team huddles have led to the implementation of multiple changes that continue to positively impact workflow. Lean team members from the lab continue to actively participate in successful and ongoing projects aimed at reducing error rates within the lab and simplifying processes for sharing samples across laboratory boundaries. The lab has continued its progress as one of 7 UMHS sites to receive additional training of all staff as part of a Lean Implementation Teams (LIT) 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.

The Automation section of the lab continued its efforts to move additional tests to the line. 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. Testing for intact PTH was validated and moved to the automation line. This simplified and reduced distribution area workflow because PTH samples no longer need-



Turn-around time trends

sistent trend towards overall TAT reductions. Approximately 22% of the over 78,000 samples a month processed on the Chemistry automation line are STAT's. Currently, less than 0.7% of inpatient 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. The ongoing activities



ed to be aliquotted and stored. The test which was previously performed only twice a week is now offered 24/7 with a less than 2-hour turn-around time. This has allowed the endocrine surgery group to better monitor their parathyroidectomy and total thyroidectomy patients in real time. The lab has performed a validation and correlation study for methotrexate testing, which is ready to move from a small stand-alone semi-automated analyzer to the automation line. This will simplify workflow on the 2nd and

3rd shift for STAT methotrexate orders. The lab purchased and validated a Biomerieux VIDAS analyzer for procalcitonin testing. This marker for sepsis will be offered to inpatients in the first quarter of the next fiscal year. The leadership efforts of Eric Vasbinder have been key to the continued smooth operation of the automated chemistry section.

In the Special Chemistry Section, oversight of the STAT Lab functions in both the adult and pediatric Emergency Departments continues to be managed by Special Chemistry personnel, supervised by David Harro. 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. Negotiations are ongoing to establish a means of supporting io-PTH testing for surgeries in C&W hospital. The special chemistry area completed the purchase process for 2 new Horiba Pentra 400 analyzers as replacements for the 18-year-old Cobas MIRA analyzers and validated testing for ethylglucuronide, aldolase, angiotensin converting enzyme, serum hemoglobin, urine oxalate, and urine citrate on these new systems. The special chemistry area began evaluation of a new automated direct immunoassay for plasma renin as a potential replacement for the manual RIA of plasma renin activity.

In the Toxicology section, lab leadership and department administration completed an over \$500,000 capital program request to acquire 1 new LC-MSMS analyzer 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 new Waters LC-MSMS system was installed and work begun on validating assays for plasma metanephrines and the urine metabolites HVA, VMA, and 5HIAA. The Toxicology group has finished development and validation of an LC-MS assay for methotrexate to be used in the rare cases when high dose methotrexate toxicity is treated with the recombinant enzyme Glucarpidase.

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 continues 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 with-

in UMHS with approximately 500 new technology meters. The lab completed an interference study on two new meters as part of the replacement meter project. 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 POC group evaluated two different whole blood prothrombin time meters for use in the emergency Department Lab in order to meet the turn-around-time requirements for the newly accredited Stroke Center. Implementation of this additional ED lab test is being scheduled for August 2013.

The lab continues its significant role in education. Pathology residents on a monthly rotation through the lab met daily with Dr. Giacherio, Dr. Annesley, or Dr. Keren 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 one week of laboratory testing exposure, and two Allergy Fellows for a one day exposure to IgE allergy testing by immunoassay.

In the coming year, the Chemistry Laboratory will continue its lean efforts to improve TAT for testing, continue searching for ways to automate manual testing, and work toward bringing in additional testing from the list of send-out tests. The lab will be actively involved in multiple projects that include:

- ◆ Deploy replacement glucose meters throughout the health system.
- ◆ Bring up new tests on the LC-MSMS system.
- ◆ Complete an RFP for new specialty immunoassay analyzers with a goal of new instrumentation with expanded test menu to allow bringing in additional send-out testing (bioavailable testosterone, free PSA, bone alkaline phosphatase).
- ◆ Implement immunochemical testing for fecal occult blood.
- ◆ Work on plans to move batched non-STAT testing to new space (NCRC) and begin the planning for replacement of the chemistry automation line.

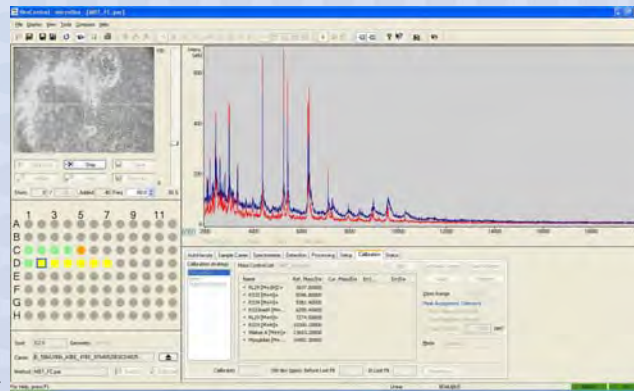
Clinical Microbiology/Virology Laboratories



Dr. Duane Newton led the Clinical Microbiology and Virology Laboratories again this year. With the continued increases in volumes and further impact of constricted space, major focuses of the last year continue to be identifying opportunities to increase efficiency without compromising service. In addition to the substantial time and effort dedicated to implementation of the new Soft Laboratory Information System into the laboratory, the following are some additional 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.

Major developments have occurred in the molecular diagnostics area:

- ◆ A dedicated staff focused on molecular testing has been fully implemented.
- ◆ Expansion of staffing to the second shift to increase capacity, particularly during respiratory virus season.
- ◆ Conversion of HSV detection and typing from culture to automated molecular system.
- ◆ Redistribution of instruments and personnel in microbiology and molecular/virology has been undertaken to improve processes in both areas.
- ◆ Requests for addition space in Mott/Neuroscience Hospital were successfully negotiated with UMHS; some of the space has begun to be utilized.
- ◆ RFP review and instrument evaluations were completed for qualitative molecular assays; assay verification studies are nearly complete.
- ◆ Changeover of HBV, HCV, and HIV viral load assays to Abbott platforms and assays have been completed.



Flex-Control software running in conjunction with the MALDI-

A second major area of activity has been the addition of MALDI-TOF as a platform for microorganism identification. We have initially focused on gram-positive and gram-negative aerobic bacteria and yeast identification, but are also currently developing protocols for the identification of *Nocardia*, *Mycobacterium*, and anaerobic bacteria. We initially utilized the technology for routine identification of aerobic bacteria and yeast from positive blood cultures; the platform has now been fully implemented for identification of these organism groups from all specimen types. We have also completed a study in collaboration with the antimicrobial stewardship team to examine the impact of this rapid identification on time to optimal antibiotic therapy and patient outcomes. We showed significant decreases in time to reporting, time to initiation of optimal therapy, length of ICU stay, and mortality during the intervention phase of the study. This also translated into several million dollars in reduced costs in managing patients. The data were presented in poster form at the ASM meeting, and the resulting manuscript is currently under review. We continue to investigate ways to incorporate outcomes studies into our research activities as the clinical, scientific, and administrative benefits can be substantial.

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 process for notification of laboratory managers 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. These are 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 of 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.

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.

Multiple senior staff, including the laboratory's administrative manager, supervisors and Sr. Technologists, attended regional or national scientific meetings during the year. Several other staff attended national and regional scientific meetings of interest. All of the above-mentioned individuals were involved in presenting posters at national meetings, and some are in the process of being written as manuscripts. The laboratory continues to be active in multiple research projects that involves many bench-level technologists and provides them with opportunities to attend scientific

Blood Product	2011	2012	Percent change	Apheresis Proc. Unit	FY 12	FY 13	Percent change
Red Blood Cells	25,698	27,664	7.7	Therapeutic apheresis	1101	1195	8.5
Platelets	61,093	63,712	4.3	HPC collections	423	413	-2.4
Plasma	10,951	9,655	-11.8	LDL apheresis	332	298	-10.2
Cryoprecipitate	4,873	4,930	1.7	RBC exchange	41	44	7.3
				Total procedures	1897	2177	14.8
Cellular Therapy Lab	FY 12	FY 13	Percent change	Reference Laboratory	FY 12	FY 13	Percent change
Units processed ¹	496	465	-6.3	Antibody identifications	1053	1045	-0.8
Bags frozen	692	699	1.0	ABO resolution	89	96	7.8
Transplants, autologous	158	143	-9.5	M-Labs/referrals	22	28	9.1
Transplants, allogeneic	48	35	-27.1	BMT	894	661	-26.0
Transplants, unrelated	53	74	39.6	Eulates	231	187	-19.0
Transplants, total	259	252	-2.7	Adsorptions	303	309	1.9
				Titers	130	144	10.7
				Total activity ¹	3202	3029	-5.4
				Prof. Billing	FY 12	FY 13	Percent change
				Gross charges	\$696,406	726,476	4.3
				Charge units	2,290	2,385	4.1

¹ Includes procedures not listed above

meetings, which additionally enhances the academic visibility of the laboratory and department.

In addition, the Laboratory subscribed to audio-conference programs which provided multiple 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 in-service programs to the laboratory staff.

Blood Bank/Transfusion Medicine



Dr. Robertson Davenport continued to provide strong leadership for the Blood Bank and Transfusion Medicine section. The major focus of the laboratory was implementation of the replacement laboratory information system. This was a particular challenge for the Blood Bank due to FDA regulations pertaining to blood establishment computer software, which require extensive validation. The blood bank also worked extensively with the Transfusion Committee to implement and refine the massive transfusion protocol (MTP). Use of the MTP has improved delivery of blood components for massively bleeding patients, reduced over ordering, and improved communication with the blood bank.

Data for Blood Bank main laboratory activity reflect the calendar year 2012. The data for FY 13 reflect July 2012—June 2013. Overall utilization of blood components and total testing performed by the laboratory were increased, reflecting increased clinical activity.

Overall activity in the Cellular Therapies Laboratory was similar to the previous year. There was an increase in the number of unrelated allogeneic transplants, which also reflects increased complexity and demand for transfusion.

Overall activity in the Apheresis Procedures Unit increased. A decrease in HPC collections and LDL apheresis was offset by an increase in other procedures. The decrease in HPC collections reflects a shift toward a higher proportion of allogeneic transplants, and greater utilization of marrow as a stem cell source.

Reference laboratory activity was slightly decreased over all, largely due to decreases in bone marrow evaluations and eulates. This was largely accounted for variation in transplant and hematology patient activity. It does not reflect the complexity of reference laboratory work.

In support of the educational mission, the fellowship in blood banking/transfusion medicine was filled by Matthew Elkins, MD, from the University of Michigan. In FY 13, the faculty and fellow participated in a clinical elective for M2 students that is intended to provide them with an in-depth clinical experience. The primary goal for the Department of Pathology is to expose the students early to the practice of pathology as a recruiting tool for potential residents. The elective was offered in October, for three 2-

hour sessions open to 2 to 4 student. Topics covered included pretransfusion testing, selection of appropriate blood components, antibody identification, evaluation of transfusion reactions, and evaluation of apheresis patients. Overall, the student evaluations of the elective were good to excellent.

Members of the faculty and staff also participated in teaching M4 medical students, clinical pathology house officers, hematology fellows, and medical technology students. Participation in the medical technology internship has required approximately .25 FTE, but has been a valuable source of new employees in the past.

Professional Activities

The technologist staff was highly active on the regional and national levels. **Suzanne Butch** served on the Clinical Laboratory Standards Institute (CLSI) Consensus Committee on Automation and Informatics, Consensus Committee on Quality Systems and Laboratory Practices, and Document Development Committee on Laboratory Internal Audit Program; ICCBBA Board of Directors, and as Board Secretary; AABB Coding and Reimbursement Committee, and as Assessor for Blood Banks & Transfusion Services; Michigan Society for Clinical Laboratory Science as Historian; and ASCP Board of Certification Lab Management and Safety Committee. She also presented invited lectures at the ASCLS Annual Meeting, North Carolina Association of Blood Banks Annual Meeting, AABB Annual Meeting, ASCLS-Michigan Annual Meeting, and the Collaborative Laboratory Conference, Columbus, Ohio. **Theresa Downs** served as AABB assessor for Transfusion Services; and presented invited lectures at the Current Topics in Blood Banking, ASCLS-Michigan Annual Meeting, Blood Bank Association of New York State, AABB Annual Meeting, and American Red Cross, Detroit. She also co-authored “Auditing in the Cellular Therapy Laboratory” and “Auditing in the Transfusion Service” digital downloads from the AABB. **Louann Dake** served as AABB Assessor for Immunohematology Reference Laboratories and on the AABB Immunohematology Reference Laboratory Standards Committee. She also present invited lectures at Current Topics in Blood Banking and the ASCLS-Michigan Annual Meeting. **Sheri Hagan** obtained her SBB certification and presented invited lectures at Current Topics in Blood Banking and the ASCLS-Michigan Annual Meeting. **Marsha Gott** obtained her certification as a certified quality auditor. **Sandra Hoffmann** served as AABB Assessor for Cellular Therapy and **Andrea Hickey** served as

Treasurer – ASCLS-Michigan.

Histocompatibility and Immunogenetics Laboratory



Dr. Daniel Ramon and the histocompatibility laboratory are very pleased to announce the full implementation of our HLA-specific laboratory information system, called HistoTrac. This system allows us to better manage our patient information and results, and enables us to coordinate with the KPD program, searching for new living donor candidates for our highly-sensitized patients. This tool will allow us to monitor our QA and QC parameters, sample storage and update our billing system. We completed the data migration from the old Oracle database on May 2012 and in the same month we partially went live for HLA typing, and as of June 2013, all our results are fully interfaced with Soft, the new laboratory-wide information system.

Recognition as one of the Platinum Level Sustainable Laboratories by the Office of Campus Sustainability gives us the impetus to reduce our paper consumption, saving \$17,000 per year and, most importantly, saving technologist time, improving our TAT by 5%.

The entire HLA team embarked on a large project to change the sample storage system from alphabetical order to a specific **Frezer N°/Box N°/ Lane and column** position, as dictated by HistoTrack software. This information is directly linked to the patient and sample information. The new system will represent a projected saving of more than \$21,000 per year in serum aliquoting, filing and retrieval time.

In FY13, we validated an in-house anti-HLA IgM antibody screening (Luminex) and are in the process of completing the EIA for quantitative determination of Anti-AT1R antibodies, increasing our panel of reactions to assist the transplant team in the diagnosis of Antibody Mediated Rejection.

Our Histocompatibility Laboratory Fellow start her second year and fellows from Blood Bank, Molecular Pathology and Nephrology, as well as Internal Medicine, are rotating in our lab throughout the year.

Molecular Diagnostics Laboratory

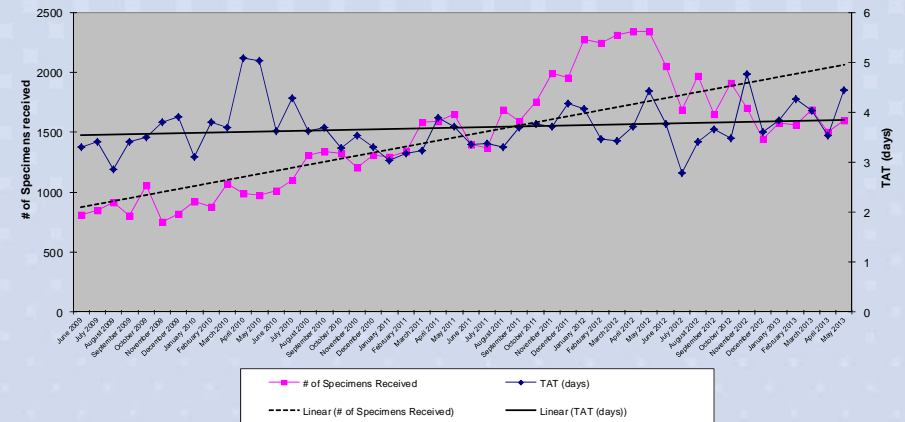


The Molecular Diagnostics laboratory is directed by **Dr. Kojo S. J. Elenitoba-Johnson**. Dr. Thomas Wilson is the Associate Director, and the laboratory's Technical Director is Dr. Bryan Betz.

This has been a very productive year for the laboratory. Due to the discontinuation of a critical reagent, no new tests were brought on-line as immediate redevelopment/re-validation of 7 existing tests was required. In addition three additional tests were updated due to the conversion to an FDA-approved version. Updated versions of all ten tests were implemented in time to avoid lapses in testing services. Two additional tests were converted to more efficient, comprehensive platforms. The laboratory currently has

Updated Tests
B-Cell Clonality (IGH gene rearrangement)
FLT3 mutation
JAK2 exon 12 mutation
MPL mutation
BRAF V600E/V600k mutation
EGFR mutation
UGT1A1 genotyping
Factor V Leiden mutation
Prothrombin 20210 mutation
MTHFR C677T mutation
Apolipoprotein E Genotyping by Allelic Discrimination
BCR-ABL quantitative test
In Development
EGFR mutation by sequencing
IGH/CCND1 t(11;14) translocation by FISH
ROS1 rearrangements by FISH
Bone marrow engraftment analysis test
UroVysion FISH for bile duct brushings
Multi-gene mutation testing by next generation sequencing

Molecular Diagnostics Laboratory
Specimens Received and TAT
June 2009 - May 2013



another six tests under development that are expected to be completed prior to June 2014, with yet another six tests in the planning stages.

Over the past year, the laboratory experienced a 7% decrease in specimen volume following two years of rapid growth (55% and 43% in FY 12 and 11) with a 3.8% increase in turn-around times. The laboratory processes specimens seven days/week with weekday service (8:00 am—8:30 pm) and weekend service (12:00 pm—8:30 pm). In addition, three new technologists were brought on board and a part-time technologist moved to full time.

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 conducts regular monthly Administrative Project Meetings, which include the director, technical director, attendings, 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.

Cytogenetics



Over the past fiscal year, the Cytogenetics Laboratory, led by Dr. Diane Roulston, experienced a decrease in sample volume for the first time in 5 years. A total of 4,323 tests were performed, representing a decrease of 6.2% overall. The decrease is attributed to fewer requests for oncology and prenatal chromosome analysis (karyotypes) and fewer constitutional fluorescence in situ hybridization (FISH) tests. (See appended Table.) New FISH and microarray testing is expected to add to

the test volume in the coming year. The laboratory Director is Diane Roulston, Ph.D., and the Assistant Director is Lina Shao, M.D., Ph.D. Thomas Glover, Ph.D. (Professor, Department of Human Genetics, Department of Pathology) continued to provide invaluable expertise and sign-out coverage, primarily for constitutional genetics cases.

Clinical

The total number of oncology and constitutional standard karyotype analyses was lower than the previous year in every

category except constitutional blood karyotypes, for an overall decrease of -10.3% (-317 cases). The bone marrow samples continued at the lower rate first noted in the middle of last year, for a decrease of -9.98% compared to last year (-207 cases). Solid tumor and lymphoma sample volumes were lower as well. For constitutional karyotypes, significant decreases in prenatal samples (amniocentesis and chorionic villus samples) were somewhat offset by the gain in constitutional blood samples. The sample volume for tissues (skin fibroblasts and products of conception) stayed the same. (See Table for details.) The impressive decrease in prenatal testing (-32.9%, -85 cases) is likely due to a change in referral patterns caused by the development of noninvasive prenatal screening of maternal blood samples for fetal aneuploidy.

The overall number of FISH tests increased slightly this year, for a total of 2.1% (+31 tests) over FY2012. The overall increase was due to significantly increased oncology FISH requests (+16.8%, +205), especially for FISH panels. Constitutional FISH testing decreased significantly, due to a change in the method of confirmation of constitutional microarray results: PCR-based

Sample Volumes in Clinical Cytogenetics Fiscal Year 2012-2013			
Sample Type	# of Tests	Increase (Decrease)	% Change
Bone Marrows	1,888	(207)	(9.98)
Tumor/Lymph Nodes	248	(55)	(18.2)
PB Constitutional	379	29	8.3
Prenatal: Amnios	90	(52)	(36.6)
Prenatal: CVS	83	-33	(28.4)
Tissues (POC)	104	(1)	0.97
Subtotal (Chroms)	2,772	(317)	(10.3)
Tissue Culture Only	10	0	0
Tissue Culture for AM, CT or TI	15	0	0
FISH			
Genetics	99	(174)	(63.7)
Oncology	1,268	145	12.9
Panels	159	60	60.2
Total FISH	1,526	31	2.1
Total Tests	4,323	-286	(6.2)

confirmation is now performed in the Pediatric Molecular Genetics Laboratory.

New oncology FISH tests that were validated included probe sets for chromosome abnormalities that have prognostic significance in multiple myeloma: two translocations that produce gene fusions (*IGH/FGFR3* and *IGH/MAF*), and deletion of 13q. Also validated was the probe set for the gene fusion *RPN1/MECOM* produced by inversion or translocation of chromosome 3 at those gene loci, which are associated with a poor prognosis in acute myeloid leukemia and myelodysplastic syndrome.

A type of FISH testing new to the lab that is in development is the use of formalin-fixed, paraffin-embedded slides for FISH analysis. In collaboration with Arul Chinnaiyan, M.D., Ph.D. and the Michigan Center for Translational Pathology (MCTP), the aim is to develop clinical FISH testing for prostate cancer and renal cell carcinoma, to detect chromosome rearrangements that aid in diagnosis and/or have known prognostic significance. Also, specific rearrangements may be indicators for targeted therapy. Under the direction of genitourinary pathologist Rohit Mehra, M.D., a technologist was recruited and began optimization of FISH probes. Thus far, conditions have been optimized for probe sets that will detect rearrangements of the *TFE3*, *TFEB*, *FGFR1*, and *PTEN* gene loci.

The microarray section of the laboratory was established this year under the direction of **Dr. Lina Shao**, with the acquisition of the Affymetrix CytoScan system for cancer microarray analysis, and a technologist was recruited to begin validations. Thus far, 40 hematologic malignancy samples and 8 pediatric solid tumor samples have been processed and analyzed for the assay validation. The microarray results will provide valuable diagnostic and prognostic information in solid tumors, especially when chromosome analysis fails. Also, important prognostic information and markers to follow response to therapy will be provided for most hematologic malignancies, which is especially useful for cases where traditional karyotypes are normal. The microarray assay is expected to eventually supplant multiple FISH panels that are more expensive and labor intensive.

With regard to staffing, the lab administrators replaced two departing technologists this past year, one of whom was accepted into a post-doctoral fellowship training program in Clinical Cytogenetics at the University of Chicago. **Nanci Lefebvre** was promoted to the position of Supervisor, and one technologist was promoted to Technologist II.

Other significant activities included participation in several department-wide

initiatives, including obtaining out-of-state licensures for the laboratory and directors, implementing a new document control system, preparation for the external CAP inspection, and extensive programming for the SCC/Soft LIS, followed by a successful "Go Live." A workshop for the hospital-based initiative, Service Excellence, was held and resulted in implementation of SE huddles on both shifts. As part of continuing efforts to address areas identified by the staff and the Employee Engagement survey, a facilitator conducted individual interviews of technologists, which were followed by workshops in Team Building and Diversity.

Education

Graduate students, residents and fellows from a wide range of specialties performed rotations in the laboratory last year. These included Genetic Counseling graduate students (6), Pathology residents (11), fellows from training programs in Molecular Genetics in Pathology (1), Hematopathology (2), and Pediatrics residents in Clinical Genetics (2). The residents and fellows presented brief talks on relevant topics in cytogenetics for the technologists, making a much-appreciated contribution to continuing education.

As part of the renewal process for the training programs in laboratory-related fields in Medical Genetics, the Clinical Cytogenetics Training Program post-doctoral fellowship was re-accredited, with renewal approved for 5 years.

The Clinical Pathology Symposium featured presentations by Cytogenetics Lab Administrator, **Beth Cox**, and Supervisor, **Nanci Lefebvre**, who gave a one hour joint presentation, "Topics in Cytogenetics." Many interesting cases from the laboratory archives were used to demonstrate cytogenetics concepts. Beth related the development of techniques in cytogenetics using illustrations from the early years of the lab. For regional meetings, two technologists attended the annual Great Lakes Chromosome Conference in Toronto for presentations on genomic microarrays.

Research

The laboratory continued to benchmark well in 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 and over 20 case studies were submitted. **Dr. Roulston** served on the Cytogenetics Committee for COG, was a moderator at the COG workshop, and served as chair of the SWOG Cytogenetics Committee. The laboratory also supported clinical trials of JAK2 kinase inhibitors, with Dr. Moshe Talpaz, PI. Two technol-

ogists assisted with FISH confirmation of microarray research results resulting in a publication in *Blood* (S. Malek, MD, PI).

Future Plans

Laboratory automation systems, such as slide scanners to locate metaphase cells, and FISH slide processors, are available and recommended as a way to further increase efficiency, so will be investigated in the coming year.



Our Combined Hematopathology Service Team—2012-2013

Back, L-to-R: Dr. Amir Behdad, Dr. Daniel Leino (Fellow), Dr. David Keren, Dr. Lloyd Stoolman, Dr. Bertram Schnitzer, Dr. Jason Cheng, Dr. Lauren Smith, Dr. Charles Ross, Dr. Andrew Shubeck (Fellow)

Front, L-to-R: Kelly Dotson, Dr. Megan Lim, Dr. Denise Sulavik, Dr. Joanne Vergilio, Pamela Warwashana, Dr. Nathanael Bailey



Kelly Dotson and Pamela Warwashana ably supported the Clinical Pathology Division in 2012-2013.

Division of Pathology Education

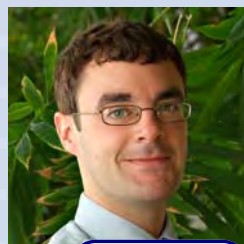
Barbara J. McKenna, M.D.
Endowed Professor of Pathology Education
Director, Division of Pathology Education



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. In addition, many pathology faculty play key roles in education in other clinical departments throughout the Medical Center, and in University departments outside of Medicine. Similarly, our trainees are part of the educational process for their more junior counterparts and for others in the health system. The ways in which we fulfill this core mission are constantly evolving and adapting to new circumstances and demands.

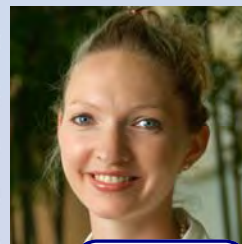
GRADUATE MEDICAL EDUCATION—PATHOLOGY RESIDENCY PROGRAM

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. The 2012-13 academic year was marked by significant achievements, as outlined below. The leadership and administrative team consists of the Program Director, Barbara J. McKenna, M.D., Associate Program Directors Scott Owens, M.D., Education Supervisor and Fellowship Coordinator



CHIEF RESIDENT

Randall Butler M.D.



ASST. CHIEF RESIDENT

Megan Alderman, M.D.

Marie Sassano, Residency Program Coordinator Pamela Howard, Medical Student Program Coordinator and Conference Coordinator Beverly Lange, and Academic Human Resources Manager Sarah Dudley-Short. The Residency Program GME Committee included Jonathan McHugh, M.D., David Keren, M.D., Nathaniel Bailey, M.D., David Lucas, M.D., Thomas Annesley, Ph.D., and the Chief and Assistant Chief Residents Randall Butler, M.D. and Megan Alderman, M.D.

Recruitment: We continue to recruit high caliber residents from a wide geographic region. All incoming first year residents for 2013-14 were highly ranked (top 20) by UM in the NRMP match. Their mean USMLE scores were Step 1: 240, and Step 2: 250, which are at the 82nd and 92nd percentiles nationally. This group hails from Michigan, Indiana, Missouri, Texas, and California.

Achievements: The current resident and fellow group, in addition to all of their clinical and educational activities, is academically productive and organizationally involved. They report 39 peer-reviewed publications, 37 abstract presentations at the meetings of 19 different national, international and regional medical meetings, service on 3 institutional and 15 national pathology and other medical organization committees, involvement in teaching M1 and M2 pathology laboratories, as well

Pathology Education

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

as interacting with all of the M4 elective students, and receipt of 10 awards from national and regional organizations. Three current residents are enrolled in or have completed the UM GME Scholars Program with emphasis on administrative skills.

Board results: 100% of the 27 residents who completed the residency since 2009 have passed their American Board of Pathology primary certification examinations on the first attempt. (One graduate has not taken the exam).

Practice settings of graduates: Of the 28 residents who completed residency since 2008 and are now in practice, 41% are in academic practices, 52% are in community/commercial practices, and 7% are working in the VA system.

The current residents have been critical to the maintenance of good patient care during the challenges of the new LIS implementation, doing much more than their usual tasks, and staying much later than ever before.

Graduate Medical Education—Fellowship Programs

The fellowship training opportunities have grown dramatically. With the approval of the Forensic Pathology fellowship, and the addition of approved positions in Molecular Genetic Pathology, there are now 8 ACGME-approved fellowships offering 15 approved positions, and 9 additional subspecialty training programs offering 11 positions. Interest in these fellowships has grown steadily, with increasing numbers of applications each year. Our fellowship banner and links on Pathology Outlines receive between 400 and 600 hits per month, generating traffic to our own department website, and reflecting the interest in our programs.

A Fellow Selection Committee has been convened that has successfully standardized the fellow candidate application, interview, and offer timeline in a way that should insure that the best possible candidates are chosen for our fellowships.

A number of fellows have contributed to the total of publications and abstracts cited above.

Medical Student Teaching

M1 and M2 Teaching

The Department has a long history of playing an integral role in pre-clinical medical student education. We have a unique presence in the M1 year,

starting with the first sequence, titled Patients and Populations, introducing pathology concepts and terminology. This is reinforced by additional lectures and laboratory sessions in the winter and spring of the M1 year. The M1 Histopathology course has been led by two celebrated pathology faculty, **Drs. Gerald Abrams** and **Stephen Ramsburgh**. Both have retired and assured the smooth transition to new direction by **Drs. Michael Roh** and **Scott Owens**, both of whom consider Medical Education a key part of their career development. The M2 systems-based curriculum includes specialty-specific pathology faculty in the planning of each sequence, with **Dr. Paul Killen** providing oversight throughout the year. Lectures and laboratories are conducted by many pathology faculty members, often in sequences related to their areas of interest, although not exclusively. In the 2013-14 academic year, pathology members teaching the laboratories will be organized into teams, one assigned to each laboratory section. Altogether, there are 35 faculty members involved in conducting 41 lectures and 124 laboratory sessions each year for M1 and M2 students. Medical student evaluations of pathology faculty teaching remain high, as they have been for many years, with mean scores for expectations, organization, effectiveness, feedback, and responsiveness ranging from 4.23 to 4.41 (on a scale of 5, 5 being the most positive).

Starting in the 2012-13 academic year, the Transfusion Medicine faculty and fellow have offered a clinical elective for M2 students intended to provide them with an introductory Transfusion Medicine experience. While the experience will be of benefit for students entering many specialties of medicine, the elective will also expose the students to the practice of pathology and has the secondary objective as a recruiting tool for potential residents. The elective is offered in October, for three 2-hour sessions open to 2 to 4 student. Topics covered include pre-transfusion testing, selection of appropriate blood components, antibody identification, evaluation of transfusion reactions, and evaluation of apheresis patients. The student evaluations for 2012 were good to excellent. The elective will be offered again in 2013. **Dr. Robertson Davenport** oversees the elective, and the Transfusion Medicine Fellow takes an active role.

M4 Pathology Elective Rotation

In recent years, the caliber of the M4 Pathology Elective experience has dramatically improved, under the direction of **Dr. Jonathan McHugh**. Students electing this experience gain exposure to many areas of Anatomic and Clinical Pathology, with required tours and observation. They select cases for presentation at daily meetings, and must either make a formal

case presentation to the department or write a paper of similar depth to successfully complete the elective. In the past academic year, 66 senior medical students (40% of the graduating class) rotated in Pathology, with 50 making a formal presentation to the department, 16 submitting papers, and 44 of them earning a grade of Honors.

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 25 students who are presently in Pathology Department laboratories performing their Ph.D. thesis research. This past year, 7 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 2013 class for the Program in Biological Sciences (PIBS) and successfully recruited 6 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 theses 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 has been 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. Last year's keynote speaker was **Dr. Jeffery Kelly** from The Scripps Research Institute, known expert in the field of protein folding. During the symposium, they also organize a poster session that this past year had 33 posters from laboratories in the Pathology Department. This event has become a true success and highlights the students' enthusiasm, collegiality, and passion for research.



NICK LUKACS, PH.D.

Director, MCP Grad. Program

ZANETA NIKOLOVSKA-COLESKA, PH.D.

Incoming Director, MCP Grad. Program

Last year, through collaboration between **Drs. Thomas Wilson, Barbara McKenna and Zaneta Nikolovska Coleska**, a new course named Translational Pathology (Transl Path 862) was established which, for the first time, will start to be offered in the fall semester 2013. Translational Pathology is a graduate-level course designed to bridge the gap between basic science and clinical practice. The uniqueness of this course is the integrated experience involving both graduate students and clinical residents/fellows with training in the state-of-the-art techniques and principles in molecular medicine and applying those advances into clinically useful interventions to improve human disease outcomes. An additional new initiative is developing a Training grant in translational medicine as part of the MCP graduate program. The major focus of this training grant will be to educate and train a new cadre of biomedical PhD scientists to work at the interface of basic and clinical research. The Department of Pathology, along with others at Michigan, has significant strength in molecular medicine and is well poised to train the next generation of basic and translational scientists.

Finally, effective July 1, 2013, **Dr. Zaneta Nikolovska-Coleska** will be appointed as the new Director of the Molecular and Cellular Graduate Program. We would like to thank **Dr. Nicholas Lukacs** for his 8 years of generous and dedicated service and wish him success in his new position as the Associate Director of the Michigan Institute for Clinical and Health Research (MICHR), as he works to advance and bridge the basic and translational research programs.

We look forward to another productive and outstanding year for our graduate MCP Program.

PATHOLOGY EDUCATION SERIES

A vibrant and varied morning Pathology Educational Series takes place most mornings at 8 am, from September through mid-June. In 2012-13 there were 185 conferences, each offering CME credit. 24 were presented by faculty invited from other departments, 4 by visiting professors, 46 by residents, 6 by fellows, and the remaining 105 by departmental faculty.

The morning conference series may be the one venue that most often draws together residents, fellows, AP faculty and CP faculty.

Plans are being made to offer a course on translational pathology research in the morning conference series, bringing graduate students and residents together to share experiences.

2012-2013 PATHOLOGY RESIDENTS AND FELLOWS



Randall Butler, MD
HO IV
CHIEF RESIDENT



Megan Alderman, MD
HO III
ASSISTANT CHIEF RESIDENT



Noah Brown, MD
HO IV



Amanda Fisher-Hubbard, MD
HO IV



Alero Inyang, MD
HO IV



Maria Pietneva, MD, PhD
HO IV



Laura Walters, MD, PhD
HO IV



University of Michigan
Department of Pathology



David Arpa, MD
HO III



Karen Choi, MD
HO III



Shih-Hon LJ, MD, PhD
HO III



Andrew McDaniel, MD, PhD
HO III



Steven Smith, MD, PhD
HO III



Jennifer Stall, MD
HO III



Ted Brown, MD
HOII



Stephanie Chen, MD
HOII



Charles Harmon, MD
HOII



Carolyn Haus, MD
HOII



Jennifer Hipp, MD, PhD
HOII



Marlin Ishikawa, MD
HOII



Nilam Virani, MD
HOII



Kristina Davis, MD
HOI



Andrew Hanosh, MD
HOI



Carlos Murga, MD
HOI



David Seward, MD, PhD
HOI



Nathan Shaller, MD
HOI



Jiaqi Shi, MD, PhD
HOI/PHI



Reena Singh, MD
HOI



Aaron Udager, MD, PhD
HOI



Amir Behdad, MD
FELLOW
HEMATOPATHOLOGY



Monisha Dandekar, MD
FELLOW
DERMATOPATHOLOGY



Matthew Elkins, MD, PhD
FELLOW
BLOOD BANK



Larissa Furtado, MD
FELLOW
MOP PATHOLOGY



Thomas Hocker, MD
FELLOW
DERMATOPATHOLOGY



Beatrice Lee, MD
FELLOW
CYTOPATHOLOGY



Daniel Leino, MD
FELLOW
HEMATOPATHOLOGY



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



Suntra 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



The 2012-2013 academic year was an exceptionally busy period for the Pathology Informatics Division, with it accomplishing a number of major projects in tandem with its decade-long initiative of transitioning the department-at-large from the prior legacy Cerner-Pathnet laboratory information system to the newer SCC-Soft SoftLab modular lab information system. This effort, in particular, was noteworthy as it occurred in tandem with an enterprise-wide initiative to significantly upgrade the University of Michigan EPIC implementation (MiChart), on the June 1st - June 2nd weekend. In addition to the implementation of the new laboratory information system, there were a number of significant information technology efforts, all geared at either enhanced departmental IT productivity or at supporting the replacement of legacy-era infrastructure much in need of updating. The following synopsis reflects an overview of the most significant projects accomplished over this last period, with the SoftLab project being highlighted as the primary initiative (reflecting the fact that in terms of sheer number of hours expended, the LIS project consumed the far majority of available technical and consultative resources).

LABORATORY INFORMATION SYSTEM UPGRADE (SCC Soft Computer):

Activation of the new laboratory information system represented the culmination of a generational effort (recognizing that the first efforts to replace the LIS originally commenced in 1998) to replace an aging and functionally incomplete legacy

lab information system with a thoroughly-modern and architecturally rich new solution. Many aspects of the SCC- Soft solution, recognizing its relative newness and immaturity in the overall clinical LIS market, were actually optimized and tuned using the University of Michigan collective laboratories as the “first-light” test bed. This type of optimization and customization activity may be viewed as a two edged sword, in that it both affords precise customization and local unique workflow specialization, but similarly imparts challenges intrinsic to activating software which does not benefit from being informed by prior operational experience. Specifically with this latter observation, there were expected to be a number of operational deficits with the new software, and indeed there were a number of “first-light” activation defects on June 1st. Fortunately, the department has been very efficient with respect to having responded appropriately to such defects since that time. Notwithstanding this operational limitation, overall, the activation and deployment still can be considered as an overwhelming success in that the department was able to fully transition to use of the new workflow on the SCC-SoftLab platform without the concurrent use of the former legacy system.

Overall, given the significant magnitude and complexity of the SCC-SoftLab rollout, it is most appropriate to highlight the major accomplishments in two high level categories: Intrinsic and Extrinsic functional areas. Intrinsic functional areas are those areas representing workflow unique to the Department of Pathology and pathology-related process workflow. Extrinsic

Pathology Informatics

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

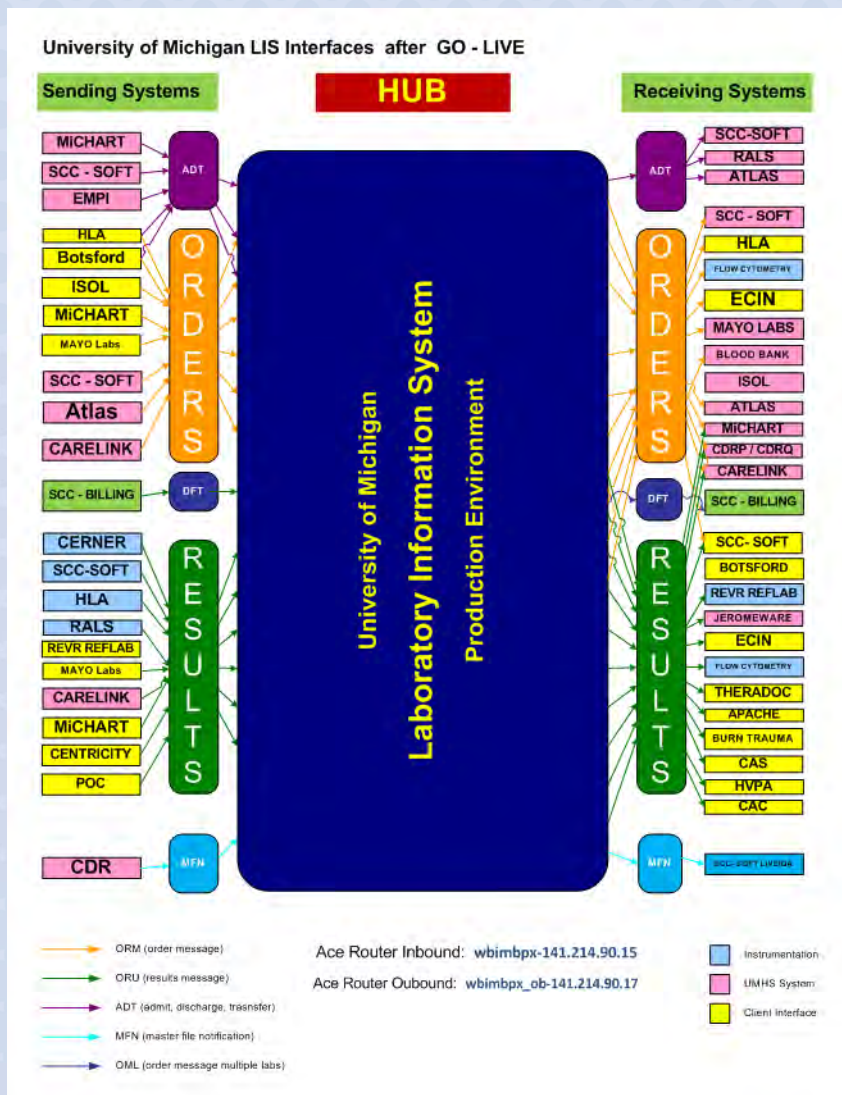
being areas of electronic data interconnectivity with the health enterprise's electronic environment at large. For the latter category, complexity of these efforts was made all the more acute and demanding in their implementation, in that the required due date for both validation and ultimate implementation of major hospital IT initiatives fell on the same date as that of the LIS deployment, doubly-challenging the Informatics Division to deliver on both fronts simultaneously.

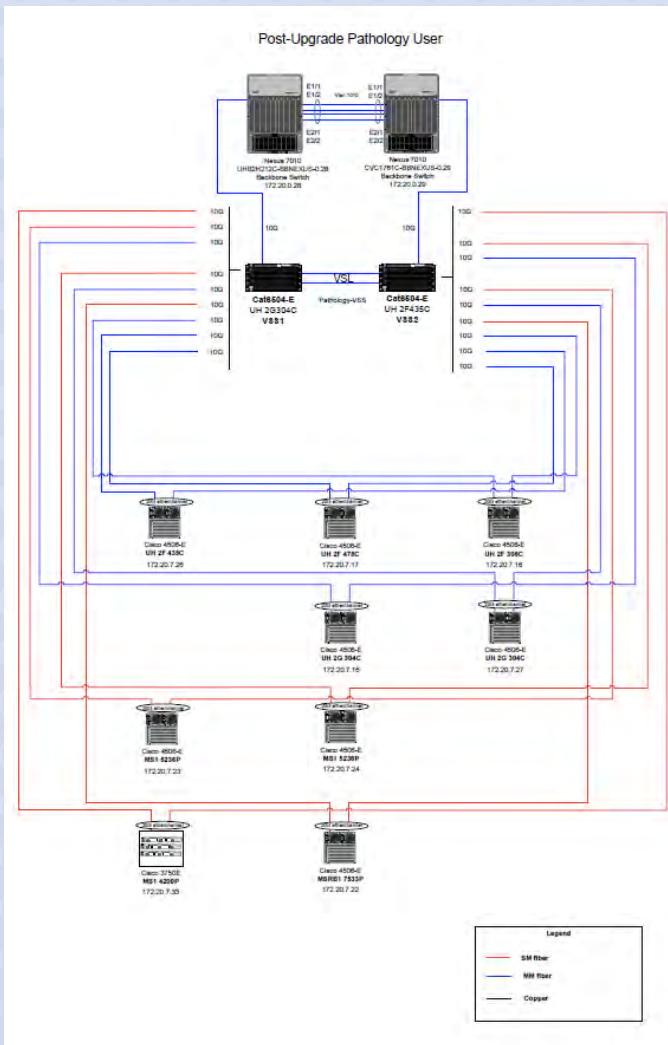
Intrinsic Informatics Implementation Projects

- ◆ Implementation of Core laboratory information system modules within SCC-Soft included the General Lab, Blood Bank, Microbiology, Anatomic Pathology, Flow Cytometry, Cytogenetics, Molecular Pathology, Soft-ID Positive Patient Identification, SoftMedia, Pediatric Molecular Genetics Lab.
- ◆ System interfaces were developed to Paradigm clinical testing and MLabs general internal workflow data pipelines.
- ◆ Deployment of major new hardware infrastructure elements for Anatomic Pathology workflow (scanners, printers, and peripheral display devices), as well as incremental workflow hardware for all laboratory areas is ongoing.
- ◆ Conversion of AP and Gene areas from manual paper-based order entry to electronic order entry for both inpatient and outpatient UMHS settings was completed.
- ◆ Electronic interfacing was completed for orders and results for MiChart (EPIC Denali), CareLink (All Scripps Eclipses), Mayo Medical Laboratories, Botsford Hospital, Histotrak-HLA workflow application, and MLabs intramural application as well as results interfacing for the intramural UMHS CareWeb application, and of ADT results to the intramural pathology informatics-developed EMPI enterprise application.
- ◆ Electronic interface of Soft-lab to the extant portfolio of advanced integrated reporting for advanced molecular diagnostics multimedia reporting (BCR/ABL integrated report test formats, etc.) was completed.
- ◆ Pre-activation validation was undertaken for all incremental SCC-Soft workflow models and application extensions prior to go-live application date of June 1st.

Extrinsic Pathology Informatics Projects

(Activities beyond that of laboratory information system deployment/optimization) included: Bi-directional electronic interface design and deployment of SCC-Soft to the GE-Centricity application and the Theradoc application environment; the interface of SCC-Soft to the CAS application, the burn trauma clinical information environment, and to HPVA, at the enterprise level; and the design and implementation of SCC-Soft multiple

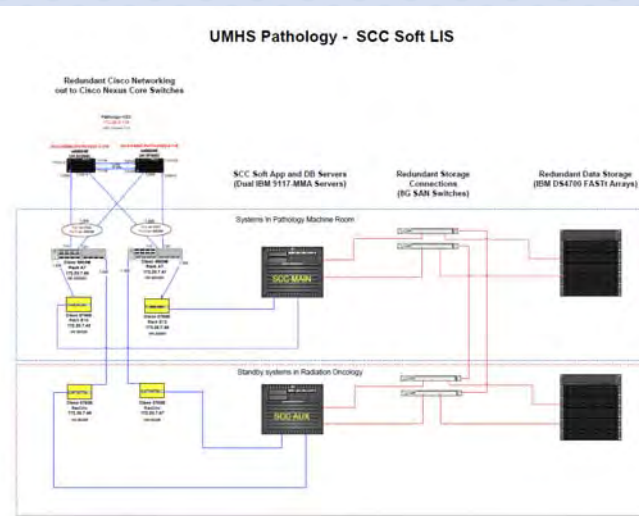




interfaces to JVHL, the clinical Apache application layer and to the Athena electronic environment.

ACADEMIC AND EDUCATIONAL ACTIVITIES:

Over the preceding year, the division has been active in continuing its three primary investigative thrusts of a) whole slide imaging machine vision optimization, b) natural language processing and knowledge management and c) continued collaborative development of subspecialty boards for the overall field of Pathology Informatics. Towards this third development, which represents a watershed event in the brief history of pathology



Fault-tolerant technology used throughout Pathology Informatics: By use of dual network fabrics, single points of failure are eliminated as a source of interruptions in service. At present, all clinical systems in Pathology Informatics make use of the dual-fabric construct.

informatics as a professional pursuit, efforts of the division with the American Board of Pathology and American Board of Preventative medicine have been extremely productive. Collectively, the four active pathology informatics fellowships have been successful over the two preceding years in shaping the upcoming clinical informatics board examination such that pathology informatics is appropriately covered, in terms of subject matter. A key enabler for identifying and sharing this content has been the collective curricula of the four active fellowships (including U-M) such that relevant and contemporary material is appropriately covered in the examination. At present, the first pool of candidates is scheduled to sit for these new clinical informatics subspecialty boards in October of 2013, with the University of Michigan being one of the three major contributing academic centers for pathology content.

Along the digital imaging front, continued investigation and optimization of the SIVQ algorithm continues, with the exciting development that the fellowship program's immediate past fellow, Dr. Jason Hipp, is now using SIVQ as the basis for a new clinical core laboratory at the National Cancer Institute. The service goal of this new core is the offering of automated laser capture micro-dissection services for biopsies with rarefied tumor components, thus allowing for up to 10^5 enrichment. SIVQ serves as the computational backbone allowing for this extreme degree of automation.

A highlight of the natural language parsing efforts is a new computational engine, based upon a systolic array architecture that will allow for automated cancer case extraction from routine surgical pathology reports. Such an approach will increase the overall case capture efficiency and at the same time, do so with enhanced timeliness (a chronic challenge for prior, manual review-based case examination). Should subsequent validation efforts be successful, the current plan is to offer this solution as an open source toolkit (realizing an unmet need) for other sites that have sim-

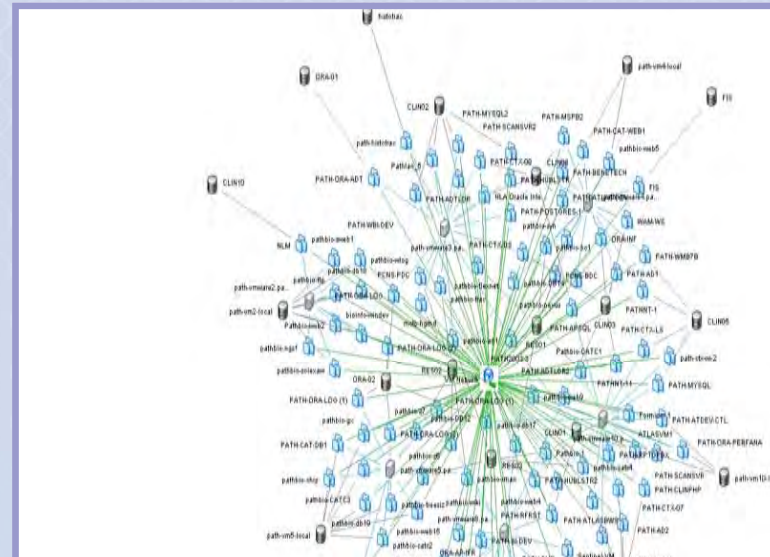
ilar case identification and reporting obligations.

Finally, over the preceding year, the division has been active in further expanding its collaborative activities with Sony Corporation, and specifically, the newly organized health products division. At present, Sony is preparing to enter the field of digital pathology as a major competitor and is investigating the use of U-M as a major academic partner. Technologies under development include both high performance whole slide scanners and viewers, along with sophisticated cased management software.

APPENDIX A. Large and Mid-sized Implementation Projects

1. Deployment of IBM Websphere version 8.0
2. Conversion to interface type tree version 2.5 (enterprise level)
3. Implementation of MiChart outpatient capabilities version 2010 (Denali) in August of 2012
4. Implementation of an entirely new layer of vmWare hardware support (blade centers) thus replacing legacy vmWare infrastructure
5. Implementation of Internet Explorer 8 across 1500 department-sponsored personal computers
6. CHCB interface development and implementation
7. Design and implementation of a major EMPI upgrade including intramural web services and functional process monitoring
8. Redesign and code rewrite of significant aspects of billing support for intramural charge master monitoring
9. Preparation and implementation of initial stages of Windows 7 rollout, in partnership with enterprise wide efforts
10. Implementation of the Glance™ solution in support of frozen section workflow and strategic frozen section diagnostic areas of anatomic pathology
11. Upgrade of core content management system web code
12. Upgrade of the educational Camtasia infrastructure server workflow and back end server architecture
13. Implementation and further upgrade of web-based infrastructure supporting the AP Forensics conference an New Frontiers Surgical Pathology conference

14. Upgraded implementation of workflow solutions and data representation needs of the intramural human resources tracking and documentation system (specifically upgrades for offer letter documentation)
15. Implementation of enhanced HL7 log viewer capability via web services
16. Implementation of change control capabilities via departmental website
17. Implementation of web-based online document management system (Master Control) for policies and procedures.
18. Transition of MLabs website hosting to a third party commercial service provider with seamless interconnections back to the core department parental website
19. Implementation of federated architecture and link structures between the core departmental web pages and the third party hosting service
20. Continued stewardship of all existing departmental operational services in tandem with ongoing extramural and intramural development initiatives, as enumerated above.



vmWare Resource Topology – Real time map: Advanced monitoring and disaster recovery tools made possible by virtualization technology such as vmWare allow the division to deliver services with higher overall availability.

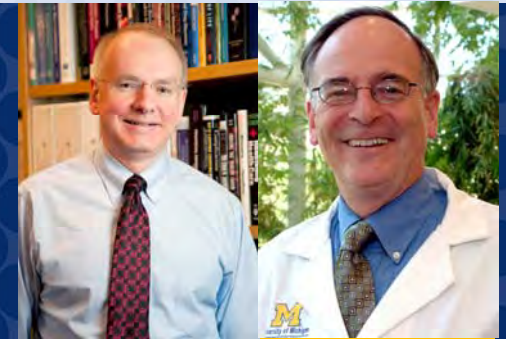
Division of Sponsored Research

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



This has been another productive year for research within the department. We have continued the departmental strategy of focused investment in research in key thematic areas including biomarker discovery, inflammation, epigenetics, proteomics, drug discovery and aging. Over the past year, the faculty published a wide range of papers in high-impact journals such as *Cell*, *Cell Stem Cell*, *Journal of Experimental Medicine*, *Molecular Cell*, *Nature*, *Nature Methods* and *PNAS*.

While this section focuses on the Division of Sponsored Research, this is a somewhat artificial compartmentalization of our research efforts. Almost all our faculty, regardless of Division, carry out or contribute to research advances and we make funding available to support such efforts. While many of our faculty members focus primarily on research, we also have a high proportion of faculty who are physician-scientists in addition to our clinical faculty who make important contributions in more translational areas of research. The Department provides a diverse range of funding mechanisms to support such research. For example, the AP Division continues to provide an intramural funding mechanism based on peer review and up to \$150,000 annually for projects. As an example of this breadth of research, faculty in the Division of Anatomic Pathology published over 200 peer-reviewed publications in FY13, with nearly 110 abstracts presented at national and international meetings, over 130 invited lectures and visiting professorships, and representation on over 30 editorial

boards. Of note, the University of Michigan was among the top ten departments in the country at the USCAP meeting for the number of abstracts submitted.

The Michigan Center for Translational Pathology's MI-ONCOSEQ continued to identify molecular drivers and potential therapeutic targets in human cancers. Based on its track record of success, the Center, led by **Dr. Arul Chinnaiyan**, was recently awarded a multimillion-dollar U01 award for the sequencing of pediatric tumors.

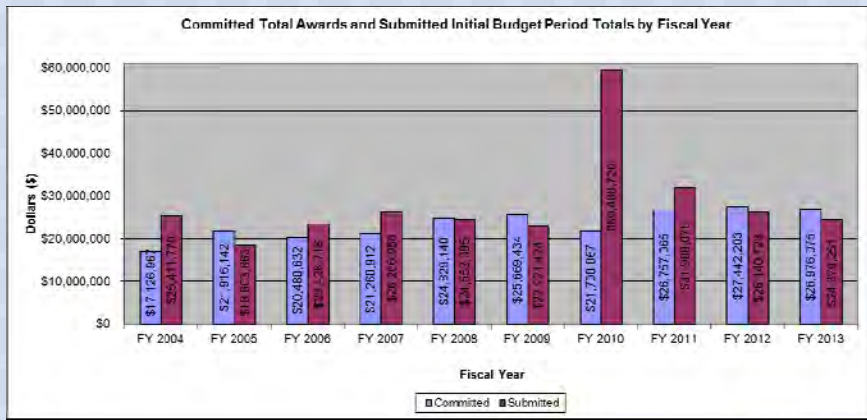
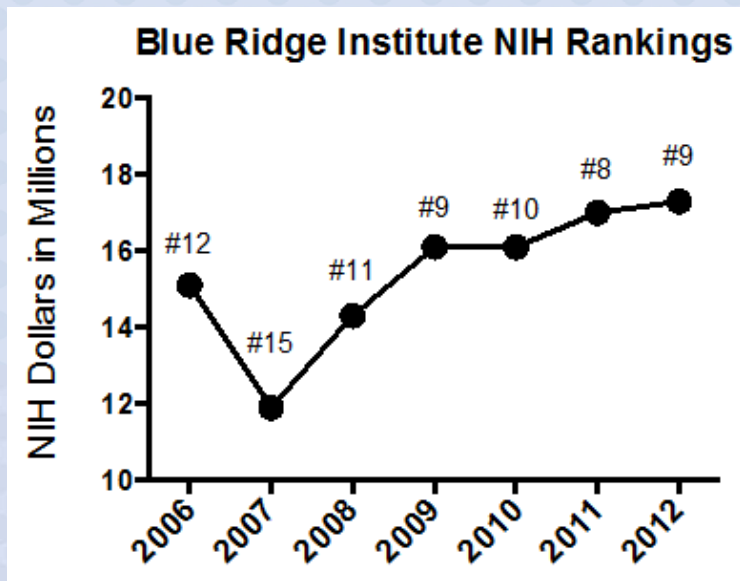
Despite a challenging research funding environment, the past 8 years, during **Dr. Hess'** tenure as Chair, the Departmental Government, Pharmaceutical, and Foundation funding has grown to over \$30 million, a more than 40% increase (**Fig. 1**). As a key indicator of departmental productivity, the Indirect Cost (IDC)/sq. ft. of the >55,000 sq. ft. of research space is presently \$131/sq. ft., which is well above the University of Michigan Medical School benchmark of \$110/sq. ft. The strength and sustainability of the Department's research programs is further demonstrated by the Department's mid year NIH funding, which ranks 5th among Pathology departments nationwide.

The Department played a particularly important role in research at the Medical School level this year. **Dr. Steven Kunkel**, Professor of Pathology and Senior Associate Dean for Research, led the FastForward initiative, the goal of which was to

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**

make informed decisions about how to invest \$100 million in Medical School resources to accelerate research and clinical translation at Michigan. This entailed getting widespread faculty input and creating a Research Board of Directors (RBOD) comprised of Department Chairs and Center Directors. **Dr. Hess** served in an important capacity on the RBOD Executive Committee in addition to his role on the Board. Medical School financial challenges resulted in decreasing the level of funding for this initial year of the FastForward initiative, however, ultimately two research themes, the Microbiome and Protein Folding were selected, the latter co-chaired by Dr. Andrew Lieberman of the department. In addition, the RBOD also approved funding for an Epigenetics Core, which will be under the direction of **Dr. Maria Figueroa**, Assistant Professor of Pathology.



The Department of Pathology has seen consistent improvement in its NIH rankings over the past several years, with early 2013 numbers showing the Department in the Top 5 Pathology Departments in the United States.

July 29, 2013 NIH Rankings: Pathology	
Rank	NIH Institution
1	University of Pennsylvania
2	Emory University
3	University of Washington
4	Columbia University Medical Center
5	University of Michigan at Ann Arbor

IDC as of 06/30/2013 **\$131/sq ft**
Benchmark **\$110/sq ft**

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 is charged with the responsibility of establishing core infrastructure to facilitate patient-oriented and disease-related research. Hence the long-term plans for the Division include the implementation of key qualitative and quantitative core research tools such as mass spectrometry, microarrays, and multiparameter single-cell flow cytometry. The Division also includes the Mass Spectrometry-Driven Proteomics Laboratory, the Tissue Procurement Laboratory and Molecular Pathology Research Laboratory led by Drs. Thomas Giordano and Dafydd Thomas and the Analytical Flow Cytometry Laboratory led by Dr. Lloyd Stoolman. The activities in all of these laboratories show steady increase in volume, without attendant incremental changes in personnel. Laboratory services are subsidized by the department but charge-back mechanisms are in place to defray costs incurred by the facilities. These core infrastructures have a critical role in the scholastic productivity of the basic, translational and clinical faculty and have established merit campus-wide and with external clients.



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, etc.

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 differential-

Translational Pathology

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

ly expressed proteins. To perform 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.

In FY13, the PRF provided services to 38 Principal Investigators, both internal and external to the University of Michigan. Ten manuscripts have been accepted or published in peer-reviewed journals with the proteomic data generated at the PRF, and one patent was filed, entitled "Compositions and Methods Relating to Fusion Protein Biomarkers".

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 45 undergraduates, graduate students, post-docs, research associates and principal investigators from 17 laboratories used this instrument in FY13 for a total of 2,550 hours: 2,305 hours of Departmental use, 78 hours of non-departmental use, which was recharged, and 106 hours of downtime for service maintenance. Based on the University of Michigan Cancer Center Core rates, the departmental subsidy of this activity saved users over \$138,300. Users report that this Core contributed to 20 publications in peer reviewed journals, 9 abstracts and a minimum of 31 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, 5,00 slides were scanned, a year-over-year increase of 7%, 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 servers currently have ~12 terabytes of online storage that contain ~18,000 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.
 - **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.
 - **University of Michigan Department of Pathology Slide Box, Open University** This new initiative provides a new, user-friendly web access from any device (including iPad) for a growing collection of anatomic pathology virtual slides with ~1,000 slides currently available. This tool allows users to search by collection, organ, diagnosis, or to hide/show diagnosis for self-testing, or select a slide-by-slide viewing option for comparison of multiple cases. Patient identifiers are stripped so trainees can view them on the World-Wide-Web without constraint.
- Investigators report that this Core contributed to 15 peer-reviewed publications, 5 abstracts, and 6 NIH grants (active).
- **The Virtual Microscope Teaching Project** The Core continues to support this project, which 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+ on-campus and off-campus users.

ONLINE BIOREPOSITORY



Under the guidance of **Drs. Lloyd Stoolman and Megan Lim**, 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 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 Hematopathology Tissue Procurement Service is led by Dr. Megan Lim, M.D., Ph.D. and supported by Farah Keyoumarsi. The TPR archives discarded clinical samples from the flow cytometry laboratory and the gross room. There are approximately 850 snap frozen tissue specimens composed of both reactive and neoplastic hematopoietic conditions.

Samples from the flow cytometry laboratory are also stored in a repository that consists of more than 10500 cryopreserved specimens. These specimens are searchable by diagnosis. A repository of formalin fixed tissue microarrays of over 2000 lymphoma blocks is currently maintained in the TPR. Two publications and six abstracts were published utilizing tissue specimens from the TPR in FY13.

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.



This year has been the first year that the MPRL and the Cancer Center histology core have worked as a single organization. The MPRL has been working on expanding our technical abilities in FISH studies

and in implementing image analysis. The MRPL initiated several projects during the last academic year, as outlined below. The services provided include the following: tissue embedding and frozen sectioning (in part through the UMCCC Tissue Core), DNA extraction, RNA extraction, protein extraction, PCR, quantitative RT-PCR, DNA microarray analysis thru the UMCCC Microarray Core, DNA sequencing through the UM DNA Sequencing Core, western blots, *in situ* hybridization, chromogenic and Fluorescence *in situ* hybridization (CISH/FISH), quantitative *in situ* antigen detection (via AQUA analysis), tissue array construction, and immunohistochemistry.

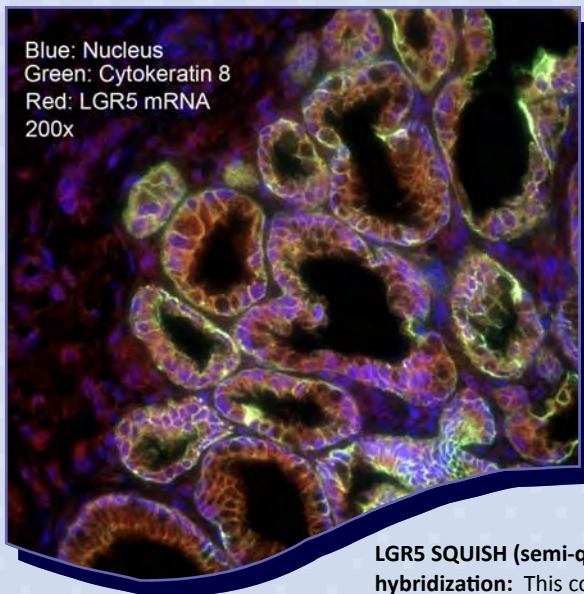
Since the last annual report, the MPRL has been involved in supporting efforts for 9 manuscripts published in high-impact journals, 12 abstracts presented at the Annual Connective Tissue Society, United States and Canadian Academy of Pathology, American Association for Cancer Research, and the American Society for Clinical Oncology annual meetings. The faculty of the MPRL also served on the SPP Research Committee, reviewing abstracts for the fall and spring meetings of the SPP as well as serving as *ad hoc* reviewers for several journals.

Most of the projects in FY 13, as in prior years, involved the construction of tissue microarrays followed by immunohistochemistry. The MPRL is intimately involved in offering high-quality, rapid immunohistochemical staining as an adjunct to sarcoma clinical trials, in addition to supporting all the SPORE programs at the University.

As noted last 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, Dr. Jeffrey Myers, Director of Anatomic Pathology, approved the purchase of an upgraded 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 have subsequently shown that we can perform AQUA-style quantitative ISH. The expectation of the MPRL is that these types of sophisticated assays will become the norm, rather than the exception, over the next few years. In anticipation of this, the MPRL will upgrade our software capability to offer image analysis.

The main research interest has been the use of the AQUA platform to identify stem cells in breast cancer resection and to correlate their expression with distant temporal metastasis. We have been working to define an AQUA signature to intrinsically subtype breast cancer specimens, which will have a profound impact on breast cancer management, enabling oncologists to stratify their patients into groups which should or should not be offered adjuvant chemotherapy.



LGR5 SQUISH (semi-quantitative *in-situ* hybridization): This colon portion was stained using a combination *in-situ* hybridization/immunohistochemistry technique for analysis using the MPRL's AQUA facility

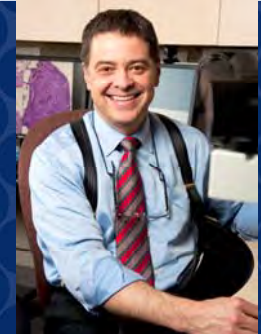
Project	Status
PCR project involving viral causes of placental infection. RNA and DNA were extracted from placental samples with chronic villitis and RT-PCR performed for a variety of viral pathogens.	Ongoing
EWS Project: Novel Chr 4:19 translocation. Cases identified. FISH probes ordered and first round of FISH completed. RT-PCR performed and demonstrated no evidence of classic EWS translocation in index cases. DUX4;CIC PCR was positive.	Ongoing. Manuscript accepted in the Am. J Surg Path.
Performed multiple immunohistochemical stains	Ongoing. Results presented at USCAP Manuscript published
In situ hybridization probe for Fbxo45 prepared.	Ongoing
Sequencing of Telomerase gene promoter 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.	Ongoing
Spindle cell carcinoma TMA constructed. Immunohistochemical stains performed	Ongoing
FISH analysis of brain lymphoma TMA underway.	Ongoing
IHC analysis of gliomas	Ongoing
Extraction of DNA, PCR for CYP SNP and sequence analysis.	Correlation to suspected drug overdoses found.
IHC for mouse WT-1 as a means for identifying glomeruli defects.	Ongoing



MLabs Outreach Program

Jeffrey L Myers, M.D.

A. James French Professor of Pathology
 Director, Division of Anatomic Pathology
 Director, MLabs Outreach Program



MLabs serves as a portal to ensure that those from outside of the University of Michigan Health System have easy access to the expertise and sophisticated testing of the Department of Pathology faculty, staff and laboratories. As we celebrate our 28th anniversary in the reference laboratory business, we have become recognized as a leader for advanced diagnostic testing, helpful consultations and exceptional customer service. We remain focused on our core mission – ‘to deliver the highest quality laboratory results to meet the needs of today’s patients in a cost effective manner’. MLabs understands that providing the right result, to the right patient for the right reason is fundamental to our continued success. Doing so in an environment with steadily decreasing reimbursement is our challenge.

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 subspecialty referral hospitals, 3 national reference labs, 4 extended nursing care facilities along and 100 + ‘other’ miscellaneous clients. Servicing the needs of this diverse mix of clients is a MLabs team of dedicated professionals along with

the combined effort of the Department of Pathology’s faculty and staff.

MLabs continues to experience consistent growth. Working together, the MLabs team acquired 30 + new clients during FY13, representing primarily new AP consultation business with growth potential for molecular diagnostics referral testing. We anticipate sales and marketing effort third and

fourth quarter FY13 will be demonstrated early FY14. Implementation of a new laboratory information system (SOFT) in June 2013 has delayed availability for complete data set for the month of June; therefore FY13 * total is lower than actual (Fig 1).

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 specialize services and surgical pathology consultations is national.

MLabs categorizes its business into 6 Market Segments.

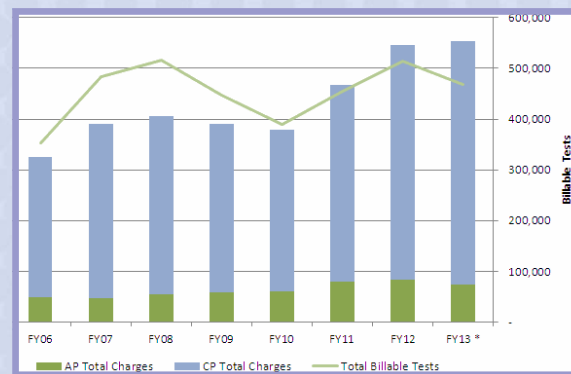


Figure 1: MLabs Total Gross Charges (Professional and Technical) Trend FY06-FY13*

MLabs Outreach Programs Serving

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

Physician Office – all Specialties

Hospital – both full service and those sending specialized testing

Reverse Reference Laboratories – commercial/independent labs

Consultations (AP and Hematopathology)

Nursing Home – extended nursing and acute care facilities

Other – Miscellaneous ‘catch all’ category (8999 REFR)

The majority of MLabs Gross Charges are CP (Technical) Charges. While data for FY13 is incomplete, MLabs’ estimated billable tests FY13 CP charges are 467,500 compared to 48,300 billable professional charges. **Figure 3** shows % of professional charges by market segment. Interesting to note that the majority of the 42% attributed to physician office market represents MLabs’ professional fee billing on specimens received from dermatology physician offices. Consultations, a targeted area for sales and marketing, continue to increase year over year.

MLabs Physician Office Market will continue to grow organically but sales and marketing effort is needed to acquire new Hospital full Reference Laboratory clients. The area of most potential continues to be the Reverse Reference Lab.

Physician Office Market Segment (35% of Total Gross Charges)

MLabs provides laboratory testing to over 125 individual offices in the greater Washtenaw county service area. Majority of this testing is sent to MLabs by two primary care provider groups in this region, Integrated Health Associates (IHA) and Allied Primary Care (HVPA). MLabs is interfaced with the IHA practices (electronic orders in and results out) and the rewards from that bi-directional interface are evidenced by the sustained/increased volume of referral testing from the IHA practices. During FY13, MLabs successfully completed another interface project with one of the largest HVPA practices, Partners in Internal Medicine. Again, volume increase demonstrates a return on our interface and informatics investment. Many HVPA physician offices are in the queue for result interfaces to their EMRs. We remain challenged in our ability to respond expeditiously to these interface requests. The dermatology offices contribute significantly and remain our biggest opportunity for growth in the physician office market. FY13 experienced a slight decrease in total gross charges from our dermatology clients primarily as a result of reorganization within the Grand

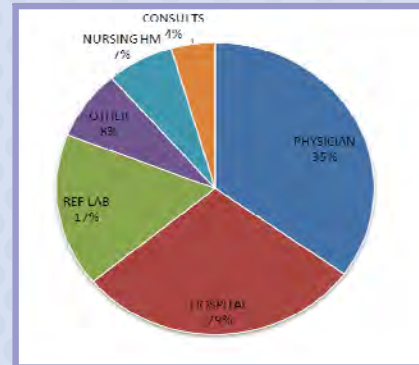


Figure 2: MLabs AP (Professional) & CP (Technical) Gross Charges by Market Segment

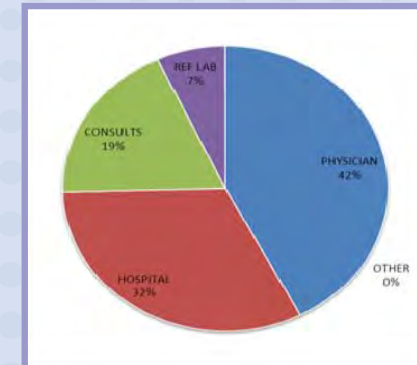


Figure 3: MLabs AP (Professional) % Charges by Market Segment

Rapids dermatology community – MLabs retained a large percentage of our existing business there, but not all.

Hospital Market Segment (29% 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 serves another 50 + hospital clients around the country that routinely use the Department of Pathology consultative service. Mount Clemens General Hospital (now McLaren-MaComb) began its mandatory transfer of sendout testing to the McLaren Core Lab facility in Flint and accounts for the decline (-2.5%) in overall gross charges in hospital market segment.

Reverse Reference Laboratories (17% of Total Gross Charges)

The sustained success in the Reverse Reference Lab market segment reflects the outstanding combined effort of the Molecular Diagnostic Laboratory, MLabs focused marketing effort and its Client Services Staff, and Pathology Informatics ability to keep up with the challenging IT demands of these clients. With increased competition in the marketplace and advances in technology, we are beginning to see molecular diagnostic testing performed in larger hospital systems similar to other esoteric testing. MLabs must continue to stay on the cutting edge of precision molecular diagnostics to maintain our position as a national provider of this specialized testing. Our reverse reference laboratory clients are increasing in number;

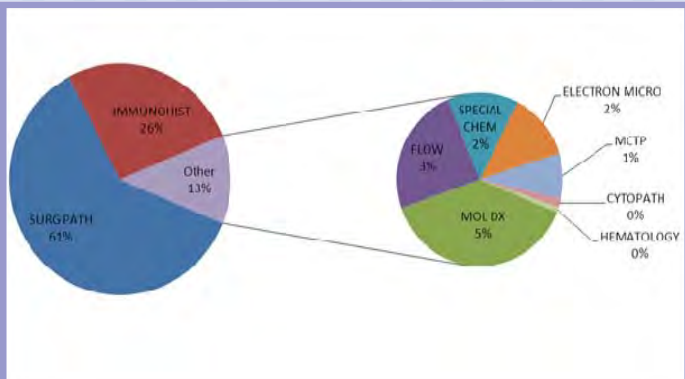


Figure 4: MLabs AP (Professional) % Charges by Lab Section

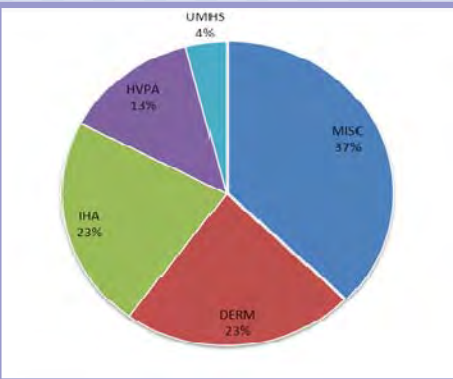


Figure 6: Physician Office Market Segment by

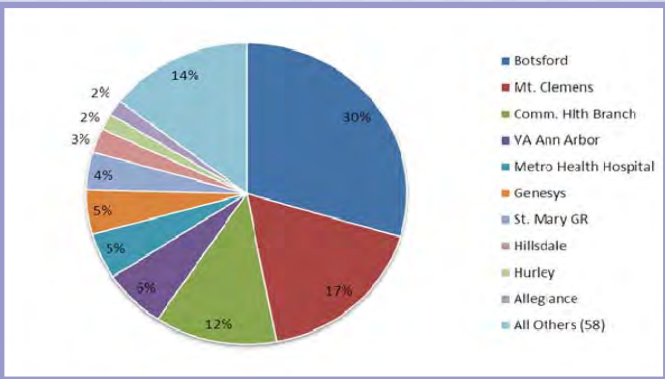


Figure 7: Hospital Market FY13

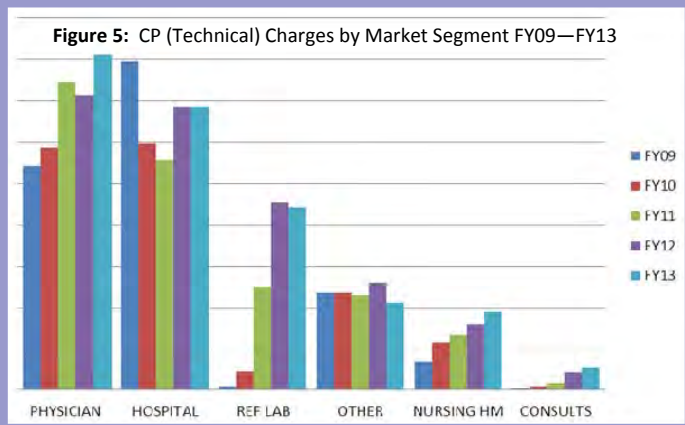


Figure 5: CP (Technical) Charges by Market Segment FY09—FY13

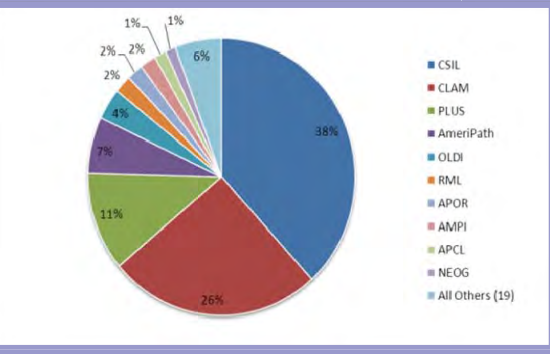


Figure 8: Reverse Reference Laboratories FY13 Referring

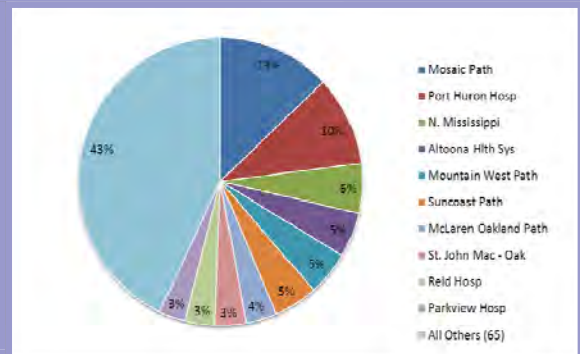


Figure 9: Top 10 Clients Referring Consultations

Fig 7 includes several that are referring PCA3 testing to MLabs.

AP Consultations (4.5% of Total Gross Charges)

Our Surgical Pathology, Dermatopathology and Hematopathology 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 over 75 established clients referring consult cases to us. Most diagnosis are rendered within 24-48 hours of receipt and result reporting primarily by facsimile. We are anxious to expand our result reporting options and have introduced electronic reporting for several large accounts. As an avenue to gain exposure to international opportunities for digital pathology, MLabs joined PathCentral's new digital pathology network and anticipate some activity from this ar-

angement within the next few months.

Extended Care Nursing Facilities (6.8% of Total Gross Charges)

MLabs provides laboratory and phlebotomy services to 5 regional nursing home and acute care facilities in support of UMHS strategic initiatives.

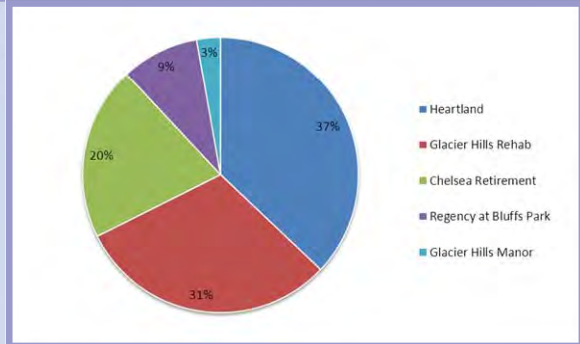


Figure 10: Acute Care Nursing Facilities

FY 13 INITIATIVES

MLabs New Website and Introduction to Social Media

An intense, dedicated effort first and second quarter resulted in a successful content and graphical revision to create our new MLabs Website. a marketing, educational and useful tool for both our internal and external customers. It is a professional visual representation of who and 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.

Social Media has become a small but necessary part of our marketing strategy. The tools available to MLabs within social media (Facebook, Twitter, LinkedIn, YouTube) represent new ways to support our goal to enhance MLabs reputation (brand awareness) and promote our services. We have contracted with an outside agency to manage this activity. Preliminary data indicates that we are being seen, heard and followed.

Successful Transition to new Laboratory Information System (SOFT)

As the portal to the Department of Pathology, MLabs primary informatics responsibility is to ensure that a test order is successfully entered into the LIS and the verified result is delivered efficiently in the manner that best meets the needs of the individual client. Today, many of our clients send us electronic test orders and 75% of our clients receive results electronically via multiple interface platforms and secure delivery systems. MLabs IT staff in partnership with Pathology Informatics worked diligently to ensure that interfaces in place successfully migrated into SOFT with as little impact as possible to our clients. We are anxious to explore the information technology functionality that SOFT can provide MLabs that will facilitate opportunities to meet the escalating demands for laboratory information and data.

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. Exhibiting at regional and national meetings affords

us an opportunity to ensure that we are recognized as a national reference laboratory provider. FY13 MLabs exhibited at three national meetings (USCAP, AACC and ASCP) as well as several regional pathology meetings. While our focused sales and marketing effort has been the Molecular Diagnostic Laboratory, we continue with efforts to market the services of various sub-specialties within Pathology (HLA Laboratory, MCTP, Dermatopathology). Strategic plan in place to expand MoLDx referral business as well hospital full reference laboratory services FY14.

Our partnership with Paradigm has allowed for some collaborate sales and marketing initiatives with prospective clients as well as planned joint exhibit at national meetings FY14.

MLabs Statewide Laboratory Network Participation

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) 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 UMHS Managed Care Operations Office with lab related issues from their various contracted groups, e.g., IHA, HVPA.

ACKNOWLEDGEMENT

The MLabs Division continues to experience solid growth and remains successful in retaining existing clients in a very competitive market. 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.

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 (VAAHS) is a University of Michigan affiliated tertiary health care provider for veterans. It is 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 VAAHS Pathology and Laboratory Medicine Service (PALMS) maintains a close relationship with the University Department of Pathology at every level. All pathologists in the VAAHS have medical school appointments and participate in university activities in a manner similar to other departmental sections. Recruitment for VAAHS 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 VAAHS laboratory retains full accreditation by the College of American Pathologists. The VAAHS satellite laboratory at the Toledo Outpatient 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 VAAHS PALMS provides specimen testing for these sites and oversees all ancillary testing. All sites are fully accredited by the College of American Pathologists (CAP).

ANATOMICAL PATHOLOGY

Surgical Pathology

In addition to serving local hospital and clinics, the VAAHS PALMS is currently performing all surgical pathology for the 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 began providing Anatomic Pathology services to the Aleda E. Lutz VA Medical Center, in Saginaw, MI.

Case load: 12,838 surgical cases were accessioned and reported during this reporting period, this represents a 13% increase

VA Ann Arbor Health System Laboratories

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

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 VAAHS 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.

Informatics, infrastructure and automation: In FY13 the VAAHS PALMS was awarded grant funding from the VHA Rural Health program to institute a digital telepathology consultation pilot between VAAHS and the Northern Indiana Healthcare System. Installation of equipment is expected for FY14.

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 30d. Autopsies performed at the VAAHS may also be

presented at the Extended Gross and Clinical-Pathologic Correlation conferences.

Case load: 16 autopsies were performed during the reporting period.

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

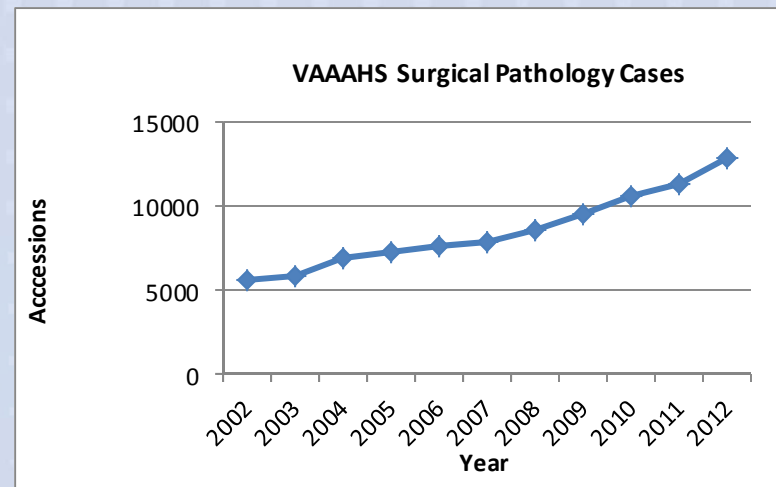
Cytology

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 VAAHS workload. The VAAHS 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: 4,974 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.

Surgical Pathology - 2011	
Surgical pathology diagnosis under 48 hr:	97.60%
Average surgical pathology report turn-around-time:	1.5 days
Case concordance (internal and external second reviews):	95.80%
Average frozen section turn-around-time:	10.0 min
Frozen section to permanent section concordance:	99.00%
Autopsy Service	
Autopsy completion turn-around-time average:	12.8 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%



CLINICAL PATHOLOGY

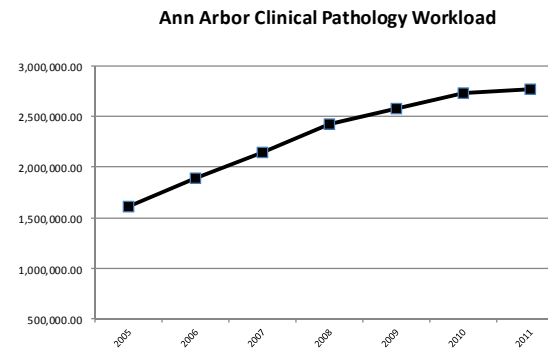
During the period of this report 2,718,743 clinical pathology tests were performed in the Ann Arbor laboratory. Chemistry there were 1,812,561; in Hematology/Coagulation/Urinalysis 507,449 in Microbiology 88,336 and in Blood Bank 66,362. A total of 124,906 phlebotomies were performed. In FY13 a new affiliated community-based outpatient clinic laboratory with an expanded service menu was opened Toledo and performed 399,305 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.

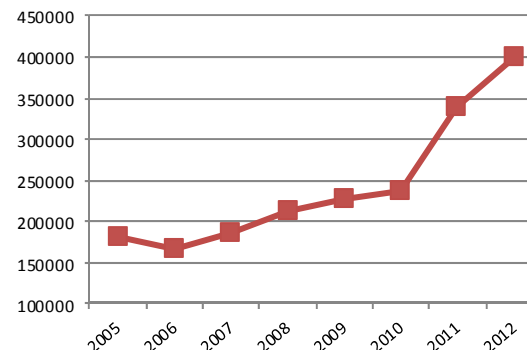
Quality assurance: An extensive quality assurance program is in place monitoring all aspects of clinical laboratory activities, including proficiency testing, precision, turn-around-times, safety, education, and staff competency.

Informatics, infrastructure and automation: The VAAHS clinical laboratories have continued to incorporate as much automation as possible employing state-of-the-art analyzers. In FY13 new analyzers were installed to perform automated urinalysis.

Clinical Pathology	
Chemistry	1,812,561
Hematology/ Coagulation/ Urinalysis	507,449
Microbiology	88,336
Blood Bank	66,362
Phlebotomy	124,906
Total Ann Arbor Cases	2,718,743
Toledo CP Cases	339,305
Total VAAHS CP Cases	3,058,048



Toledo Laboratory Workload



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 VAAHS is physically close to the University, the residents are expected to attend the appropriate teaching conferences at the University. VAAHS pathologist staff contribute to teaching of medical and graduate students at the University of Michigan. 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 elsewhere. 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 VAAHS. All staff participates in various clinical studies and collaborates with a variety of investigators. The laboratory, in general, serves the VAAHS 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 VAAHS, the pathology staff members serve on all major committees involved with institutional policies and procedures.

SUMMARY

The VAAHS 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 VAAHS 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



Michigan Center for Translational Pathology

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

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.

We continue to make 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 over the past year. While our basic "bench" research continues to be strong as we discover novel mechanism of cancer initiation and progression to lethal disease, our clinical sequencing program (MI-ONCOSEQ) has accelerated and led to significant findings since its nascent phase two years ago, resulting in two publications. In a report published in the journal *Nature Genetics* (2013 Feb;45(2):180-

5), we utilized an integrative sequencing approach to identify a novel gene fusion NAB2-STAT6 in a patient with a rare cancer, solitary fibrous tumor (SFT). When we examined other SFT patients (51 total), we found the exact NAB2-STAT6 gene fusion in every case. This discovery is significant in that it identifies the causative mutation in likely all SFT cases as well as pinpointing the target for development of therapies, either against the gene fusion itself or downstream effectors in the pathway. Recently, we identified gene fusions involving FGFR2 in 4 MI-ONCOSEQ patients with cholangiocarcinoma (2), breast cancer (1), and prostate cancer (1). Subsequent examination of other tumor cohorts revealed additional FGFR fusions with intact kinase domains in lung squamous cell cancer, bladder cancer, thyroid cancer, oral cancer, glioblastoma and head and neck squamous cell cancer. Importantly, these FGFR gene fusion-positive cancers have enhanced susceptibility to existing FGFR inhibitors. The results of this study were published in *Cancer Discovery* (2013 May 13).

RESEARCH BRIEF

Identification of Targetable FGFR Gene Fusions in Diverse Cancers



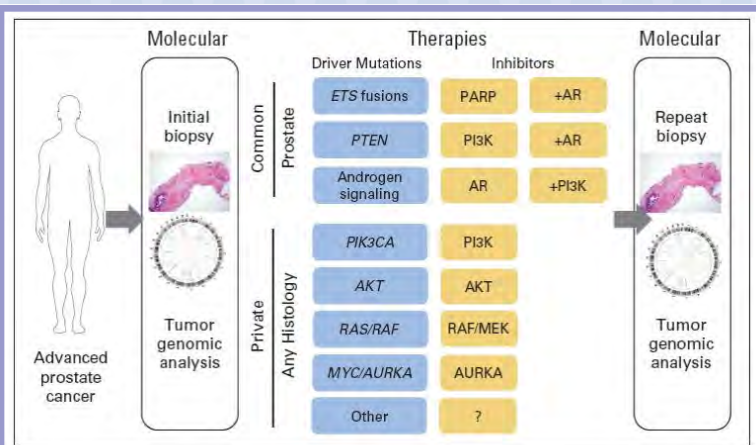
Yi-Mi Wu^{1,2}, Fengyun Su^{1,2}, Shanker Kalyana-Sundaram^{1,2}, Nikolay Khazanov¹⁰, Bushra Ateeq^{1,2}, Xuhong Cao^{1,7}, Robert J. Lonigro^{1,8}, Pankaj Vats^{1,2}, Rui Wang^{1,2}, Su-Fang Lin¹¹, Ann-Joy Cheng^{1,2}, Lakshmi P. Kunju^{1,2}, Javed Siddiqui^{1,2}, Scott A. Tomlins^{1,2}, Peter Wyngaard¹⁰, Seth Sadis¹⁰, Sameek Roychowdhury^{1,4}, Maha H. Hussain², Felix Y. Feng^{1,4,8}, Mark M. Zalupski², Moshe Talpaz⁹, Kenneth J. Pienta^{1,3,6,8}, Daniel R. Rhodes^{1,2,5,10}, Dan R. Robinson^{1,2}, and Arul M. Chinnaiyan^{1,2,6,7,9}

Wu, YM, et al. Identification of targetable FGFR gene fusions in diverse cancers. *Cancer Discovery*. 2013 June; 3(6):636-47. A Spotlight article.

Overall, we published 40 papers from 2012-present, four of which were in journals with an impact factor >20 (*Nature*, *Nature Genetics*, *Cell* and *Molecular Cell*). Our publications are highly cited with 2500 citations in 2012 and a current H-index of 54 (Web of Science®).

The Center continues 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.

MCTP researchers continue to engage in 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) and the international SU2C-PCF Dream Team's research initiative to study and develop personalized treatment for castrate resistant prostate cancer. The sequencing of CRPC patients across the SU2C clinical sites as well as associated clinical trials are well underway. Other collaborations include Metabolon, Ventana, GenProbe, Armune BioScience and WaferGen to develop clinical testing platforms.



This diagram outlines a path to genomics-driven trials for prostate cancer patients. Roychowdhury, S., Chinnaiyan, AM. Advancing precision medicine for prostate cancer through genomics. *J Clin Oncol*. 2013; 31(15):1866-73.

Our major research discoveries include the characterization of the EZH2-MMSET histone methyltransferase regulatory axis in cancer (*Mol Cell*. 2013 Jan 10;49(1):80-93); outlier kinase expression as targets of precision therapy (*Cancer Discov*. 2013 Mar;3(3):280-93); and the role of sarcosine metabolism in prostate cancer progression (*Neoplasia*. 2013 May;15(5):491-501).



Arul Chinnaiyan, M.D., Ph.D.

Care Foundation Richard D. Williams, M.D. Prostate Cancer Research Excellence Award and UM's Distinguished University Innovator

In addition to our publications that widely impact the scientific research community, our work is disseminated to the public through various media outlets. This past year, MCTP's research continues to gain press attention, appearing in media outlets such as *The New York Times*, *Detroit Free Press*, CBS news, among others. Jyoti Athanikar (MCTP science communication specialist) has been working with a web design company to completely overhaul the MCTP website platform and design; the new website is expected to be released this summer. The increasing interest of patients in MI-ONCOSEQ program and other clinical services underscores the importance of a user-friendly, streamlined website that is easy to navigate and find critical information by the public as well as treating physicians.

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 the recipient of the Urology Care Foundation Richard D. Williams, M.D. Prostate Cancer Research Excellence Award. He was also named the 2013 University of Michigan's Distinguished University Innovator and the 2013 Massachusetts General Hospital Cancer Center "100".

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



Bioinformatics graduate student, Alejandro Balbin was the recipient of the 2013 AACR Minority Scholar in Cancer Research Award for participation in the AACR Annual Meeting.



Drs. Irfan Asangani and Rohit Malik received the AACR-Millennium Scholar-in-Training Award for participation at the AACR Annual Meeting 2013.



MSTP candidate, John Prensner was a recipient of the ProQuest Distinguished Dissertation Award for 2012.



Dr. Nalla Palanisamy received the 2013 Department of Pathology's Employee Recognition award for Professional Development.



Dr. Paul Harms received the Dermatology Research Career Development Award entitled, "Mutational landscape of Merkel cell carcinoma by next generation sequencing".



Dr. Irfan Asangani received the Prostate Cancer Foundation's Young Investigator Award entitled, "Characterization and therapeutic targeting of MMSET in Prostate cancer".



Dr. Rohit Mehra received the Prostate Cancer Foundation's Young Investigator Award entitled, "Clinico-pathological characterization of novel lncRNAs in prostate cancer risk stratification".

MCTP continues to support the training and career development of the next generation of translational cancer biologists. MCTP faculty member **Dr. Nalla Palanisamy** was promoted to Research Associate Professor in the Department of Pathology. 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. **Matthew Iyer**, an MSTP candidate and Bioinformatics graduate student, successfully defended his thesis entitled "Discovery and characterization of long non-coding RNAs in cancer transcriptomes" on April 12, 2013; he will continue to work on his research project for another year in the lab before completing his clinical training.

Students, postdoctoral and clinical fellows that trained at MCTP have gone

on to obtain independent faculty positions. Dr. Bushra Ateeq was the recipient of the prestigious Wellcome Trust/DBT India Alliance Intermediate Fellowship and was named Assistant Professor in Department of Biological Sciences & Bioengineering, Indian Institute of Technology, Kanpur. Dr. Qi Cao was named an Assistant Member at the Center for Inflammation and Epigenetics, Methodist Hospital Research Institute, Houston.

MCTP funding continues to be strong despite the current fiscal climate. This past fiscal year, the Center obtained \$7,019,335 in committed awards. In addition, we received \$1.5M in funding from Howard Hughes Medical Institute Award. Dr. Chinnaiyan was renewed for another 5 years as a Howard Hughes Medical Institute Investigator. Fundraising efforts for MCTP resulted in a total production of \$4,899,375 including PCF matching funds.

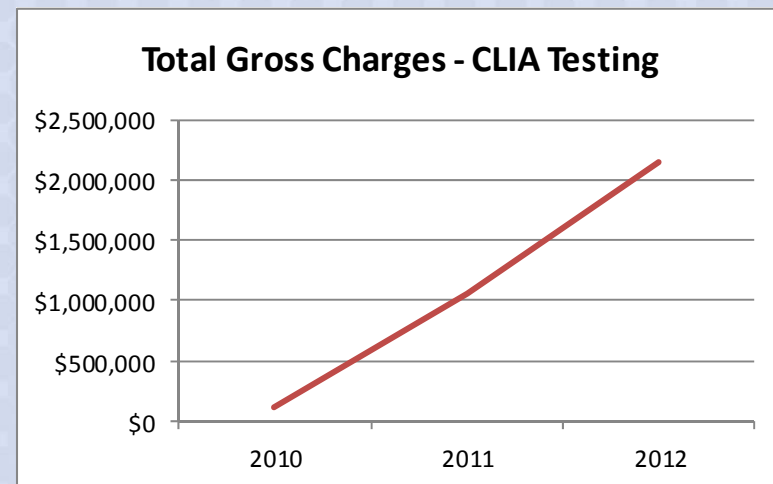
The total gross charges continue to increase each fiscal year for our CLIA testing. Fiscal year 2013 saw total gross charges of \$2,148,238, an increase from \$1,946,557 in 2012, \$1,050,661 in 2011 and \$112,652 in 2010. Net collection of the invoices is approximately 35%. We will be introducing a combined T2ERG/PCA3 test in fiscal year 2014.

Overall, we have had a successful year on all fronts and made remarkable progress towards our goal of translating basic laboratory discoveries into clinical applications. We continue to remain at the forefront of and make a significant impact on cancer biology, bioinformatics and the emerging field of precision medicine. With continued and sustained efforts we anticipate exciting new discoveries that impact patient health in the coming year.



Bushra Ateeq, Ph.D.

Recipient of the Wellcome Trust/DBT India Alliance Intermediate Fellowship



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, and the Revenue Cycle Advisory Committee. Mr. Lawlor serves as Chair of the Administrative Modernization Research Subcommittee, which oversees implementation of the Post Award standardization processes and procedures and is charged with improving quality and finding cost efficiencies in Research Administration across the School of Medicine. Mr. Lawlor also serves as Chair of the Executive Committee for the Joint Venture Hospital Laboratories as well as Co-Chair of the Diabetes Working Committee which has been charged by the EVPMA cabinet to recommend a structure that will facilitate one voice for diabetes care, research and education in addition to developing an initial strategic plan. This was an especially challenging year that included an outpatient MiChart go-live, a CAP inspection, a new LIS implementation, and an electronic documents control system.

Some key Divisional highlights orchestrated by Mr. Lawlor this

academic year include:

- Managing the Wayne County Medical Examiner's Office contract (through September 2014) and Washtenaw County Medical Examiner's Office contract (through September 2015), which has allowed us to add 8 new faculty positions and 2 new fellowships.
- Launching a new nonprofit joint venture with Paradigm for personalized medicine and incorporating it into our workflow.
- Planning space solutions for NCRC Buildings 35 & 36.
- 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.

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

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 FY2013 was \$538,957,092, compared to \$516,458,041 in FY2012, an increase of 4.4%. During this period, total laboratory expenditures were \$97,834,521. Pathology is responsible for 10.0% of total Hospital Gross Revenue and 4.2% 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. Suzanne Butch for maintaining licensure and accreditation for our laboratories.



Mr. Thomas Morrow oversaw the Clinical Pathology Laboratories. During this challenging year in which the Hospital's Physician Order Entry System, MiChart, was upgraded and the Laboratory Information System (LIS) was replaced, we still experienced positive results. Clinical pathology laboratory activity was above last fiscal year's levels, as was Clinical Pathology revenue.

Mr. Morrow served as the Administrative lead for restructuring our Mlabs client organization. Concurrent with the implementation of the MiChart upgrade, he also assisted with the planning and conversion of our LIS from Cerner Pathnet to Soft Computer Corporation. The deployment of the Soft LIS, required a major upgrade to our specimen label printing, slide label printing and document imaging applications and equipment, which was coordinated by Mr. Morrow. Mr. Morrow was instrumental in putting together submissions and ROI's to get our capital needs met, as well as leading LEAN workflow improvements. Several long-term contracts with major vendors like, Mayo Medical Laboratories, Ventana and Atlas Medical Systems were re-negotiated under Mr. Morrow's supervision this year.



Ms. Kristina Martin, Clinical Pathology Operations Coordinator, oversees our blood donations which have allowed us to improve our partnership with the American Red Cross and set better contract terms. She has also been instrumental in the implementation and training of our new laboratory document control system

Master Control. She is responsible for the Clinical Operations meetings and serves as the department liaison with nursing.



Ms. Christine Rigney, Anatomic Pathology Operations Administrator, oversees the Anatomic Pathology Laboratories. These labs include Surgical Pathology, Cytology, Electron Microscopy, Immunoperoxidase, Autopsy and Forensic Services, Transcription Services and Central Accessioning. Ms. Rigney is the department lead for many building and renovation projects which include 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 was also involved in the development of the new Laboratory Information System and its deployment. Additionally, she continues to participate and represent Anatomic Pathology in many LEAN projects with the Cancer Center, Operating Rooms and Office of Clinical Safety. Each has had a positive impact on the safety and quality of service that we provide to our patients and colleagues.



Ms. Suzanne Butch, Administrative Manager, is responsible for maintenance of all department and hospital laboratory licensure and accreditation for JC, 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, 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 LCC and Safety Committee.

Office of Academic and Business Affairs—Medical School



Mr. David Golden is responsible for all administrative operations associated with 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 \$3,900,222 in gross charges and \$1,462,129.02 in incre-

mental net revenue, and managed the UMHS and All Funds expenditures and forecast processes. Total All Funds expenditures for FY 2013 (Pathology and MCTP) were \$60,171,689 and Hospital expenditures were \$97,834,521. He also developed the 2014 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 189 research proposals submitted to external sponsors this year. 57 of these proposals were submitted to the NIH. Committed awards were \$26,976,075. Actual sponsored research revenue was \$30,033,867. Overall, the academic side of the Department saw a 5.66% increase (\$2.86M) in the following revenue components: component billing, net patient care, federal and non-federal research and other revenue (Washtenaw and Wayne County contracts, Royalties, rebill activities, operating transfers) from FY 2012 to FY 2013. FGP Net Patient Care was up year-to-year (7.74%). Overall gross charges for Pathology's group practice were up 8.64% (\$4.74M). Mr. Golden and his billing team played a pivotal role in the launch of the new LIS (Soft). They successfully transitioned all of professional and technical billing to the new LIS with minimal impacts to revenue capture. He 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 \$538,957,092 and professional fee gross charges of \$54,921,411. 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. Soft implementation this year had a profound effect on front-end billing with the addition of many new tasks and a complete overhaul of professional and technical billing charge capture functions. This implementation resulted in a new internal Oracle billing system as well as significant changes to workflow processes within the 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 \$30,033,867. Mr. Harris manages a staff of two accountants and two procurement spe-

cialists. This year, Mr. Harris and his team began managing all faculty and staff effort and funding changes. 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 research program 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.

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. Cathy Bearman and Ms. Jodi Simpson. Our Staff Human Resources Team provides support for Pathology's hospital laboratories (approximately 700 FTEs) and Medical School support staff, including our research programs (approximately 218 FTEs).



Faculty Affairs is the responsibility of Ms. Sarah Dudley-Short, who coordinates appointments, reappointments and promotions for our faculty (127.10 FTEs). Ms. Dudley-Short is 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 Education Teaching Programs for the M1 and M2 laboratories and the M4 Clerkship Program. Ms. Dudley-Short also maintains and updates the online Academic HR Tool.



Ms. Laura Labut is responsible for administration of the Molecular and Cellular Pathology PhD program with 30 students actively pursuing their doctorates. Management responsibilities are focused 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. Ms. 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. Ms. Labut performs the human resource functions for the department's graduate students (47 including 17 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 to lead the monthly mentoring series for our administrative support staff. Ms. McCain also provides board support for Paradigm, a joint-venture non-profit organization chaired by Dr. Hess. Ms. McCain was recognized for completion of a Master's in Health Services Administration and a Graduate Certificate in Health Informatics at our Annual Employee Recognition Celebration. She is currently working as the project manager with Dr. David Keren, the Medical Director, on establishing the Genetic Testing Resource and Quality Consortium, with the Coordinating Center located 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 Implementation Team, the Service Excellence Steering Committee, the Lab Formulary Committee, and the Diabetes Working 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

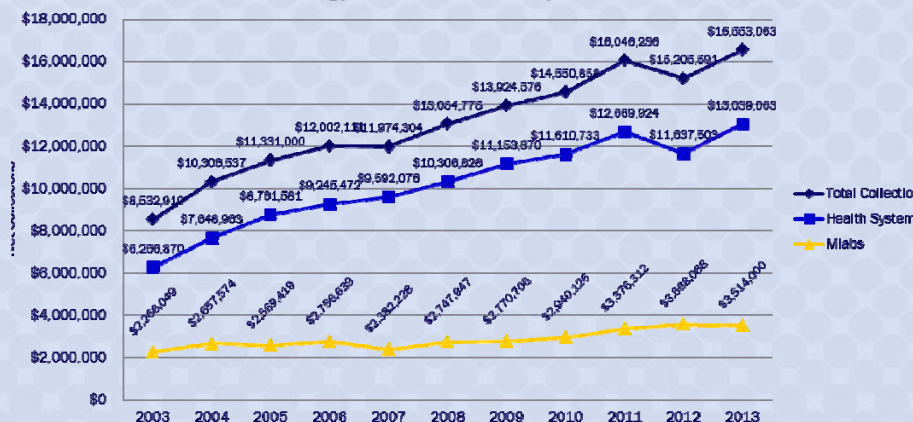
also taken part in the planning and implementation of the Advances in Forensic Medicine and Pathology Conference.

Pathology Professional Fee Billing Office



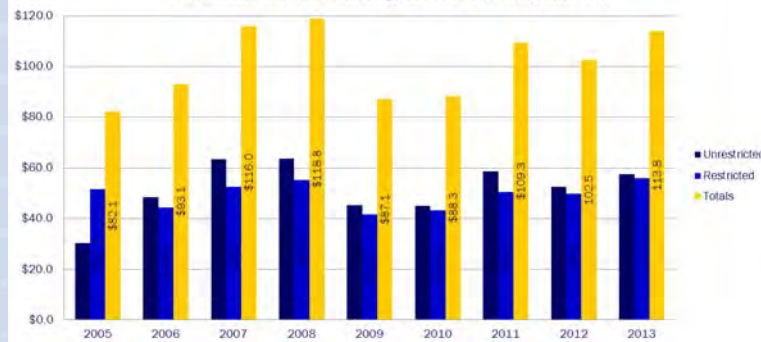
Ms. Holly Daul continues in her role as Revenue Cycle Director of Professional Billing for the specialties of Pathology, Radiology, Radiation Oncology, Physical Medicine, and Neurology. She supervises 35 FTE staff and is responsible for accounts receivable management and collections of professional fees 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.

Pathology Net Collections By Fiscal Year



90,220 Surgicals 1.4% increase from FY12
 10,301 Extramural consults 6.1% decrease
 1,370 Medical renal cases 17.5% increase

Department of Pathology Net Assets \$ (Millions)



ACKNOWLEDGEMENTS

A special thanks to Liz Walker and Mark Deming for their exceptional photographic contributions to this publications.

Thanks are also extended to David Golden and Christine Shaneyfelt for their data contributions in support of the efforts of the Department and to each of the Division Directors, Section Heads and their Administrative Support staff who provided the input and data for this report.

This report would not have been possible without your combined contributions!

Lynn A. McCain, MHSA, PMP
Editor



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