DEPARTMENT OF PATHOLOGY
UNIVERSITY OF MICHIGAN

2013-2014
Annual Report

Department of Pathology 2014

University of Michigan Medical School
Department of Pathology

Kathleen R. Cho, MD
Peter A. Ward Professor and Interim Chair

This has been a very exciting year for the Department of Pathology, the University of Michigan Health System (UMHS), and the University of Michigan (UM). Dr. Mark Schlissel, an internationally recognized biomedical researcher and physician-scientist, began his term as the 14th President of the UM on July 1, 2014. President Schlissel succeeds Mary Sue Coleman, who retired after 12 years of strong leadership. Ora Pescovitz stepped down from her role as Executive Vice President for Medical Affairs (EVPMA), and Dr. Michael Johns is currently serving as interim EVPMA while a search for a permanent EVPMA is underway. I have had the honor of serving the Department of Pathology as its Interim Chair for the last year. Although we were sorry to bid farewell to our former Chair, **Dr. Jay Hess**, in August of 2013, we were delighted to welcome **Dr. Charles (Chuck) Parkos** as the Carl V. Weller Professor and Chair of Pathology in mid-September of 2014. Dr. Parkos was recruited from the Emory University School of Medicine, where he served as Vice Chair of Pathology, Director of Experimental Pathology, Director of Gastrointestinal Pathology, and Director of Emory's Medical Scientist Training Program. Dr. Parkos brings an exceptional portfolio of scholarship and leadership to our department and I expect the next several years to be very exciting and productive ones.

Charles Parkos

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While we awaited selection of our new Chair, our faculty continued to be highly visible on the national stage, holding important leadership positions in our profession. **Dr. Jeffrey Myers** completed a very successful term as President of the United States and Canadian Academy of Pathology (USCAP) and **Dr. Henry Appelman** was honored with the USCAP 2014 Distinguished Pathologist Award. In addition to giving the Nathan Kaufman Timely Topics Lecture at the annual USCAP meeting, **Dr. Arul Chinnaiyan** was elected to the 2014 Class of the American Academy of Arts and Sciences (AAAS), one of the nation's most prestigious honorary societies and a leading center for independent policy research. **Dr. Celina Kleer** was inducted in the American Society for Clinical Investigation, an honor society of physician-scientists who translate findings in the laboratory to the advancement of clinical practice. **Drs. Kojo Elenitoba-Johnson, Megan Lim, and Mark Kiel** were awarded first place in the Michigan Collegiate Innovation Prize competition for their development of software used to analyze genome sequencing information.

Many of our faculty received institutional accolades this past year. The East Ann Arbor Intraoperative Breast Cancer Management Practice (including **Drs. Jeffrey Myers, Julie Jorns, and Angela Wu**) was awarded the 2013 Clinical Program of the Year. The Neurosurgery residents selected **Dr. Sandra Camelo-Piragua** as the recipient of the 2014 Friends of Neurosurgery Teaching Award, and **Dr. Lauren Smith** was chosen to direct a new Ethics Pathway of Excellence, an area of scholarly concentration for our medical students. **Dr. Scott Tomlins** was named as a Taubman Emerging Scholar; through the Emerging Scholar program, the Taubman Institute provides support for clinician-scientists to take on high-risk, high-reward projects while in the early stages of their careers. We also had the pleasure of inaugurating two new endowed Professors this year, **Dr. Andy Lieberman** as the Gerald D. Abrams Collegiate Professor of Pathology, and **Dr. Nick Lukacs** as the Godfrey Dorr Stobbe Research Professor of Pathology. The celebration of the new Abrams Professorship was particularly meaningful, as **Dr. Abrams**, Emeritus Professor of Pathology, was able to participate in the event honoring his many contributions to the department and the institution during his lengthy and distinguished career.

Our faculty continued to grow in FY14 in order to meet continued growth in clinical activity and to expand our research programs. Although we bade fond farewells to **Drs. Cory Hogaboam** (Cedars Sinai) and **Lindsay Schmidt** (Marshfield Clinic), six outstanding new faculty members were recruited in the past year, including:

- **Noah Brown, MD** – completed his AP/CP residency and fellowships in Hematopathology and Molecular and Genetic Pathology in our department. Noah assumed his role as Associate Director of the Molecular Pathology Laboratory in July of 2014.
- **Evan Farkash, MD, PhD** – completed his AP/CP residency and fellowship training at Massachusetts General Hospital, where he also served as Chief Resident in CP. Evan joined our AP faculty with a primary subspecialty interest in renal pathology as a Clinical Lecturer in September of 2013.
- **Jeffrey Hudson, MD** – completed his AP residency and fellowship training at the University of Toledo, as well as a fellowship in Forensic Pathology at the Wayne County Medical Examiners Office. Jeff joined our WCME faculty in May of 2014.
- **Madelyn Lew, MD** – completed her residency training at Massachusetts General Hospital and her fellowship training in Cytopathology at Brigham and Women's Hospital. Madelyn joined our AP faculty as an Assistant Professor in July of 2013 with primary clinical responsibilities in cytopathology.
- **Lee Schroeder, MD, PhD** – completed his CP residency at Stanford University where he also performed decision analysis, informatics, and outcomes research. He also has interests in Clinical Chemistry and serves on the Chemistry Resource Committee of the College of American Pathologists. Lee joined our CP faculty in September of 2014.
- **Andrew Sciallis, MD** – completed his AP/CP residency and fellowships in Surgical Pathology and Cytopathology at the Mayo Clinic and then joined our department as a Gynecologic Pathology fellow in 2013. Andy transitioned to the faculty in Surgical Pathology in April of 2014.


Noah Brown


Evan Farkash


Jeffrey Hudson


Madelyn Lew


Lee Schroeder


Andrew Sciallis

Given the large size and complexity of our faculty, which currently numbers 136 (over 150 including Emeritus, Adjunct and Visiting faculty), our Faculty Affairs team now has three "leads" who work with the Chair on faculty appointments and promotions. **Dr. Henry Appelman** single-handedly guided this important process for decades! He is now ably assisted by **Drs. Joel Greenson** and **Nick Lukacs**, and a reconfigured departmental advisory committee.

Our clinical services experienced further growth as detailed in the various section reports. We continue to be very proud of our laboratory management; Pathology accounted for 10% of total hospital gross revenue, but only 4.5% of total expense in FY14. The past year was marked by several successes in the clinical arena, including full implementation of electronic document control, an unannounced FDA inspection of our blood bank that yielded zero citations, and transition from CareWeb to MiChart for inpatient electronic health records. Our entire Pathology Informatics team, led by **Dr. Ul Balis** and **Kathy Davis**, has been working tirelessly to optimize our Soft Laboratory Information System (LIS), which went live in June of 2013. Although the transition from Pathnet to Soft has been challenging, we are beginning to experience many of the advantages that our new LIS provides and we anticipate a more rapid pace of optimization over the coming year with the addition of several servers and fewer distractions related to MiChart-Soft integration.

In addition to directing our Division of Anatomic Pathology, **Dr. Jeffrey Myers** continued in his role as Director of the MLabs outreach program. MLabs experienced additional growth in a very competitive market environment. Gross charges for FY14 were up by ~$3M over FY13, and 85 new clients were acquired. Paradigm, the non-profit joint venture that was launched during Jay Hess' tenure as Chair of Pathology, currently provides its comprehensive, next-generation cancer diagnostic test (PCDx) through MLabs.

The department's clinical and basic research programs continue to thrive and funding remains very strong, despite the flat NIH budget and keen competition for extramural grants. Recent large awards from the Glenn Foundation for Aging Research (**Dr. Rich Miller**, PI) and the National Cancer Institute (Prostate Cancer SPORE, **Dr. Arul Chinnaiyan**, PI) are particularly notable. **Dr. Yali Dou** was selected as one of two recipients of the 2014 Dean's Basic Science Research Award. Several Pathology faculty members are actively involved in the Medical School's Fast Forward Initiative, led by Senior Associate Dean for Research, **Dr. Steven Kunkel**, which completed its first full year. These include **Drs. Andy Lieberman** and **Kojo Elenitoba-Johnson** (protein folding diseases), **Duane Newton, Naohiro Inohara, Gabriel Nunez**, and **Michael Bachman** (host microbiome), and **Maria (Ken) Figueroa** (epigenetics core). The Michigan Center for Translational Pathology, under the direction of **Dr. Arul Chinnaiyan**, has established itself as an international leader in the discovery and characterization of disease biomarkers and therapeutics using an integrated, multi-disciplinary approach. Arul and his colleagues continue to bring personalized medicine to clinical care through the Michigan Oncology Sequencing Center (MI-ONCOSEQ). In order to sustain ongoing research for faculty members with funding gaps in this extremely challenging funding environment, the department established guidelines for obtaining bridging support.

Pathology's educational programs remain top-notch under the capable leadership of **Drs. Barbara McKenna** and **Scott Owens**. Despite the leadership transition in the Chair's office, we had a very successful match for our eight available residency positions. Interest in our clinical fellowships also remains very high and competition for our 16 ACGME-approved slots and several non-ACGME fellowship positions is becoming increasingly keen. A new fellowship in Clinical Chemistry was approved by the ACGME this past year. Several of our faculty members were inaugural inductees into the League of Educational Excellence (**Drs. Abrams, Appelman, McKenna, Nesvizhskii, Ramsburgh, and Stoolman**). **Drs. A. Lieberman** and **Nikolovska-Coleska** (Director of our Molecular and Cellular Pathology Graduate Program) submitted a new NIH T32 application for a "Training Program in Translational Research" this past year. The goal of the T32 program is to educate next-generation Ph.D. scientists working at the interface of basic biomedical science and clinical research. In addition **Drs. Nikolovska-Coleska** and **McKenna** launched a new course in Translational Pathology to provide both graduate students and clinical residents/fellows with training in the methods and principles involved in translating basic science findings into clinically useful interventions to improve human disease outcomes.

The financial picture for UMHS improved substantially compared to FY13. The Hospital and Health Centers (HHC) ended FY14 with an operating margin of $16.6M, slightly below the budgeted and forecasted amounts. Strong activity in the outpatient setting was a major driver, with clinic visits exceeding 2M for the first time (6% growth relative to FY13). The Medical School concluded with a loss of approximately $20M, significantly less than what was projected. Improved performance is attributable to strong patient care revenues, margin sharing, and philanthropy. The Department of Pathology remains in a very strong financial position; current assets will provide Dr. Parkos with the means to recruit new faculty, expand existing programs, and launch new initiatives in the Department.

An introduction to this year's annual report would not be complete without an update on plans for expanding our clinical laboratory space. Over the past year, I and many others in the department worked diligently with HHC and Medical School leadership to identify a space solution for Pathology that is years, if not decades, overdue. Earlier this year, the HHC Executive Board approved a plan for Pathology to move most of its clinical operations to four buildings at the North Campus and to renovate existing Pathology space in the University Hospital to accommodate an automated core lab and upgrade other laboratories that will remain at UH. This project, termed the Pathology Relocation and Renovation (PRR) project, is now in full swing. We have engaged a project manager, a Lean design coach, and architectural and engineering firms to assist with the PRR planning. Presentation of a detailed plan to the Regents is anticipated in early 2015. Assuming Regental approval to move forward is obtained, most of Pathology's clinical operations will move to the North Campus in late 2016/early 2017 and the UH renovation will be complete by late 2018/early 2019.

I would like to close by thanking all of the faculty, trainees, and staff in the department for their wonderful support during my fourteen-month tenure as Interim Chair. Our group of Division Directors (**Drs. Myers, Keren, Elenitoba-Johnson, McKenna, Balis, Kunkel**, and **Marty Lawlor**) is second to none and Dr. Parkos is "inheriting" a terrific group of individuals who really know how to work together as a team. I also want to personally thank **Marty Lawlor** and **David Golden** for their hard work and skilled oversight of our Division of Administration and Finance. Marty is the 2014 Dean's Administrator of the Year awardee, an honor that he richly deserves. Finally, I'd like to thank **Laura Zaborski, Angie Suliman**, and **Liz VanderElzen**, who ably and cheerfully assisted me in the Chair's office this past year. It has truly been a joy and an honor to serve the department as its interim Chair and I look forward to the exciting times that lie ahead.

Division of Anatomic Pathology

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

Anatomic Pathology (AP) 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) implemented in June 2013, was significantly enhanced and largely stabilized through the combined efforts of staff and faculty in Anatomic Pathology and Pathology Informatics.

Dr. Madelyn Lew joined our Cytopathology team as Assistant Professor in July 2013. **Dr. Evan Farkash**, Clinical Lecturer, joined our Renal Pathology team in September 2013 with a significant proportion of his effort devoted to research in the laboratory of Dr. Jeffrey Platt, Professor of Surgery and Microbiology and Immunology. **Dr. Jeffrey Hudson**, Clinical Lecturer, joined our Forensic and Autopsy service in April 2014 and is based at the Wayne County Medical Examiners Office to fill the position vacated by **Dr. Allecia (Lisa) Wilson**. Dr. Wilson's leave of absence allowed her to complete a UMHS fellowship in pediatric and perinatal pathology. She rejoined the faculty in July 2014 as Assistant Professor with primary responsibilities in our UMHS-based integrated autopsy and forensic service, meeting the needs of the Washtenaw County Medical Examiners Office. Lisa will also participate in our pediatric and perinatal pathology service. Also joining our faculty in April 2014 as Assistant Professor with subspecialty interest and expertise in gynecologic pathology was **Dr. Andrew Sciallis**, who will broadly participate in various surgical pathology services.

Madelyn Lew

Evan Farkash

Lisa Wilson

Andy Sciallis

Sriram Venneti

Andy Lieberman

Dr. Sriram Venneti was recruited in FY14 and will join our Neuropathology team in the second quarter of FY15 as Assistant Professor with laboratory-based research interests in cancer metabolism in primary brain tumors that he studies using innovative *in vivo* imaging techniques.

Success and vitality in our research activities remains strong as evidenced by continued visibility in peer-reviewed journals considered high impact by the academic anatomic pathology community. Extramural funding remained remarkably strong, growing by just over 8% with a corresponding 34% increase in funded FTEs in FY14 compared to FY13 despite the unfavorable national funding climate. The number of published abstracts and invited lectures remained high as did intramural funding allocated by our AP Projects Funding Committee under the leadership of **Dr. Andrew Lieberman**.

Education programs remained strong and included ongoing successes in existing fellowships. Recently accredited programs in Forensics and Pediatric Pathology graduated strong candidates at the end of FY14, and our first neuropathology fellow matriculated in July 2014 (FY15). AP faculty continued to play key roles in supporting our residency program and medical school teaching, contributing well over 1,100 contact hours to our 1st, 2nd, and 4th year medical 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

Our anatomic pathology services continues to realize steady growth, increasing from a total of 86,218 specimens in FY2013 to 91,810 in FY2014, a year-over-year growth rate of 6.5%. Our extramural consultation practice continued to be a key area of practice growth with 10,619 consultation cases signed out in FY2014 compared to 10,079 in FY2013, an annual increase of 5.4%. The total number of work-relative value units (RVUs), the measure by which Medicare and other payers recognize and reimburse professional activity, grew at an annual rate of 5.2% from 200,709 in FY2013 to 211,156 in FY2014.

Faculty clinical productivity, measured as RVUs/FTE, climbed to an unprecedented high. Expressed as a 12 month rolling average, faculty generated an average of 590 RVUs/FTE/month in June 2014 compared to 512 RVUs/FTE/month in June 2013. This reflects the combined impact of service growth and a decreased number of FTEs.

Surgical Pathology

UMHS surgical pathology services continued to demonstrate strong growth in nearly all services as reflected in Table 1. The largest growth in numbers of accessioned cases was realized in our GI and general surgical ("Room 1") services compounded by an annual increase of over 13% in our transfer patients (see Table 1).

Surgical pathology continued to support four separate frozen section labs: University Hospital, Cardiovascular Center (CVC), East Ann Arbor, and Mott Hospital. Faculty participating in the Surgical Pathology Officer (SPO) rotation established in FY13 continued to play a key role in supporting frozen section practices at CVC and Mott Hospital. Renovations of the CVC frozen section laboratory were completed in the 2nd quarter resulting in laboratory space much more supportive of timely intraoperative consultations.

Table 1: Surgical Pathology Clinical Activity, FY10 – FY14

	FY10	FY11	FY12	FY13	FY14	YOY % change
breast	2,322	1,960	2,220	2,330	2,346	0.7%
gastrointestinal	16,870	17,431	16,857	17,570	18,144	3.3%
genitourinary	2,701	2,537	2,387	2,304	2,381	3.3%
gynecological	6,350	6,274	5,988	6,166	6,013	(2.5%)
surgical pathology – general ("Room 1")	9,465	9,412	9,318	9,686	10,658	10.0%
transfer cases	4,402	4,968	5,067	5,885	6,669	13.3%
TOTAL	42,110	42,582	41,837	43,941	46,211	5.2%

Pediatric and Perinatal Pathology

The pediatric and perinatal pathology service continued to flourish in FY14 under the direction of **Dr. Raja Rabah**. As summarized in Table 2, the pediatric surgical service grew at an annual rate of 27.5%, with nearly 2,800 cases from the CS Mott Hospital ORs. In addition there were over 200 transfer cases and 100 outside consults. 1,715 placentas from the Von Voigtlander Women's Hospital were examined reflecting a 3.9% annual increase over FY13.

Raja Rabah

Table 2: Pediatric Pathology Clinical Activity, FY10-FY14

	FY10	FY11	FY12	FY13	FY14	% Change
Peds (IP)	1,655	1,794	2,177	2,191	2,793	27.5%
Placentas (PL)	1,166	1,474	1,456	1,650	1,715	3.9%
Pediatric Autopsies			29	25	37	48.0%
Fetal Examinations			36	115	129	12.2%

In addition to surgical cases and placentas, the pediatric team covers all pediatric autopsy cases from Mott Hospital. Thirty seven autopsies were performed through May, 2014 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. One hundred twenty nine exams were done in FY14, more than triple the number of examinations performed in FY12. The pediatric team continued to provide consultation services for the pediatric and perinatal autopsy cases from St. Joseph Mercy Health System (Ann Arbor), a practice that began in the last quarter of FY13.

The team participated in over 135 multidisciplinary and teaching conferences at Mott and Women's Hospital and over 1,149 patient's cases were discussed.

Dr. Lisa Wilson finished a one year fellowship training at our accredited fellowship program and started as faculty in the pediatric service effective July 1, 2014.
Volume, quality, and turn-around time are continuously improving as depicted in Figures 1-4.

Figure 1: Pediatric Surgical Case Volume and TAT, FY12-FY14 May YTD

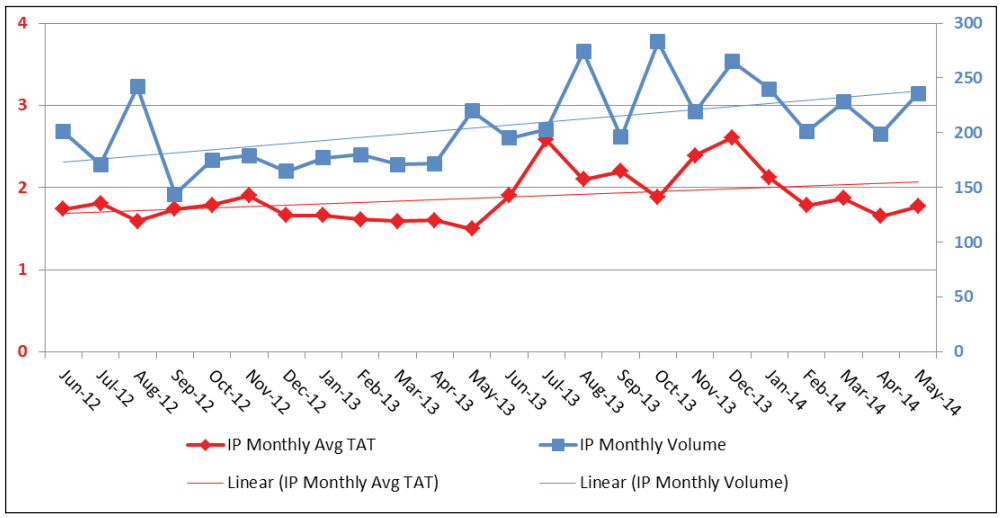


Figure 2: Placenta Case Volume and TAT, FY13-FY14 May YTD

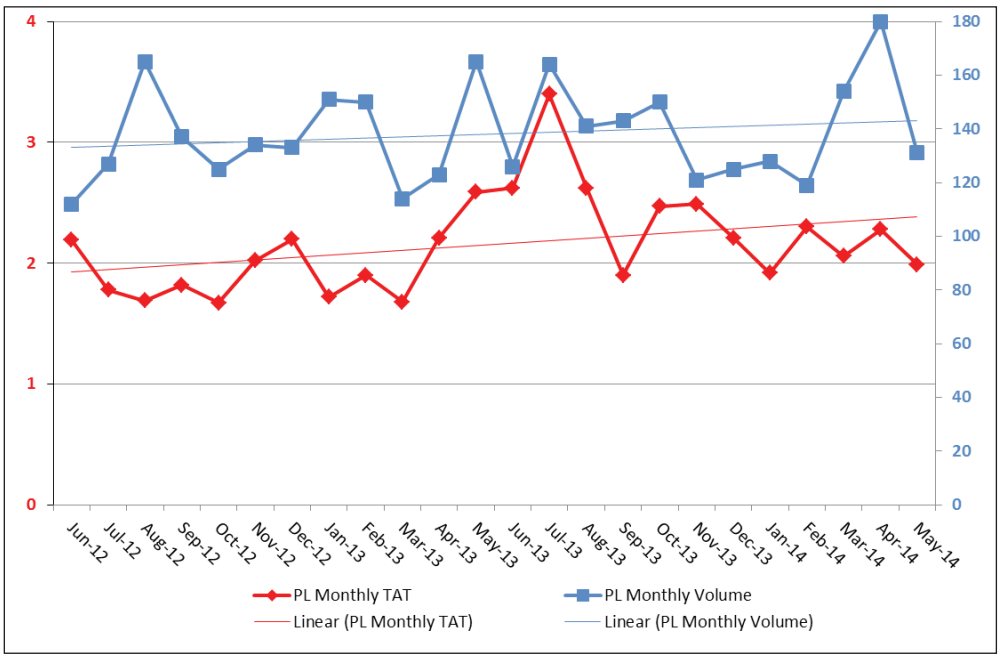


Figure 3: Fetal Examination Case Volume and TAT FY13 May YTD

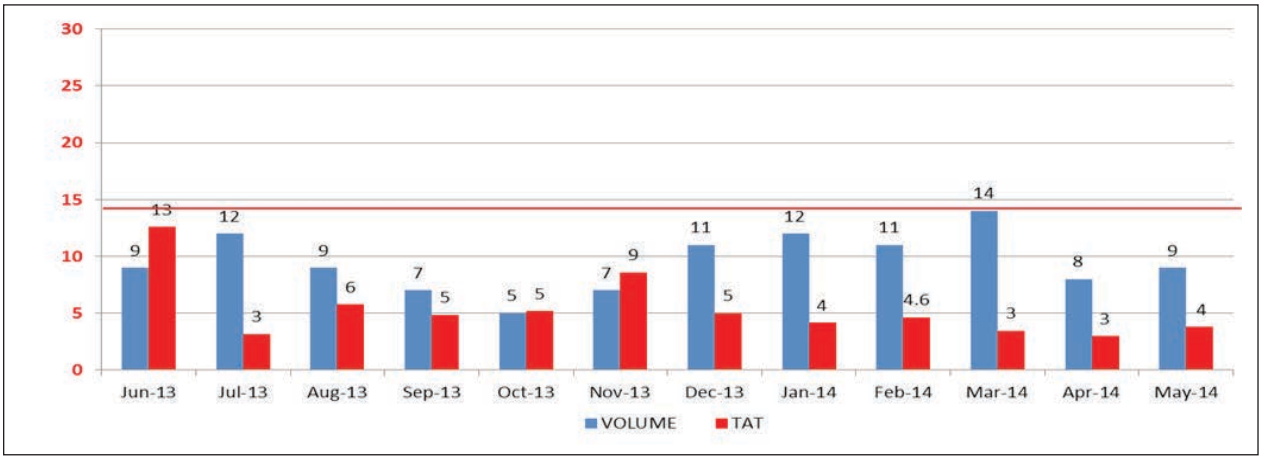
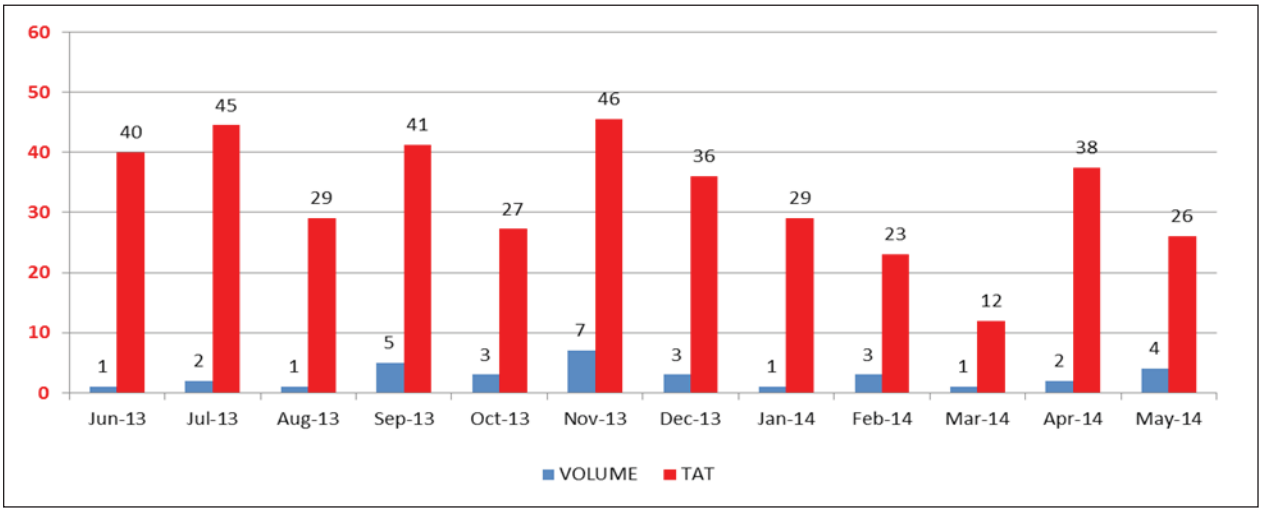


Figure 4: Pediatric Autopsy Volume and TAT FY13 May YTD



Dermatopathology

Doug Fullen

Dr. Doug Fullen leads our Dermatopathology service team, which 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. 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, and the Cutaneous Lymphoma Conference and Tumor Board. Dermatopathology maintains an integral role in all of these programs.

Dermatopathology continues to be a high volume practice (see Table 3) and realized substantial growth across all services. Internal volumes recovered from the dip that followed implementation of MI-Chart in outpatient areas in FY13 and included substantial year-over-year increase in transfer cases. Biopsies processed through MLabs (MD) also showed strong growth, building on a trend that began in the last half of FY13.

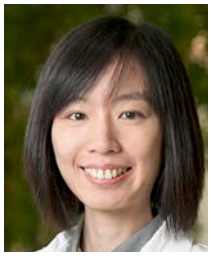
Table 3: Dermatopathology Clinical Activity, FY12-FY14

	FY12	FY13	FY14	% change (FY13 - FY14)	% change (FY12 - FY14)
ID	13,716	13,461	13,906	3.3%	1.4%
MD	7,412	7,418	8,199	10.5%	10.6%
Consults	2,263	2,205	2,416	9.6%	6.8%
Transfer	3,566	3,732	4,652	24.6%	30.4%
TOTALS	26,957	26,816	29,173	8.8%	8.2%

The past academic year has been a period of stability in the Dermatopathology section with no departures or additions of personnel to the service. **Dr. Aleodor Andea** has been actively engaged in development of a Dermatopathology Molecular Research Laboratory (DMRL) through validation of molecular diagnostic tests for cutaneous malignancies, obtaining CLIA certification of the laboratory, and supporting research investigations 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** continues to provide invaluable hematopathology expertise, as well as broad diagnostic dermatopathology, to the service and is primary support for the Cutaneous Lymphoma Tumor Board. **Dr. Paul Harms** continues as a Clinical Lecturer, providing 25% effort to the Dermatopathology diagnostic services while remaining extremely active in basic science research pertaining to cutaneous neoplasia under the mentorship of Dr. Arul Chinnaiyan.


Aleodor Andea


Rajiv Patel


May Chan


Alexandra Hristov


Paul Harms


Lori Lowe

This was a very productive academic year for the Dermatopathology faculty with high visibility at national and international meetings. **Dr**. **Lori Lowe** received two prestigious awards this past academic year – the Outstanding Clinician Award at the University of Michigan and the Walter Nickel Award for Outstanding Teaching from the American Society of Dermatopathology. **Dr. Doug Fullen** was appointed Chair of the Mentorship Committee of the American Society of Dermatopathology. **Dr. Harms** continues his research with support from a Dermatopathology Research Career Development Award (7/2013-7/2016) from the Dermatology Foundation. **Drs. Patel, Harms** and **Chan** participated in a short course entitled *Dermatopathology Greatest Hits: Top Ten Lessons Learned (So Far) from Academic Consultative Practice* at the United States and Canadian Academy of Pathologists in March 2014. **Dr. Andea** became Director of the Dermatopathology Fellowship and saw his first two fellows successfully complete the program. Collectively the Dermatopathology faculty had 38 abstracts (10 more than last year) presented at national or international meetings, and authored or co-authored 49 peer-reviewed publications (eight more than last year), either published or currently in press. Moreover, Dermatopathology faculty members were nationally or internationally invited speakers on 32 occasions.

Neuropathology

Drs. 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. **Dr. Sriram Venneti**, currently a Research Associate at Memorial Sloan Kettering Cancer Center, was recruited in the third quarter of FY14 and will join the Neuropathology faculty as a physician-scientist in the 2nd quarter of FY15.


Sandra Camelo-Piragua


Constance D'Amato


Andy Lieberman

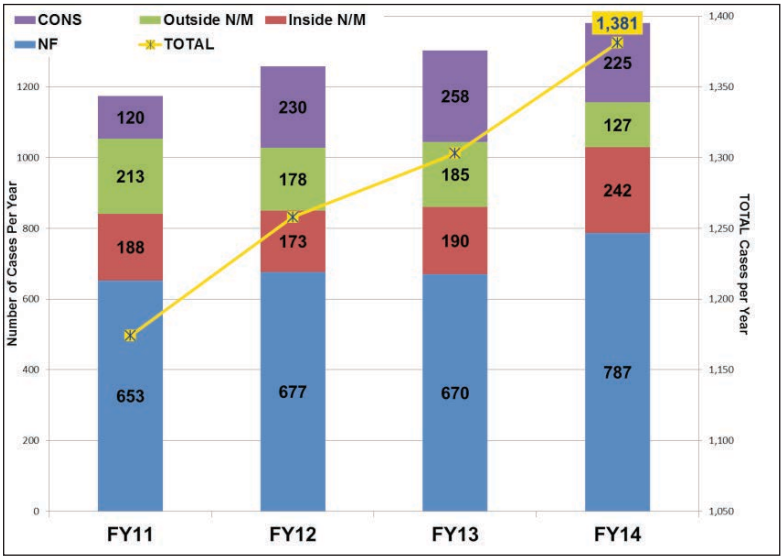

Paul McKeever

There were 1,381 neurosurgical cases examined this year compared to 1,303 in FY13 representing year-over-year growth of 6% (see Figure 5). UMHS surgical patients comprised 57% of the accessioned cases and accounted for the growth in the Neuropathology practice with 787 cases in FY14 compared to 670 in FY13, an annual growth rate of 17.5%. The nerve and muscle biopsy service is staffed by **Drs. McKeever** and **Camelo-Piragua** and was stable with a minor 1.6% year-over-year decline. Consultation cases dropped 12.8% from 258 in FY13 to 225 in FY14. An additional 162 transfer cases were signed out by neuropathology faculty and were not included in the 1,381 total.

Neuropathology faculty staffed the following conferences: twice weekly Neuropathology Case Conference; monthly Neurosurgery CPC; weekly Brain Cutting Conference; weekly Nerve and Muscle Conference; and weekly Brain Tumor Board. The Neuropathology Case Conference was expanded from once to twice weekly to share difficult and interesting cases.

Fifty-six cases were examined at the Brain Cutting Conference. Of these, 34 were UH hospital cases, seven were ME cases, and 15 were acquired through the UM Alzheimer's Center and required a more extensive evaluation.

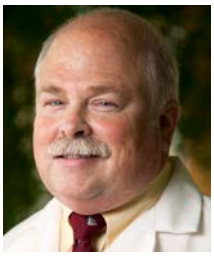
Figure 5: Neuropathology Case Volumes, FY11-FY14



Neuropathology case volumes grew at an annual rate of just under 5% due mainly to growth in UMHS nerve and muscle biopsies and extramural consultation cases.

Medical Renal Pathology

Drs. Paul Killen (Director) and **Jeffrey Hodgin** were joined by **Dr. Evan Farkash** in September 2013 to bring the total to three for the number of faculty supporting our Renal Biopsy service. Evan was recruited from Massachusetts General Hospital and currently devotes a significant portion of his effort pursuing translational projects in the laboratory of Dr. Jeffrey Platt, Professor of Surgery and Microbiology and Immunology.



Paul Killen

Jeffrey Hodgin

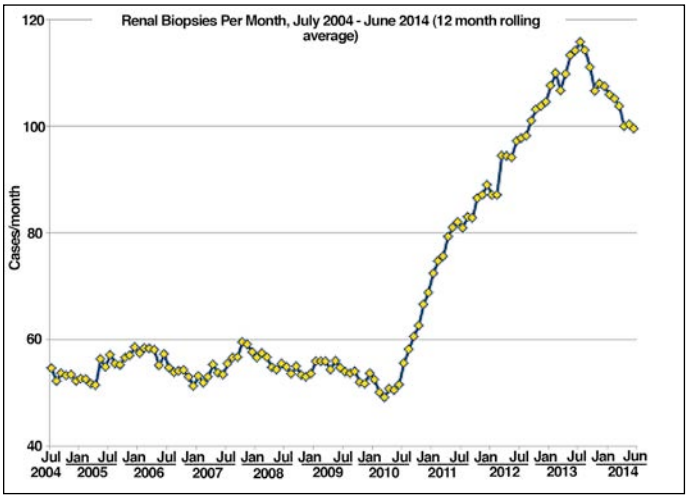
Evan Farkash

Our renal biopsy practice stabilized in FY14, accessioning 1,194 cases compared to 1,370 in FY13, reflecting a 12.8% year-over-year decline (see Table 4 and Figure 6). This is the second highest number of cases accessioned in a single year and is the third consecutive year in which annual volumes have been above 1,150 cases. The 4th quarter of FY14 was especially strong (332 cases) and suggests that the practice has stabilized at a level that is double the mean annual case volume prior to FY11. Whole slide scanning remains an aspirational goal as a method for archiving and virtual review of biopsies from renal transplant patients.

Table 4: Renal Biopsy Case Volumes, FY11-FY14

FY11	FY12	FY13	FY14	% Change (FY13-14)	% Change (FY10-14)
984	1,166	1,370	1,194	(12.8%)	93.2%

Figure 6: Renal Biopsies Per Month



The strong growth realized from FY11 through FY13 stabilized in FY14, making it the 2nd highest number of cases in our history.

Cytopathology

Michael Roh

Kalyani Naik

This year marked the return of **Kalyani Naik** to the Cytopathology Laboratory as Supervisor alongside **Dr. Michael Roh**, Director of Cytopathology. It was also the start of **Dr. Madelyn Lew's** appointment as faculty to Cytopathology. Our Cytopathology fellows, **Kurt Bernacki** and **Scott Kantola**, performed admirably and successfully completed their fellowship in cytopathology.

Table 5: Cytopathology Clinical Activity, FY11-FY13

	FY11	FY12	FY13	FY14	% Change
Gyn Total	34,014	32,866	26,928	26,078	(3.2%)
Non-Gyn Total	9,812	9,664	10,319	12,053	16.8%
Non-Gyn Exfoliative	7,123	7,034	7,357	8,808	19.7%
ASP Total	2,604	2,630	2,962	3,245	9.6%
ASP 1	962	862	826	670	(18.9%)
ASP 2	1,423	1,526	1,802	2,345	30.1%
ASP 3	219	242	208	230	10.6%

As indicated in the above table, non-gynecologic cytology specimens numbered 12,053, a 16.8% increase from last year. Fine needle aspirations (FNAs) totaled 3,245, a 9.6% increase from last year. FNAs performed by pathologists at the Cancer Center totaled 230 (93 performed using ultrasound guidance), representing a 10.6% increase from last year. Assisted FNAs (ASP2) grew at an annual rate of 30.1% totaling 2,345, while aspirates performed by clinicians without our assistance (ASP1) dropped 18.9% to a total of 670. The increase in the assisted FNAs is fueled by our continuous communications with clinical colleagues reinforcing the value of on-site cytology assistance and its impact on patient outcomes. It also drives increased demand for laboratory personnel, cytotechnologists, fellows, and faculty to provide the needed service across a geographically dispersed clinical care environment. In response, we have increased cytotechnologist hospital coverage to three cytotechnologists in order to meet the increased demand and support the cytopathology fellowship program goals.

The mean turnaround time for non-GYN cytology cases, including FNAs, was 1.62 days. Total gynecologic cytology specimens continued to decline as a consequence of changes in follow-up Pap test recommendations for HPV negative women, dropping 3.2% to 26,078. The mean turnaround time was 5.82 days.

Summary of Service Initiatives and Lean Activities in Cytopathology

- The Cytopathology laboratory staff takes pride in the successful transition to the new SoftPathDx laboratory information system. Their patience, engagement, and eagerness to continuously devise creative solutions to optimize workflow in light of this transition is appreciated and applauded.
- Cytopathology staff actively participated and presented at Anatomic Pathology (AP) QA meetings.
- Laboratory staff continues to be actively engaged in problem solving and practicing lean thinking in a standardized manner utilizing the A3 and root cause analysis tools. Volunteers are sought to lead small groups to study any individual problem and develop an A3.
- Cell blocks, which are frequently utilized for molecular diagnostic assays, are now being temporarily stored for at least one month prior to filing in the Cytopathology signout room. This serves to minimize unnecessary movement of blocks in and out of the slide library and provides easy access for histotechnologists and the AP Service Center who can easily pull the blocks when a request for molecular testing is received.
- In response to the escalating ASP2 volume, including cardiovascular center and otolaryngology clinic FNAs, a mobile telecytology cart has been constructed and successfully employed during this past year.
- Cytopathology continues to work with the Virology laboratory to improve the triage of Pap testing vials for HPV testing and improve the timeliness of HPV result reporting.
- Pathologists performed ultrasound-guided FNAs in the Cancer Center Clinic this past year.
- Cytopathology continues to collaborate with the Molecular Diagnostics Laboratory in their development of new assays. This year, FISH testing for bile duct brushings was validated and is available for clinical use. Furthermore, cell blocks are prepared using cell lines which are utilized as positive controls for various other FISH assays.
- In collaboration with the Breast pathology service, cytotechnologists continue to be involved in utilizing the Ventana iScan Coreo/Virtuoso system for scoring ER/PR and Her2/Neu expression in breast tumors. A total of four cytotechnologists are currently trained (Binita Naylor, Kim Luckett, Brian Smola, and Kent Traylor) and are performing scoring on approximately 750 breast biopsies annually. Additional cytotechnologists will be trained in the upcoming year.
- The end of FY14 marks the four-year anniversary for the implementation of the telecytology program designed to cover the endocrinology/thyroid FNA program from Domino's Farms. The on-site adequacy assessment via the web was successfully implemented with no major difficulties and continues to grow three years later. The service has grown to operate three days/week requiring staffing by one cytotechnologist for 4-6 hours on each of these days.

Autopsy and Forensic Services

Jeffrey Jentzen

The Autopsy section provides faculty and resident coverage for hospital autopsies at the UMHS and VA hospitals, as well as medical examiner (ME) cases for Washtenaw and Wayne counties. Residents complete three one-month rotations on the Autopsy service to comply with ACGME requirements. Regular educational conferences include a weekly gross autopsy conference, a monthly forensic conference, multidisciplinary clinical conferences on request, and an M3 lecture on death certification. The autopsy faculty consists of our director, **Dr. Jeffrey Jentzen**, and a forensic pathologist at our UMHS campus, and eight full-time faculty based at the Wayne County Medical Examiner's Office.

A total of 617 autopsies were completed at the UMHS morgue in FY14, reflecting an annual increase of 6.6%. The total included 214 complete adult hospital cases, 13 pediatric cases, and five autopsies performed through MLabs in support of St. Joseph Mercy Hospital. Of the 385 medical examiner cases, there were 351 full autopsies, 31 external examinations, and three limited autopsies. The combined hospital and medical examiner case loads accounted for approximately 30% of hospital deaths.

Wayne County in FY14 accounted for an additional 2,738 cases of which there were 1,897 complete autopsies, 32 limited, and 810 external inspections. Turnaround times were 87% within 60 days and 93% with 90 days.

Lisa Wilson

Dr. Jentzen provides autopsy coverage for approximately 40% of hospital cases as well as Washtenaw and Wayne County cases. **Dr. Lisa Wilson** joined the UMHS-based forensics faculty in July 2014 and will provide additional hospital and medical examiner coverage. Eight pathologists assisted by two fellows provide coverage for Wayne County. In addition to the coordinator of autopsy services, there are two full-time death investigators/autopsy assistants at UMHS who provide autopsy support and investigation from 7:00 am to 11:00 pm daily. A group of five part-time investigators provide 3rd shift coverage from 11:00 pm to 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.

Current initiatives for the section revolve around improved turnaround time for UMHS and Wayne County Medical Examiner autopsies, stabilizing the newly approved forensic pathology fellowship, providing coverage for Washtenaw County, and incorporating the Wayne County case volume and pathologists into the section activities. The staff also supports the annual conference, *Advances in Forensic Medicine and Pathology,* and a week-long *Basic Death Investigation Course*.

FY15 Goals

The Autopsy and Forensic Services group will strive for the following goals in FY15.

1. Provide memorable educational experience for fellows, residents, and students.
2. Provide for and recruit to a high quality forensic fellowship program.
3. Achieve national recognition as one of the top five forensic training programs.
4. Obtain NAME accreditation for Wayne County.
5. Finalize three-year contract with Wayne County to provide comprehensive services.
6. Develop and market a limited "Forensic Panel" for pharmacogenomic testing.
7. Grow the academic involvement of the pathology staff.
8. Enhance communication with clinical and nursing staff.
9. Switch Wayne County software to MDILog.
10. Increase attendance at annual conference to continue "cost neutral" funding.

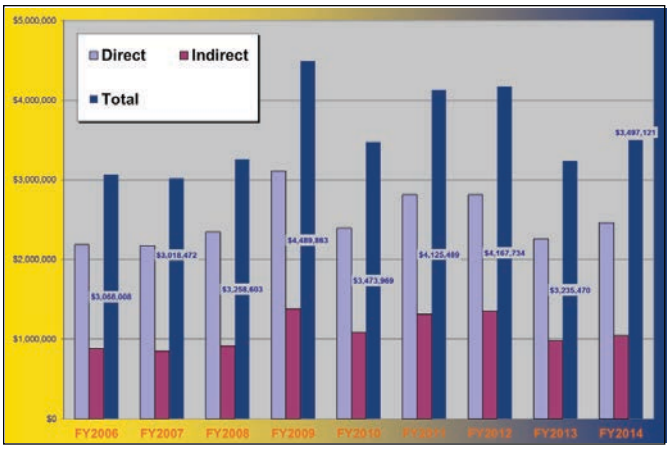
RESEARCH ACTIVITIES

The Anatomic Pathology faculty remains remarkably productive despite the demands of patient care (see Table 6). Individual faculty reported authoring or co-authoring 235 peer-reviewed publications in print or in press in FY14 compared to 223 in FY13, a 5.4% year-over-year increase and an increase of 25% compared to FY12. In addition faculty reported the results of their work in abstract form on 108 occasions, and 32 faculty served as invited lecturers, speakers, or visiting professors on 135 occasions, for an overall average of 4.2 (median 3) per participant. Clearly our faculty remains top-of-mind when looking for cutting edge speakers in anatomic pathology. In addition fourteen different faculty reported being members of 32 editorial boards, including an Associate Editor for BMC Cancer (**Dr. Celina Kleer**).

	FY12	FY13	FY14	% Change
Publications	188	223	234	4.9%
Abstracts	105	125	111	(11.2%)
Invited Lectures	101	150	136	(9.3%)
Editorial Boards	32	36	32	(11.1%)
FTEs Funded	4.5	4.0	5.4	33.8%
Research Expenditures	$4,167,734	$3,235,470	$3,497,121	8.1%

Table 6: Academic Productivity in AP, FY12-FY14

Figure 7: AP Research Expenditures, FY06-FY14

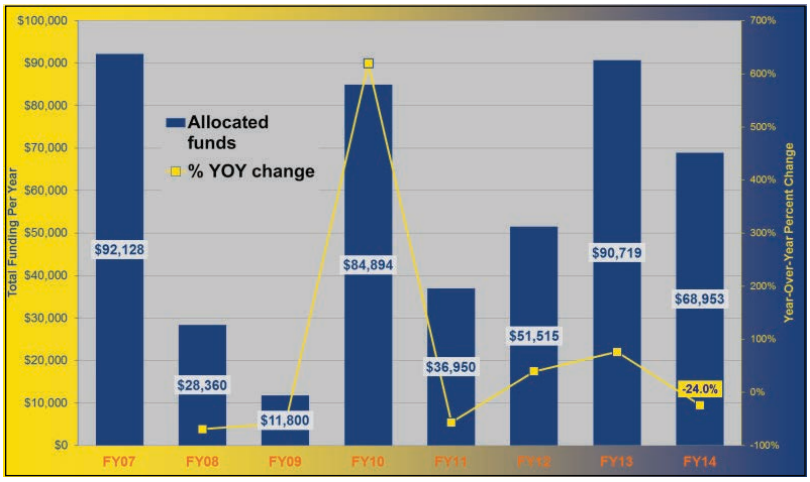


Research expenditures grew by 8.1% ($261,651) compared to FY13.

Research expenditures grew by just over $250,000, reflecting a year-over-year increase of 8.1% compared to FY13 (see Figure 7). This was attributed in large part to the early successes of four junior faculty who increased funding over the previous year through foundation grants and a new R01 that collectively accounted for over $450,000 in research expenditures. This more than off-set losses that resulted in large part from the departure of two well-funded physician-scientists who either left the institution or retired. Despite the challenges of the

extramural funding climate, research expenditures have been relatively stable for a decade (see Figure 7). Indeed research expenditures in FY14 exceeded those in FY04 by 37.9%. The total number of FTEs funded through extramural sources grew to 5.4, the highest number since at least FY06. Maintaining current levels of funding in today's environment reflects the remarkable success of our laboratory investigators, all of whom also have substantial commitments to patient care. Addition of young clinician scientists like **Drs. Evan Farkash, Paul Harms, Jeff Hodgin**, **Rohit Mehra**, **Scott Tomlins,** and **Sriram Vinneti** 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.

Figure 8: AP Project Funding, FY07-FY13



Funding for AP projects grew in FY13 compared to FY12 to a total of $90,719, the second highest budget in the seven year history of the program.

AP funding accounted for an additional $68,953 allocated in support of projects in which AP faculty and trainees served as Primary Investigators (see Figure 8). This reflects a 24.0% decrease compared to FY13, but a 33.9% increase compared to FY11. Funding this year included not only important translational projects focused in large part on molecular profiling of solid tumor malignancies, but also a unique and innovative project exploring use of a smart phone-based ultrasound imaging system in a medical examiners setting.

We hosted our 5th Annual Research Day on January 11, 2014 in collaboration with Hematopathology and Molecular Pathology. The day included 26 abstracts presented as posters (19) and platforms (7). Our Keynote Speaker was **Dr. Brigitte Ronnett** from Johns Hopkins University School of Medicine. The target audience was departmental trainees and faculty with the goal of increasing collaboration and projects. All but three (92%) of the presented abstracts had trainee authors, including house staff as well as graduate and post-doctoral students.

Tom Giordano

The Molecular Pathology Research Laboratory (MPRL), under the direction of **Dr. Tom Giordano**, continues to be an important asset for AP faculty. Since the last annual report, work performed in the MPRL has supported publication of 20 manuscripts in high impact journals, in addition to four abstracts presented at USCAP(3) and ASCO (1).

As before, most of the projects in MPRL have 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 additional to all the SPORE programs at the University. As noted in the last few reports, there has been an increased demand for more sophisticated assays, such as quantitative IHC using the AQUA platform, FISH and ISH. The expectation of the MPRL is that requests for assays of this sophistication will become the norm rather than the exception over the next couple of years. This year, with the help of departmental funds and the Breast Oncology program, we have upgraded the software capability to offer image analysis.

A primary research interest of **Dr. Dafydd Thomas'** has been the use of the AQUA platform to identify stem cells in breast cancer resection and correlate their expression with distant temporal metastasis. He has also been attempting to define an AQUA signature to intrinsically subtype breast cancer specimens. This will have a profound effect on breast cancer management, as the oncologists want to stratify patients into treatment groups.

Drs. Scott Owens and **Rajiv Patel** were promoted to Associate Professor effective September 1, 2013. **Drs. Xin Jing** and **Michael Roh** were approved for promotion to Associate Professor and **Dr. Andrew Lieberman** to Professor effective in the first quarter (September 1, 2014) of FY15.


Scott Owens


Rajiv Patel


Xin Jing


Michael Roh


Andy Lieberman

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. For example, 14 residents and 11 fellows served as authors or co-authors for 24 different abstracts presented at the 2014 Annual Meeting of the USCAP in San Diego, CA.

Fellowships in cytopathology (2), dermatopathology (2), forensic pathology (2), gastrointestinal pathology (1), genitourinary (1), gynecologic (1), pediatric (1), and surgical pathology (3) were filled by competitive candidates in the 2013-2014 academic year. Responsibility for the dermatopathology fellowship transitioned to a new Program Director, **Dr. Aleodor Andea**.

A fellowship in forensic pathology, under the direction of **Dr. Jeffrey Jentzen**, 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.

Active and emeritus faculty in AP continue to play significant roles in the medical school, accounting for 1,143 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** continue to serve as co-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 518 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.

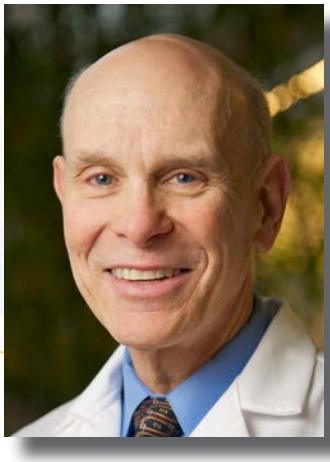
Nearly all faculty in AP participate in supporting an impressive array of multidisciplinary conferences including Tumor Boards for bone and soft tissue, brain, breast, endocrine oncology, gastrointestinal, genitourinary, gynecologic, head and neck pathology, liver, pediatric, and lung tumors. Faculty 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.

Four visiting professors visited our department through the A. James French Visiting Professorship, each presenting a lecture and slide seminar, including **Drs. John Veinot** (The Ottawa Hospital, Hamilton, ON, Canada), **Laura Collins** (Beth Israel Deaconess Hospital and Harvard Medical School), **Brigitte Ronnett** (Johns Hopkins University), and **Jingmei Lin** (Indiana University).

Multiple faculty participated in our 7th CME workshop, *New Frontiers in Pathology,* presented in collaboration with the A. James French Society. The 2013 course was held at Rackham Auditorium and again yielded very strong attendee evaluations for the quality and content of the program. **Dr. Victor Reuter** from Memorial Sloan Kettering Cancer Center served as guest faculty and the A. James French Lecturer.

Our CME offerings included the 5th year of *Advances in Forensic Medicine and Pathology*, hosted in collaboration with the Washtenaw County Medical Examiner's Office in May 2014 (Kensington Court, Ann Arbor, MI) with 100 attendees – a new attendance record. Feedback was extremely positive and this will continue to be an annual component of our CME programs.

Division of Clinical Pathology



David F. Keren, MD
Professor of Pathology
Director, Division of Clinical Pathology

FACULTY UPDATES

This past year **Dr. Jeffrey Warren** stepped down as Director of the Division of Clinical Pathology after almost twenty years of service. Dr. Warren is well known for his work in Immunopathology and Inflammation. In his years of service, he recruited a stellar faculty that has enriched the services we provide our patients and the education that our Clinical Pathology Residents and Fellows (Blood Bank/Transfusion Medicine, Hematopathology, Histocompatibility, and Molecular Pathology) receive. During the past few years, he adroitly transitioned the laboratory through the initial Soft upgrade and Outpatient MiChart implementation. Dr. Warren will continue to serve as the Medical Director of Diagnostic Immunology, as the Liaison to the Formulary Committee, and to work on his research on immunodeficiency disease.

Jeffrey Warren

Duane Newton

Dr. David Keren, formerly serving as the Associate Director, was appointed as the Director of the Division of Clinical Pathology, and **Dr. Duane Newton** was appointed as the Associate Director of the Division of Clinical Pathology.

Promotions

Dr. Lauren Smith was promoted to Associate Professor effective in the first quarter (September 2013) of FY14.

Lauren Smith

New Faculty

Dr. Dan Boyer (Assistant Professor) joined the faculty in September, 2013 with a focus in Hematopathology. Dr. Boyer graduated from Northwestern University with two degrees – a magna cum laude BA in Molecular Biology and a cum laude Bachelor of Music for Cello Performance. He received his MD and PhD from Vanderbilt where he also did his postdoctoral fellowship. He did his Residency in Anatomic Pathology and Fellowship in Hematopathology at Massachusetts General Hospital where he had the valuable experience of viewing challenging lymph node specimens with Nancy Harris. In their Flow Cytometry Laboratory, he worked with Fred Preffer to develop improved flow assays for myelodysplastic syndromes and plasma cell neoplasms.

Dan Boyer

Two other recruitments were successful during the last two quarters of FY14. **Dr. Noah Brown** (Assistant Professor) joined us as an Associate Director of the Molecular Diagnostics Laboratory in July, 2014; and **Dr. Lee Schroeder** (Assistant Professor) joined us as an Associate Director of Clinical Chemistry in September, 2014.

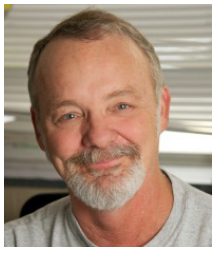
MAJOR FY14 EVENTS

Informatics

This year, the staff and faculty of the Clinical Pathology laboratories have successfully tackled the challenges of implementing three major changes in our informatics utilization: the University of Michigan Health System MiChart Inpatient go-live, the ongoing Soft laboratory information system, and the training module for MasterControl. The coordination of the MiChart and Soft implementation weighed heavily on the shoulders of Pathology Informatics (Dr. Ul Balis, Director; Kathy Davis, Manager; Cybil Rowerdink; Bill Hubbard and many others).

Ul Balis

Kathy Davis



Bill Hubbard

Without the extraordinary efforts of our laboratory managers, supervisors, and technologists, these projects would not have been possible. These efforts included managers and supervisors being on-site at all hours for upgrades and numerous unforeseen challenges. While these efforts will eventually benefit our efficiency and our ability to effectively use the extraordinary amount of data generated daily, they require ongoing commitment from our staff for training and continuing refinement of the software itself.


Kristina Martin


Brian Smola


Oliver Bichakjian

The adoption of the MasterControl training module, along with ongoing efforts to ensure proper use of the system, has been led by **Kristina Martin** (CP) and **Brian Smola** (AP) who recently were joined by **Oliver Bichakjian** (IT) to provide informatics support. The new module provides focused training based on specific tasks that include an examination to provide real time documentation of ongoing competency.

Regulatory Issues

Suzanne Butch, our Compliance Coordinator (Chief Technologist, Blood Bank/Transfusion Medicine Service), organizes the certifications of the 39 CLIA certificates managed by the Department of Pathology. The locations vary in size, volume, and test menu. These include a free clinic run on Saturday afternoons in a nearby town, laboratories in middle and high schools, off-site physician office clinics and surgery centers, as well as laboratories on the main medical campus and two off-site laboratories at the Traverwood location. The major accrediting agency for the high complexity testing performed at the Ann Arbor sites and the medical campus is the College of American Pathologists (CAP). Waived, point-of-care testing at the hospital campus is accredited by the Joint Commission. Off-site clinics that perform moderately complex testing are accredited by the Commission on Laboratory Accreditation (COLA). Waived testing sites are periodically inspected by the Centers for Medicare and Medicaid Services (CMS). Additionally, the Department of Pathology participates in voluntary accreditation programs including the American Association of Blood Banks (AABB), the American Society for Histocompatibility and Immunogenetics (ASHI), and the Foundation for the Accreditation of Cellular Therapy (FACT). On-site inspections by accrediting agencies are performed approximately every two years with a CAP self-inspection in the alternative years. This year, in addition to our internal self-inspection and external inspections from outside agencies, we performed a CAP inspection of another facility; thereby providing us with another learning opportunity.


Suzanne Butch

We successfully retained our accreditation by all of the aforementioned agencies, as well as maintained our California and Florida licenses for this past year. We are currently seeking New York State licensure for our molecular testing laboratories.

Molecular Test Committee

The Molecular Test Committee (MTC) was formed by hospital leadership and the Chairs of the Departments of Pathology and Pediatrics to provide a cohesive vision of the rapidly expanding field of Molecular Diagnostic testing by minimizing duplication and enhancing collaboration. It includes the Molecular Diagnostics Laboratory, Michigan Molecular Genetics Laboratory, Michigan Center for Translational Pathology (MCTP), Paradigm, and other laboratories offering individual molecular testing including Cytogenetics, Dermatopathology, Histocompatibility, and Microbiology. The vision statement indicates that the University of Michigan Hospital and Health Systems will be a principal provider of cost-effective molecular diagnostic testing that is supported by reasonable evidence-based medical literature. To achieve this, MTC has established a collaborative forum to engender trust and collegiality, and to foster efficient and innovative development of new, clinically relevant molecular testing. The group meets quarterly to:

1. Share current lists and techniques planned for current and future molecular testing.
2. Understand the mechanism to determine how tests are chosen for development (financial, local and national patient need, faculty interest, required space/equipment, and the challenge of regional and national competitors).
3. Develop a mechanism to determine which laboratory is most suitable to develop and perform specific new tests.
4. Identify opportunities for collaboration and to minimize duplication of tests and resources.
5. Prepare a unified capital equipment investment plan.

With the likelihood that all but the core Pathology laboratories will move to the North Campus Research Center (NCRC) as part of the Pathology Relocation and Renovation (PRR) project in the near future, the MTC is looking at opportunities to co-locate our molecular laboratories with common techniques and interests to improve their short and long-term efficiency while meeting the needs of our patients, faculty, and staff. To that end, MTC has begun an analysis of a combined service now to address faculty and staff concerns and to optimize effective use of space as the Department of Pathology plans for a shift to the new location.

Genetic Testing Resource and Quality Consortium

The Genetic Testing Resource and Quality Consortium (GTRQC) is a Collaborative Quality Initiative (CQI) between Michigan laboratories with genetic testing menus and Blue Cross Blue Shield of Michigan. **Drs. David Keren** and **Scott Owens** are Co-Directors and **Lynn McCain** is the Project Manager. The GTRQC is a quality initiative to evaluate and improve the quality of care for patients receiving genetic testing and to address the exponential growth in genetic testing. The goals of this collaborative are to:

Scott Owens

Lynn McCain

1. Determine which new tests have clinical validity and clinical utility.
2. Improve the quality of molecular diagnostic testing by reducing unnecessary testing, fostering use of best practices when ordering and performing needed tests.
3. Educating providers and equipping them with resources and expert analysis of outcomes research to test, advise and treat their patients.

These concepts are consistent with the recent FDA emphasis on demonstrating the clinical validity and utility of laboratory developed tests. During the past year, the GTRQC concept has been presented at 10 major sites across the state and has achieved widespread support.

Clinical Pathology Quality Assurance (CPQA) Quarterly Staff Meetings

CPQA quarterly staff meetings were established this year as a mechanism to improve employee engagement and to enhance involvement of staff with Lean projects. The meetings consist of an informational component where staff is apprised of the current financial situation of the University of Michigan Hospital and Health Systems, the Department of Pathology, and the Clinical Laboratories. In addition, an educational component is presented encouraging the use of Lean techniques. The major features of the meetings are presentations of Lean projects by two of three clinical laboratories. Our first meeting was held March 18, 2014. **Dr. Kathleen Cho** presented an overview of the PRR Project plan and **Marty Lawlor** updated the attendees on finances. There were two Quality Assurance presentations. **Priti Patel** reported about Lean studies on slide preparations in Hematology that resulted in improved service to our patients while dramatically decreasing work found to be superfluous. **Andrea Hawk** highlighted investigations into a problem with incubator temperature control of a water bath used in Cytogenetics. The CPQA meetings are all videotaped and shown to the afternoon and midnight staff as well as the staff at Traverwood. Dr. Keren attends those meetings to respond to comments by staff.

Laboratory Ambassadors

The Laboratory Ambassador program initially began in 2007 as a way to connect Nursing and Pathology. This earlier format had monthly group meetings and one-on-one meetings with paired nurses and lab ambassadors. The program started to lose focus and participation a few years ago. Two laboratory technologists, **Jeana Houseman** and **Christy Konieczki** (co-coordinators), reinvigorated the program in October 2013. The new format is an active email group where lab and nursing staff can ask and answer questions. When a problem is brought forward that needs more dedication, the co-coordinators set up meetings with a small working group of interested ambassadors. To date, there are 16 laboratory ambassadors and 28 nurse ambassadors involved in the program; and has had tremendous outside support from Pathology staff, including Carol Young and Kristina Martin, and from nursing administrator Barb Wetula.

Jeana Houseman

Christy Konieczki

THE LABORATORIES

The University of Michigan Health System (UMHS) Clinical Pathology Laboratories encompass the following areas:

- Specimen Processing and the Sendout Laboratory
- 20+ UMHS off-site limited function laboratories associated with ambulatory care units, phlebotomy stations, and point-of-care testing facilities
- 24 hours/day, 7 days/week inpatient Phlebotomy Service
- Full service hospital-based laboratories
  - Blood Bank/Transfusion Medicine Service – Therapeutic Apheresis/Hematopoietic Progenitor Cell (HPC) Procurement Unit, FDA-approved Good Manufacturing Process-compliant HPC Processing Laboratory, and an Immunohematology Reference Laboratory
  - Chemical Pathology – Special Chemistry, Automated Chemistry, Immunology, Toxicology-Therapeutic Drug Monitoring, Endocrinology, and UMHS-wide point-of-care testing oversight
  - Cytogenetics – routine Cytogenetics, Microarray Cytogenetics, and Fluorescence In-Situ Hybridization (FISH) testing
  - Hematology – Special Hematology, Automated Hematology, Flow Cytometry, and Coagulation
  - Histocompatibility-Microbiology/Virology – Molecular Microbiology
  - 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 Michigan Molecular Genetics Laboratory (MMGL), Pediatrics Blood Gas Laboratories, the CLIA laboratory component of the MCTP, and Paradigm [an advanced molecular testing joint venture between the University of Michigan Department of Pathology, the International Genomics Consortium (Phoenix, AZ), and the UMHS].

Financial Performance

There has been an increase of testing activity, however year-to-year direct comparison (Table 7) are complicated by changes in billing as well as in charges. The decrease in billed tests recorded for Clinical Pathology in FY14 reflects a significant change in the billing process. In 2013, molecular testing billing was done by using “stacking” codes rather than individual test codes. This means that a test was not billed as a single item based upon its use, such as the BCR-ABL test. Rather, the individual components of the test were billed separately. For an individual test, six or seven separate bills needed to be submitted. Beginning in January of 2013, this process changed. But during the first half of FY13, the billed tests were part of the previous system which inflated the number of actual tests performed. So, the minus 1.8% in billed tests reflects this artifact. This measure will be stable going forward to FY15 allowing valid comparisons. Conversely, while the gross charges do reflect our upward trend in testing, they are also influenced by a rate increase that occurred in the last six months of FY13, and the fact that some of the FY13 charges were not posted until FY14 due to issues in the new Soft system. The expenses, however, accurately reflect the increase in testing, and the increase in FTEs reveals the fact that new testing, such as molecular, is often not automated and more complex technically and requires more interpretation than routine testing.

Table 7: Clinical Pathology Laboratories FY13-FY14

	FY13	FY14	% Change
Billed Tests	5,109,497	5,015,219	-1.8
Gross Charges	$490,563,953	$546,966,965	11.4
Expenses	$72,163,336	$73,655,845	2.1
Total FTEs	517.46	534.68	3.3

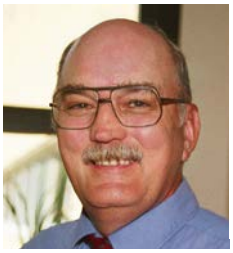
Quality Management Team

The clinical laboratories are led by our Clinical Pathology Laboratory Coordinator, **Kristina Martin**. In addition to overseeing the Laboratory Communications Committee and the Clinical Pathology Operations Committee, she has been an integral leader behind the successful implementation of the MasterControl document control system, as well as serving as the Pathology lead for the Southeastern Michigan American Red Cross Blood Drives at UMHS. She is joined by our

Compliance Officer, **Suzanne Butch**, who, in addition to her compliance duties, is the Manager of the Blood Bank/Transfusion Medicine service and led both our internal CAP inspection, as well as the 20-member team from the University of Michigan who inspected the Scott and White Baylor Medical Center Laboratories in Temple, TX this past spring. **John Perrin** leads the Clinical Pathology Quality Assurance Program and was key to the successful root cause analysis of a large scale testing problem. His efforts ensured a transparent process that put in place several practices to prevent this and similar errors in the future. **Maegan Weighman** serves as the leader of the 33-member (every laboratory domain) Laboratory Safety Committee. **Tom Morrow** provides leadership and a broad knowledge of vital information as the Assistant Administrator for Clinical Pathology Operations. Finally, much of the data we all depend upon are provided by **Christine Shaneyfelt** who leads our capital equipment tracking and acquisition, as well as financial and utilization data procurement and analysis.

John Perrin

Maegan Weighman



Tom Morrow

Christine Shaneyfelt

EDUCATION, RESEARCH, AND INNOVATION

Even with the major systemic changes occurring during FY14, the Division of Clinical Pathology was able to mount several highly successful educational efforts. Quarterly joint Hematopathology-Anatomic Pathology case review evenings were attended by Pathology residents, fellows, and faculty. There was a major commitment to ongoing participation of clinical laboratory staff, trainees, and faculty in standing departmental education programs as well as in dozens of extra departmental conferences, tumor boards, and seminars.

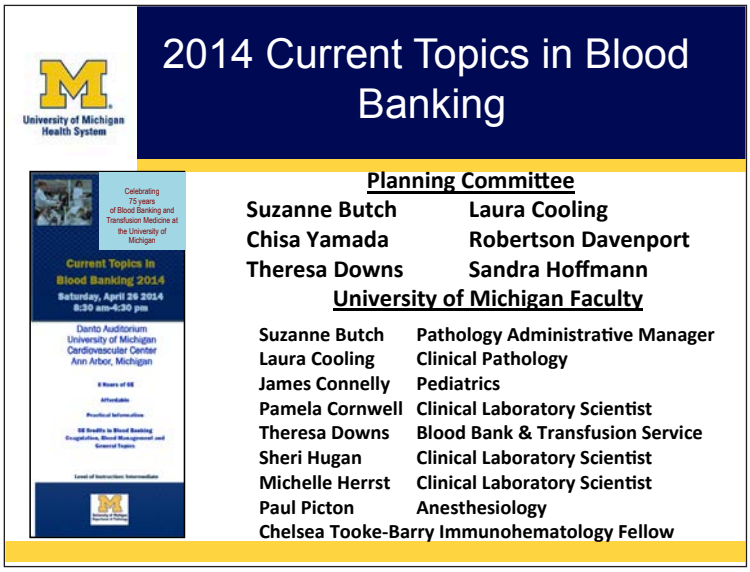
Figure 9: 2013 Clinical Symposium Agenda

In November, 2013, the Clinical Pathology Symposium (see Figure 9) provided two half-day groupings of laboratory medicine presentations featuring discussions on medical laboratory ethics by **Dr. Lauren Smith**, the laboratory's role in diagnosis and management of acute lymphoblastic leukemia by **Dr. Jo-Anne Vergilio**, the impact of the supreme court ruling on gene patents by **Dr. Jennifer Stahl**, the role of the histocompatibility laboratory in searching of new transplantation opportunities by **Dr. Daniel Ramon**, and a knowledge test on laboratory safety by **Ms. Suzanne Butch**.

The 2014 Current Topics in Blood Banking Conference, held April 2014, celebrated the 75th year of Blood Banking and Transfusion Medicine at the University of Michigan (see Figure 10). The featured speaker was Barbee I. Whitaker, Ph.D., Director of Research and Data Analysis and Director of the American Association of Blood Banking's Center for Patient Safety. The annual Harold A. Oberman, M.D. Memorial Lecture on "Immunohematology to Transfusion Medicine, 75 years of Blood Banking" was presented by **Suzanne Butch**, MLS (ASCP)CMDLM. In addition, there were presentations by the following:

- Paul Picton, MD – "A View of Transfusion from the Anesthesiologist's Perspective"
- Laura Cooling, MD – "Can A Plasma Be Used in the ED Instead of AB Plasma"
- James Connelly, MD – "Treating Primary Immune Deficiencies"
- Teresa Downs, MT(ASCP)SBB – "Who Needs Special 'Special' Blood?"

Figure 10: 2014 Current Topcs in Blood Banking Announcement



Finally, there were case studies from the trenches by Sheri Hugan, MLS(ASCP)^{CM},SBB ^{CM}, Michelle Herrst, MT(ASCP), and Chelsea Tooke-Barry, MD.

In FY14, Clinical Pathology was well represented at national and regional meetings including the American Society for Clinical Pathology, the American Association of Clinical Chemists, and the Michigan meeting of the American Society of Clinical Laboratory Science in East Lansing. As shown in Table 8, the Clinical Pathology faculty had impressive academic productivity in FY14. The 25 faculty averaged 4.8 publications (median 3) with 124 peer-reviewed publications in press or in print. Many of these appeared in high impact journals including *Blood, Molecular Cell, Nature Neuroscience, Journal of Clinical Investigation, Human Molecular Genetics*, and *American Journal of Clinical Pathology*. In addition, the faculty reported their work in 94 abstracts with 21 faculty serving as invited lecturers, speakers, or visiting professors 120 times, for an average of 5.4 (median 3) per faculty. Finally, our faculty reported service on 29 Editorial Boards including *American Journal of Pathology, Cell, Clinical Chemistry, FASEB Journal, Journal of Clinical Investigation, Journal of Hematopathology, Laboratory Investigation, Molecular and Cellular Biology, Nature, Nature Structural and Molecular Biology*, and *PLOS Genetics*.

Table 8: Academic Productivity in CP FY14

Activities	FY14
Publications	124
Abstracts	94
Invited Lectures	120
Editorial Boards	29

Michael Bachman

The Division established a Clinical Pathology Research Fund and Process led by **Dr. Michael Bachman**. The fund is designed to provide faculty and trainees in Clinical Pathology with support for high-quality research projects. Residents and fellows may apply but must identify a faculty sponsor who will oversee the project and project-related expenditures. Projects will be funded to a maximum cost of $10,000 per project with total program costs of no more than $70,000 annually. Any faculty, resident, or fellow in the Division is offered statistical support at no charge both prior to the application and when preparing an abstract or final report.

Projects are assessed and prioritized using the following criteria:

1. Aligned with institutional, departmental and division priorities.
2. Potential to expand research opportunities.
3. Likelihood to yield peer-reviewed publication(s).
4. Opportunity to increase collaboration within or across divisions.
5. Opportunity to engage pathology trainees.
6. Likelihood to yield extramural grant support (if appropriate to project).

CLINICAL PATHOLOGY FELLOWSHIPS

Blood Bank Fellowship

Robertson Davenport

Dr. Robertson Davenport is the Director of the Blood Bank and Transfusion Medicine Fellowship Program which provides experience in all aspects of blood banking in a tertiary care hospital that houses a multi-organ transplant center, including bone marrow transplantation, a large hematology/oncology service, and an extensive surgical program. The Blood Bank provides over 100,000 units of blood and components annually and includes an AABB-accredited Reference Laboratory. The Apheresis Procedures Unit affords the candidate excellent experience in therapeutic apheresis, HPC collection, and LDL apheresis. The program also provides for experience in perinatal transfusion, coagulation, histocompatibility testing, and HPC processing. Exposure to all aspects of blood procurement is provided through the cooperative participation of the American Red Cross Southeastern Michigan Blood Services. Graded assumption of responsibility for medical, administrative, and instructional activities by the fellows is encouraged. Research opportunities are provided commensurate with the fellow's interest and experience.

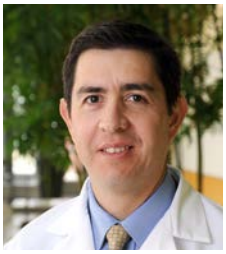
The fellow this past year was **Dr. Chelsea Tooke-Berry** who had done AP/CP at Dartmouth. She is now with a private group in Fresno, CA. Chelsea was very involved in resident teaching and also helped revise the resident on-call manual.

Hematopathology Fellowship

Lauren Smith

Dr. Lauren Smith serves as the Director of the Hematopathology Fellowship. This year's three fellows include **Drs. Maria Pletneva, Melissa Bombery** ,and **John Frederiksen.** In FY14, this group of fellows were authors on five abstracts and eight papers either published or accepted in peer-reviewed journals. An internal review of the program was submitted to the ACGME in July. The program once again filled completely with three new fellows and a fourth, Dr. Frederiksen, remaining for a second year.

Histocompatibility Fellowship



Dan Ramon

Dr. Dan Ramon serves as the Director of the two year Histocompatibility Fellowship. It is approved by the American Board of Histocompatibility and Immunogenetics. His first fellow, **Dr. Viviana Vogiatzi,** has successfully completed her final year of training.

Molecular Genetic Pathology Fellowship

Nathanael Bailey

Dr. Nathanael Bailey is the Director of the Molecular Pathology Fellowship. **Dr. Amir Behdad** and **Dr. Noah Brown** graduated as Molecular Genetic Pathology fellows in the program's fifth class (2013-2014 academic year). The new Molecular Genetic Pathology Fellow (2014-2015) is **Dr. Mark Kiel** (Michigan).

Clinical Chemistry Fellowship

Dr. David Keren is the Director of the Clinical Chemistry Fellowship that was approved this spring by the ACGME.

HEMATOPATHOLOGY LABORATORY

Hematology, Bone Marrow, Flow Cytometry, and Coagulation

Megan Lim

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 FY14. The volume of CBC testing has increased from 547,000 in FY13 to more than 600,000 in FY14. Transition to the new LIS and optimizing manpower needs to meet the changing clinical needs of the Children's Hospital and the Cancer Center are a challenge in the face of an inability to increase staff.

Clinical Hematology/Bone Marrow Laboratory

Jo-Anne Vergilio

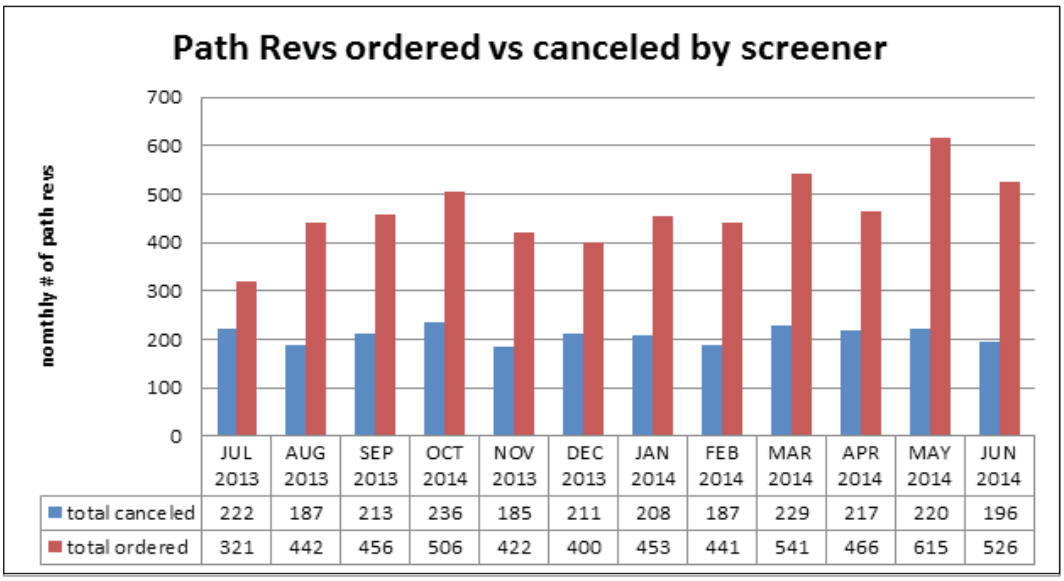
Dr. Jo-Anne Vergilio provided leadership during this difficult year, dealing with many information technology and instrument changes.

The Hematology Laboratory offers a broad-spectrum test menu that encompasses high volume automated analysis (such as complete blood counts) as well as specialized techniques (such as procurement, preparation and review of bone marrow specimens, and pathologist review of blood and body fluid smears). The volume of complete blood count (CBC) testing, a key benchmark of laboratory activity, is projected to exceed 600,000 for FY14. Dr. Jo-Anne Vergilio provided leadership during a year that presented various challenges secondary to the new laboratory information system, but that also yielded various advancements given acquisition of new instrumentation and implementation of quality process improvement initiatives.

Since the SCC implementation at the beginning of FY14, the laboratory continues to work to resolve outstanding issues and streamline operations. The Hematology Laboratory is unique since it requires both technologists and professional staff to be facile in all three of the SOFT modules (LabMic, Flow, and PathDx), and laboratory technical work requires more time/effort in each of these new systems. Staff shortages due to retirements, relocations, and internal promotions have provided additional challenges as staff are struggling to complete clinical work with the associated quality/competency measures. Little time has been able to be devoted to process improvement and/or test development.

Despite these challenges, several operational advances were achieved. The laboratory acquired Cellavision, a digital imaging device that facilitates manual peripheral smear review/differential counts and provides a system by which to archive and catalogue interesting/unusual cases for improving patient care and expanding technologist and resident/fellow educational tools. The laboratory is in the process of restructuring the marrow procurement process so as to improve the quality of bone marrow specimens. This is being accomplished currently by engaging and educating clinical providers with future plans to implement regular feedback of specimen quality to the proceduralists. Various members of the laboratory continue to work with providers in Adult and Pediatric Hematology-Oncology, as well as with students in Industrial Engineering, in order to minimize the turnaround time of STAT blood counts/smear reviews that are needed for medical decisions involving infusion patients in ambulatory clinics at the Cancer Center and C&W. A new ESR instrument is also being evaluated that uses purple top (as opposed to black top) tubes that will improve process, facilitate patient care, and lower cost given ongoing problems associated with these particular specimens.

Figure 11



Through a Lean project, they optimized requests for Pathologist's interpretation of blood/body fluid smears. As shown in Figure 11, if requests for Pathologist Review (Path Revs) are not appropriate, it increases costs and the turnaround time. We altered the policy to allow technologists to prescreen MD request slides. Over 40% of all order requests received each month are canceled saving time and decreasing the cost to the institution and patient. Technologists are assessed monthly as an audit to ensure quality.

Employee engagement has also been a focus of this year's efforts. The Laboratory used a focused engagement survey to better understand and address strengths and weaknesses in the laboratory. A "What's on your mind?" program was implemented that allows for an annual one-on-one meeting with the Medical Director. The Administrative Manager began

working one evening and one midnight shift per month to better understand the challenges of these shifts. Staff is being actively engaged in processes that directly affect them (e.g. Cellavision implementation, bone marrow procurement, and quality assessment). Competency assessment has been expanded and a continuing education program has been implemented for technical staff. Sections of the laboratory were also reorganized to streamline operations and improve the work environment.

Coagulation Section

Steve Pipe

Under the leadership of **Dr. Steve Pipe**, the following are accomplishments, with the assistance of the Senior Medical Technologist **Sara Gay**, in the Special Coagulation Laboratory to advance and enhance the services offered by this clinical laboratory and to contribute scholarly activity:

- Validated ¾ volume testing for our anti-Xa unfractionated heparin assay, saving the laboratory approximately $34,000 annually.
- Using the fluorimeter to measure both fluorescent and ELISA-based testing for consolidation onto 1 analyzer and test platform.

Sara Gay and Dr. Pipe continue participation on the Anticoagulation Subcommittee for the Pharmacy and Therapeutics Committee which has been highly productive in establishing a full complement of clinical practice guidelines for UMHS. They transitioned all heparin nomogram-based monitoring to anti-Xa assays and transitioned argatroban nomogram to anti-IIa monitoring instead of PTT. They are using a more sensitive Epinephrine reagent for the platelet aggregation and secretion testing which has led to fewer falsely abnormal levels reported.

Scholarly Activity

Dr. Pipe works on a research committee utilizing hospital databases to track compliance and complications related to anticoagulation within UMHS. Previous abstract presentations are in draft form for publication.

They were awarded the Siemens clinical site study for the evaluation of the CS-2100 and CS-5100 coagulation analyzers (approximately $100,000 site award to Department of Pathology).

Dr. Pipe contributes lectures on principles of hemostasis and thrombosis and coagulation laboratory assays to the M2 Hematology sequence for the Medical School and within the School of Dentistry. Dr. Pipe presented at the ASCLS-Michigan annual meeting on coagulation testing. He provides lectures to Hematopathology Conferences and supervises special coagulation testing interpretations with pathology residents, Blood Bank fellows, and clinical hematology fellows. Dr. Pipe and Sara Gay provide oversight for a Coagulation Rotation for the HemePath Fellows.

For the coming year, the laboratory plans to implement Xa method for the new anticoagulant Rivaroxaban and possibly Epixaban if calibrators and controls become available commercially. In addition, the laboratory will implement a Chromogenic Factor VIII (and possibly IX) assay that will be more accurate in determining factor levels in patients being treated with the new PEGylated factor replacement products coming on the market in fall of 2014.

Clinical Flow Cytometry Laboratory

The Clinical Flow Cytometry Laboratory, under the leadership of **Dr. Lloyd Stoolman**, increased test volume from 61,246 in FY13 to 72,165 in FY14 while simultaneously implementing SoftFlw (the new laboratory LIS module for Flow Cytometry). LIS performance issues impacted laboratory work-flow initially; however, collaborative efforts yielded 90% recovery of pre-Soft turnaround time performance by the fourth quarter despite the 17.8% growth in caseload and the 25% increase in clerical overhead due to SoftFlw. Ongoing redesign efforts with Soft are focused on reducing inefficiencies and incorporating the capabilities of the UM Flow Portal. The later, designed by Dr. Stoolman and **Joshua Jacques** (Flow Cytometry IT specialist), provides near instantaneous access to flow cytometry reports, histograms, list mode files, and the EMR. In addition, the Portal supports training and scholarship with keyword and free-text search of completed reports, case collections, and links to relevant literature. Currently, bridging software developed by Mr. Jacques synchronizes SoftFlw with the UM Flow Portal minimizing disruption on the clinical service while more robust integration is pursued.

Lloyd Stoolman

The laboratory is also developing polychromatic 8-10 color flow panels. A 9-color plasma cell panel is operational and a 10-color T-cell panel is in process. Joint assay development with our prime vendor is underway that will accelerate

conversion of remaining assays to state-of-the-art polychromatic panels. The extraordinary dedication and effort of our technologists, led by the Hematology Laboratory Manager, **Usha Kota**, IT specialists, trainees, and faculty are carrying the laboratory through this challenging period.

In addition to Dr. Stoolman's work with Flow Cytometry, he has developed an online slide collection for residents, fellows, and interested parties outside the institution. It currently contains 3,500 virtual slides and is accessible from computer workstations, tablets, and smartphones. It has the capacity to grow to over 10,000 slides. He has also developed a Hematopathology Slide Library with searchable cases linked to reports, as well as a Virtual Microscope Teaching Project for Health Sciences which consists of a collection of virtual slide servers, teaching laboratory websites, and personnel that jointly support Virtual Microscopy in teaching programs on the Medical Campus. The custom Flow Cytometry sign-out, management, and educational tools were developed by Mr. Jacques and Dr. Stoolman.

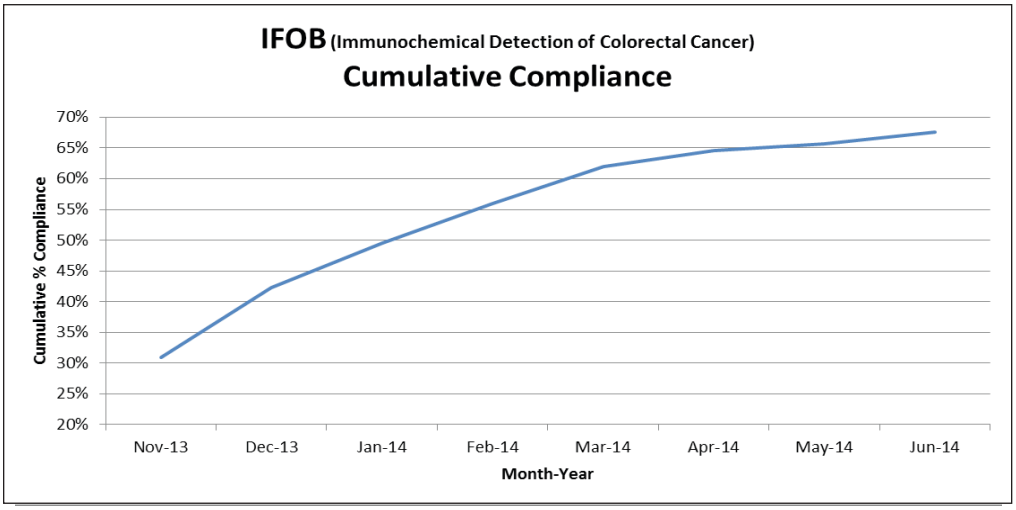
Chemical Pathology and Clinical Immunology Laboratory

Don Giacherio

The Chemistry Section, under the leadership of **Dr. Donald Giacherio**, and the administrative management of **Sue Stern**, experienced an approximate 2.5% increase in overall testing volume this year. In addition to the underlying need to accommodate continuing modifications to our new Soft lab information system and implementing the inpatient MiChart, the laboratory has moved forward with a plethora of new tests. In addition, all procedures are now on MasterControl with appropriate training modules in place. The outstanding efforts of **Sue Stern, Merry Muilenberg**, and all the lab supervisors and staff on this project are gratefully acknowledged.

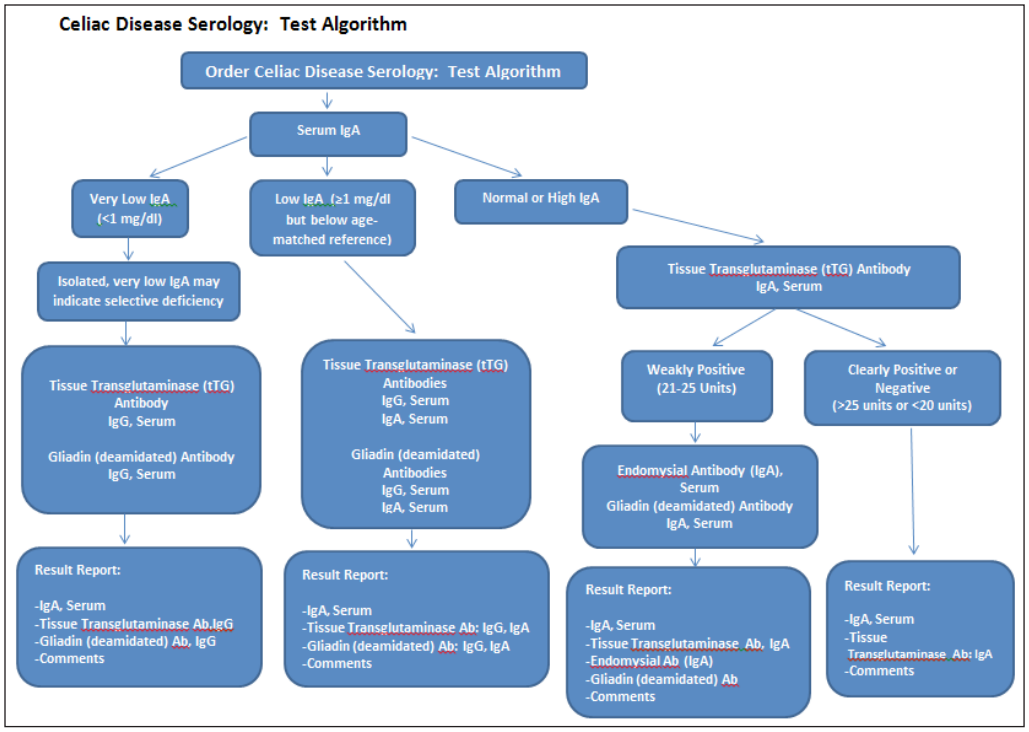
Despite this challenge, the Chemistry section has achieved an impressive list of accomplishments in FY14. They implemented the intra-operative PTH testing in the operating rooms of Children's and Women's Hospital, worked with the Formulary Committee's recommendation, and began Procalcitonin testing for the early diagnosis of sepsis. The HVA, VMA, and 5-HIAA assays have been validated on the LC-MSMS, and the laboratory evaluated and acquired a Beckman Acess II analyzer for erythropoietin and SHBG testing. A major effort was the employment of a new immunochemical fecal occult blood (IFOB) test for colorectal screening resulting in a remarkable improvement in both the quality of the test and in the compliance of testing by our ordering physicians. The previous guaiac method for detecting blood in the stool as a detection of colorectal cancer requires the patient to adhere to several diet restrictions, as well as to collect three separate stool samples. Due to this complexity, we had low compliance (< 20%). The IFOB method only requires a single sample, no diet restrictions, and has a higher sensitivity. Physicians order the test when the kit is handed to the patient. Pre-stamped envelopes provided to the patient will be returned to the laboratory where the test will be run. As shown in Figure 12, we have documented a dramatic improvement in compliance.

Figure 12



In the Clinical Immunology Laboratory, directed **by Dr. Jeff Warren**, an evaluation of the celiac disease testing showed a lack of consistent ordering of the tests used: IgA and IgG anti-tissue glutaminase (tTG) and IgG and IgA anti-deamidated Gliadin. As a result, a celiac disease algorithm was presented to and approved by the Lab Formulary Committee. In addition, the celiac disease antibody testing, along with antiphospholipid antibody tests, were evaluated for use on the automated BioPlex analyzer. An automated immunoassay was validated to replace the manual anti-Thyroglobulin test. The new Binding Site SPA analyzer was validated to remediate the problem of proper dilution for the serum free light chain test.

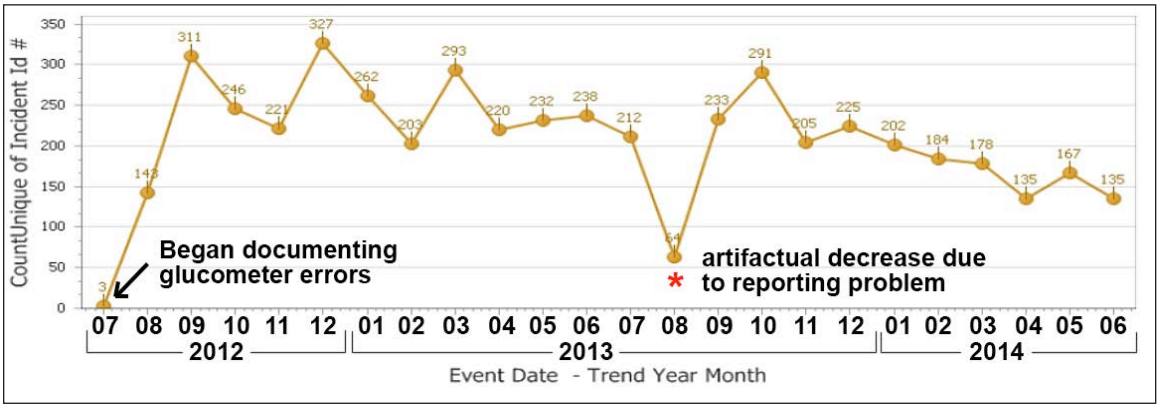
Figure 13



The Clinical Chemistry Laboratory has continued its leadership role in Point of Care (POC) testing both within the hospitals and at the off-site ambulatory care units (ACUs). Chemistry staffs the laboratories within the Emergency Departments, and this year was able to discontinue the obsolete CK-MB testing while continuing 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. In addition, the Chemistry Laboratory validated the use of POC Prothrombin time and INR testing for the new stroke center. As part of its POC mission, the Chemistry Laboratory obtained new hematology analyzers for the operating room laboratories and evaluated POC Drugs of Abuse (DAU) testing for pain management.

During FY14 we found that after MiChart was implemented, a change occurred in how the patient was identified (see Figure 14). In order to correlate billing information relative to the specific patient stay, the CSN number on the patient's wristband is used rather than the MRN. The patient's wristband was changed so that the glucometer CSN number is now a 1D barcode versus the MRN's 2D barcode. Since making this change, numerous errors have occurred where the MRN was manually entered by mistake into the RAALS laboratory middleware. These errors caused a delay in results being reported to the patient record. We reviewed this problem with nursing leadership and, as a result, the nurse educators have refocused training on this aspect and we continue to see a decrease in the number of errors. In the coming months it's anticipated this will continue to decrease because our new glucometers have screens that display the patient's name when entered correctly.

Figure 14.



This year, through the efforts of **Denise Twarkowski**, new glucose meters have been validated and deployed throughout the hospital. The laboratory is currently working with nursing staff and the company to further improve the compliance with its use and speed of data recording in MiChart.

The Chemistry Section continued its efforts at utilizing Lean principles to improve our efficiency in the laboratory while engaging its talented staff. They completed reorganization of the refrigerator storage for samples, re-worked the sample handling flow for DAU screens that required GC-MS confirmation, altered lunch and break coverage for the ED labs, and formed workgroups to discuss bringing additional help for peak workflow periods in the automation/sample distribution area.

The lab continues its significant role in education. Pathology residents on a monthly rotation through the laboratory met daily with Drs. Giacherio, Warren, Keren, or Smith and spend additional time with the supervisory staff and senior clinical technologists. Six medical technology students spent four weeks each rotating through the lab sections. In addition, the lab hosted Pediatric Endocrinology (Special Chemistry) fellows for one week of laboratory testing exposure, and two Allergy Fellows for a two day exposure to IgE allergy testing and serum protein electrophoresis interpretations.

During the coming year, we will acquire a second BioPlex analyzer and move the celiac testing (tTG and Gliadin), along with Syphilis serology testing, on to that platform. The CH50 assay will be moved to the Binding Site SPA assay and will move the anti-Thyroglobulin automated test back to the main Chemistry Laboratory. The DSX analyzer will be moved to the Special Chemistry area and be used for the Quantiferon TB test that we currently send out. In addition, we will evaluate and acquire either a new Diasorin, Abbott, or Roche Immunoassay analyzer for low volume esoteric immunoassay testing currently performed on a nine-year-old Siemens Immulite 2000 analyzer and eight-year-old Roche Integra analyzers. The 17 hydroxyprogesterone assay will be developed on the LC-MS, and we will begin development of testosterone and estradiol by LC-MS. Finally, two RFPs were put out for Hb A1c testing and automated esoteric immunoassay testing.

Clinical Microbiology/Virology Laboratory

Duane Newton

Michael Bachman

Dr. Duane Newton is the Director of the Clinical Microbiology/Virology Laboratory. **Dr. Michael Bachman** serves as the Medical Director of the Molecular Microbiology Section within the Clinical Microbiology/Virology Laboratory.

The activities with the greatest impact on the laboratory in the past year have revolved around information management: SOFT post go-live, incorporation of Master Control for document handling, and MiChart inpatient go-live. Efficiencies within the lab continue to be identified in order to better focus activities on those which are most useful clinically, as well as best utilize the new IT tools.

Major developments over the last year include:

- LEAN process assessments of multiple benches including Specimen Processing, urine cultures, wound/body fluid cultures, respiratory cultures, and stool specimen testing
  - Working to streamline/consolidate procedures
  - Eliminate waste (operational and clinical)
  - Evaluation of multiplex assay for detection of bacterial, viral, and parasitic pathogens from stool samples
  - Conduct cost/benefit analysis for incorporation of multiplex assay
- Susceptibility testing system RFP review
  - RFP submitted, responses reviewed, evaluation conducted, system selected
- Management of blood culture and AFB broth culture bottle inventory issues
  - Worked with clinical staff regarding utilization
  - Worked with Material Services to manage inventory
  - Worked with vendor to manage supply/demand expectations
- MALDI verifications
  - *Nocardia*, mycobacteria, anaerobes
- LEAN process assessments in Molecular Section
  - Acquisition and optimization of additional space
  - Reconfiguration of work schedules (10 hr. shifts) to better handle workload, overtime reduced
  - Online consolidation of QC records
  - "Real-time" testing of specimens for respiratory pathogens
- Staffing challenges and organizational structure
  - Multiple staffing vacancies have emerged and we are working to determine the optimal staffing mix and structure for the lab

- Methodology changes in Molecular Section that reduced turnaround time
  - Respiratory pathogens (Prodesse to Biofire and Focus)
  - *Bordetella pertussis/parapertussis* (BD to Focus)
  - *C. difficile toxin* gene PCR (BD to Focus)
  - HSV testing on lesions (culture to BD Viper)
  - HPV (Digene to Roche)
  - HCV genotyping (Siemens to Abbott)

All of the above are having significantly positive impacts operationally and clinically. It is worth noting specifically that clinical feedback regarding the availability of "real-time" testing and reporting of respiratory virus results has been especially positive. These changes have improved the clinician's ability to rapidly make management decisions – therapeutic and infection control – which have improved health system efficiencies. There is a desire to try to quantify these benefits through a study with Infectious Diseases and Pharmacy, planning for which is ongoing.

Furthermore, our MALDI outcomes study was published last fall. An additional study has been published this past spring by our group looking at the impact of MALDI and rapid intervention for the identification of coagulase-negative staphylococci as contaminants from blood cultures. We showed that vancomycin use was reduced (cost savings and potentially preventing resistance), and testing for vancomycin levels was also reduced. As in previous years, 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 for notification of laboratory managers of problems that might occur through the total testing process. These forms are reviewed by the Senior Technologists trend monitoring and results communicated during section meetings, then are 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.

In addition to the clinical duties, the laboratory participates in a wide variety of ongoing research projects involving studies on:

- Severe H1N1 Influenza A in the United States
- Respiratory virus detection
- Characterization of viral pathogens and subsequent immune response in children with clinical respiratory tract infections
- H. influenzae genes associated with COPD
- Epidemiology of bacterial pathogens of gastroenteritis
- Clinical and molecular characterization of C difficile
- Evaluation of placentas with chronic villitis
- Respiratory viruses and their role in reactive airways diseases
- Epidemiology of carbapenemase-producing Enterobacteriaceae
- Community acquired-MRSA in pediatric patients
- Real-time PCR detection of pathogens compared to conventional methods
- Pseudomonas fluorescens in cultures of respiratory specimens
- Impact of MALDI-TOF and stewardship intervention on outcomes in pediatric bacteremia and candidemia

- Cryptococcosis in patients with end-stage liver disease and liver transplants
- Clinical features and outcomes in immunocompromised and non-immunocompromised adults with RSV
- Microbiome of hospitalized patients from inpatient screening program
- Effects of multiple cervical inoculations of *Chlamydia trachomatis* and the pelvic inflammatory disease in the Baboon

Noah Brown

Amir Behdad

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. Two Molecular Pathology fellows, **Noah Brown** and **Amir Behdad**, completed six-week rotations that included assay development projects. Six medical technology students completed their clinical rotations. 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 senior technologists attended one or more regional or national scientific meetings during the year. Several other staff members attended national and regional scientific meetings of interest. All of the above-mentioned individuals were involved in presenting posters at national meetings, and 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 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

Robertson Davenport

Laura Cooling

Chisa Yamada

Dr. Robertson Davenport continues to provide strong leadership for the Blood Bank and Transfusion Medicine Section. **Dr. Laura Cooling** serves as the Associate Medical Director and Director of the Cell Therapy Laboratory. **Dr. Chisa Yamada** serves as the Assistant Medical Director, and this past year, Dr. Yamada also served as Co-Director of Plasmapheresis. While the change in laboratory information systems has made comparing current activity with previous years challenging, overall laboratory activity, with the exception of the Cellular Therapies Laboratory, was flat to slightly decreased. This is mainly attributable to effort of the medical staff in containment of laboratory utilization.

Total activity in the Main Laboratory decreased slightly. In part, this reflects utilization control activities of the clinical services. However, billing problems related to the laboratory information system resulted in some under billing of both tests and products.

Table 9: Main Blood Bank Laboratory Activity

Main Laboratory	FY13	FY14	% Change
Testing	287,235	273,918	-4.6
Blood Products	107,692	100,887	-6.3

Table 10: Activity in the Cellular Therapies Laboratory Increased in All Categories

Cellular Therapy Lab	FY13	FY14	% Change
Collections Processed[1]	465	538	15.7
Bags Frozen	699	785	12.3
Transplants, Autologous	143	161	12.6
Transplants, Allogeneic	35	37	5.7
Transplants, Unrelated	74	77	4.0
Transplants, Total	252	275	9.1

[1] Includes units received from outside centers.

Overall activity in the Reference Laboratory decreased slightly, but there was an increase in the number of complex procedures performed.

Table 11: Overall Activity in the Reference Laboratory

Reference Laboratory	FY13	FY14	% Change
Antibody Identifications	1045	1084	3.7
ABO Resolution	96	146	52
MLabs/Referrals	28	27	-3.6
BMT	661	425	-35.7
Eulates	187	188	0.5
Adsorptions	309	365	18.1
Titers	144	213	47.9
Total activity[2]	3029	2938	-3.0

[2] Includes procedures not listed above.

Overall activity in the Apheresis Procedure Unit decreased slightly. However, there was an increase in HPC collection associated with increased activity in bone marrow transplantation. Additionally, MiChart implementation has significantly increased charting time required of the nursing staff.

Table 12: Overall Activity in the Apheresis Procedure Unit

Apheresis Procedure Unit	FY13	FY14	% Change
HPC Cell Collections	407	418	2.7
WBC Apheresis	11	25	127.3
RBC Exchange	43	54	25.6
Platelet Apheresis	6	1	-83.3
Plasma Apheresis	1213	1217	0.3
LDL Apheresis	294	230	-21.8
Total Procedures[3]	2206	2133	-3.3

[3] Includes procedures not listed above.

Professional billing activity increased slightly. This reflects increased physician activity in therapeutic apheresis and peripheral blood stem cell collection.

Table 13: Professional Billing Activity

Professional Billing	FY13	FY14	% Change
Gross Charges	$726,476	$775,794	6.8
Charge Units	2,385	2,473	3.7

The FDA inspection of the Blood Bank this past June was successful, and we were given the rare distinction of being re-accredited without citations. The FACT inspection of Apheresis and Cellular Therapy laboratories had several minor citations which have been addressed and the FACT accreditation has been renewed.

Major accomplishments include transferring the historical Blood Bank blood type and special patient blood requirements from our legacy system to our current laboratory information system, reviewing the process of blood transport and storage outside of the Blood Bank, and improving the massive transfusion protocol. Significant activity during the year included preparing for the June MiChart inpatient go-live with major process changes for Blood Bank staff in all sections of the laboratory.

In support of the educational mission, the fellowship in Blood Banking/Transfusion Medicine was filled by Chelsea Tooke-Berry, M.D. In FY14, 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 on to the practice of Pathology as a recruiting tool for potential residents. The elective was offered in October for three hour sessions open to 2-4 students. Topics covered included pre-transfusion 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 0.25 FTE, but has been a valuable source of new employees.

PROFESSIONAL ACTIVITIES

Staff in the Blood Bank continue to be active on state, national, and international professional organizations by working as committee members and committee chairs for the Michigan Association of Blood Banks, ASCLS-Michigan, and AABB. Staff has presented posters at national meetings, and several staff members have been invited speakers as they are assessors for the AABB Accreditation program. Several have participated in CAP inspections as a part of the UM team, as well as teams from other facilities.

Histocompatibility and Immunogenetics Laboratory

Daniel Ramon

Dr. Daniel Ramon, Director of the Histocompatibility Laboratory, has experienced a busy, productive year. Changes in the leadership and tools acquired in previous years have begun to produce their advantages.

New Assays and Methods

This past year we have completed the validation of the anti-AT1r EIA test. These antibodies are associated with antibody mediated rejection in kidney transplantation. This assay, together with assays like MHC Class I Chain-related gene A (MICA) typing and antibody detection, C1q binding assay, and the Endothelial Precursor Cell crossmatch that were introduced in recent years have allowed us to differentiate our laboratory from others in the state and the region. We are already receiving samples from other hospitals in Michigan, Illinois, and Arizona for these assays.

During this past year, we also unified and validated a new HLA sequence-based typing (SBT) reagent in order to improve and simplify workflow, in addition to providing high resolution HLA typing with fewer typing ambiguities to resolve.

Workflow/Communication/Training

We have optimized the testing for low volume reactions in order to reduce supply costs and better utilize the technologist's time. A new e-mail system listing recipients is now in place where the laboratory technologists collate the paperwork and populate the fields in Histotrac. The complete packet is then transferred to medical technologists for final review. This allows us to decrease medical technologist time without compromising quality. We continue improving the use of our Luminex robotic system (LABXpress) in order to eliminate technologist-to-technologist variance to provide more consistent results. These innovations allow us to free time for our medical technologists to develop other needed assays.

The laboratory's Lean project in reorganizing freezer space was featured as part of the quarterly CPQA meeting. It continues to decrease technologist time while maximizing use of freezer space supported by the HistoTrac database. Also, we have started a sera reduction program. Reducing the volume and eliminating redundant serum samples improves our storage space, decreases the time to retrieve sera, thereby saving both time and money with less cleaning and freezer maintenance.

We now offer monthly sera mailing audits to our transplant team for patients awaiting a solid organ transplant. This system improves the accuracy of our mailing lists which are used for monthly mailings to patients when they are scheduled for a new sample. We share the data with the transplant coordinators in order to maintain a current sample at our Organ Procurement Organization.

We continue improving our communication with the Transplant Teams, and our laboratory staff has visited the hospital and met three times in the past year to give in-services on HLA. These meetings help them understand and interpret our results and alerts. They have also visited our laboratory once this past year for the same purpose. These meetings have not only been a learning tool, but have helped morale on both sides and promoted understanding that we share a common goal.

We are in the process of cross-training our technologists in all the reactions performed in the laboratory. We have cross-trained three technologists and currently there are five technologists capable of performing all assays. This improves teamwork, the level of our expertise in the laboratory, and gives us more flexibility with weekend on-call scheduling.

HistoTrac

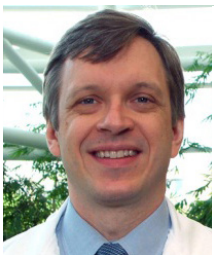
This year we are enjoying all the benefits of the LIS, which was fully implemented at the end of last year (June, 2013). The following is a list of some of the advantages of this system:

1. New serum reorganization – each sample that arrives in the lab is assigned a location by HistoTrac, pertaining to freez er, box, row, and column. The advantage is significant in reducing the sample retrieval time and freezer maintenance.
2. The same system is used for storage of our buffy coat and DNA samples which saves freezer storage space and facilitates locating samples.
3. Workflow optimization
    a. HistoTrac assigns an order for each patient sample for each test run.
    b. This list is transferred by the interface between HistoTrac with most of the instruments in our lab, thus significantly reducing the loading time of the analyzers.
    c. The raw results are then transferred by the same interface to HistoTrac for the final analysis, review, and report sign-off.
4. HistoTrac-UNOS (United Network for Organ Sharing) interface – using this interface, we automatically transfer the HLA typing, PRA, and list of antibody specificities (unacceptable antigens) in order to list the patient to receive organ offers from deceased donors.
5. HistoTrac-NMDP (National Marrow Donor Program) – we are finishing the report to transfer the HLA typing for Hema topoietic Stem Cell transplant recipient and donor with HML format. Currently, this data is manually transferred by the transplant coordinators.
6. Ad Hoc Query – HistoTrac allows us to query any type of information that is stored in the database such as TAT, repetitions, volume of reactions, results, etc.
7. New HistoTrac Kidney Pair Exchange (KPE) Module implementation – this module will help us to identify new possible transplants in the Kidney Paired Donor (KPD) program at the UMHS transplant center. It also identifies better matching options for recipients with compatible donors when matched with donors in the KPD program.

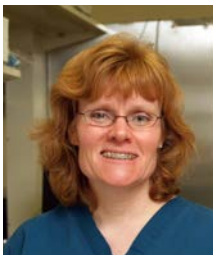
The Histocompatibility Laboratory had a challenging and productive year. All projects are the result of a team effort.

Molecular Diagnostics Laboratory


Kojo Elenitoba-Johnson


Tom Wilson


Bryan Betz


Jennifer Bergendahl


Nancy Lefebvre


Helmut Weigelin

The Molecular Diagnostics Laboratory (MDL) is directed by **Dr. Kojo S.J. Elenitoba-Johnson**. **Dr. Thomas Wilson** is the Associate Director; the laboratory's Technical Director is **Dr. Bryan Betz**; the Technical Supervisor/Laboratory Manager is **Jennifer Bergendahl**; the Laboratory Supervisor is **Nanci Lefebvre**; and the Research and Development Supervisor is **Helmut Weigelin**. 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). MDL works closely with MLabs' Outreach program. Regular meetings and phone/e-mail communications are held with MLabs clients (CSI Labs, Clarient, Neogenomics) aimed at ensuring a high level of customer service and satisfaction. They work together in planning and preparing MLabs marketing materials and requisitions for molecular diagnostics. And they work closely with MLabs administration and clients to ensure appropriate test ordering/interpretation, optimal test turnaround time, and delivery of the highest quality testing results.

This has been a very productive year for the laboratory. During FY14, five new molecular tests were validated as follows:
1. ROS1(6p22) rearrangement by fluorescence in-situ hybridization (FISH)
2. MDM2 Amplification by FISH
3. Biliary Tract Malignancy by FISH
4. MYD88 (L265P) Mutation
5. CALR Mutation

Several more tests are currently under development:
1. NRAS mutation by sequencing – this is a comprehensive test that detects NRAS mutations conferring resistance to tyrosine kinase inhibitor therapies for colorectal cancer.
2. RET rearrangement by FISH – this is a paraffin tissue FISH assay used to guide therapy in patients with lung cancer.
3. IGH/CCND1 t(11;14) translocation by FISH – this is another paraffin tissue FISH assay that is used to aid in the diagnosis of mantle cell lymphoma.
4. Bone marrow engraftment analysis test – this is being transitioned to a new test platform due to a licensing issue with the prior test platform.
5. Comprehensive disease-specific mutation testing panels by next-generation sequencing for solid tumors:
   a. Lung adenocarcinoma
   b. Colorectal cancer
   c. Melanoma
6. Comprehensive disease-specific mutation testing panels by next-generation sequencing for hematologic malignancies:
   a. Acute myeloid leukemia
   b. Myeloproliferative neoplasms

MDL 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 in which 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. Huddles are conducted on a weekly basis. The days are rotated between Tuesdays and Thursdays. The huddles are used to convey kudos to staff and any issues or changes that need to be addressed immediately.

Specimen Volume
Specimen volume in FY14 declined 26% from FY13. Many factors contributed to the decline. A major reason involved one MLabs client shifting two high volume tests to a different laboratory. An additional factor was caused by a temporary testing volume from clients whose own test went offline due to problems with their own assays.

Operational Improvements
One addition to our FTEs was increased by hiring a Laboratory Supervisor for our Main Laboratory.

Additional Faculty
A clinical track faculty position was posted Spring 2013 to support the service and continued growth of the Molecular Diagnostics Laboratory. **Dr. Noah Brown** will join as Associate Director starting July 2014.

Instrumentation
The laboratory received three new instruments – a FISH microscope, Illumina Mi Seq, and an Ion Torrent PGM. These new instruments will support future expansion of the test menu, provide instrument redundancy, and decrease our TAT's for FISH testing.

Restructuring of Clinical Testing Operations
Due to increased demands for FISH testing and with our Next Generation Sequencing startup, we have repurposed two FTE positions from the Molecular side to FISH and Next Generation Sequencing. With the repurposing of these technologists, the molecular rotation schedule is constantly being evaluated on a weekly and daily basis to see what changes or issues need to be addressed. Finally, our Saturday rotation schedule was also changed to include all technologists in Saturday rotations.

Cytogenetics


Diane Roulston


Lina Shao

The Cytogenetics Laboratory Director is **Dr. Diane Roulston,** and the Assistant Director is **Dr. Lina Shao. Dr. Thomas Glover**, Professor, Department of Human Genetics and Department of Pathology, continues to provide invaluable expertise and sign-out coverage, primarily for constitutional genetics cases.

Over the past fiscal year, the Cytogenetics Laboratory has made several important changes and additions to the clinical service. The Affymetrix Cytoscan HD microarray platform was validated and put into clinical use, making significant improvement in the diagnosis and clinical management of patients with hematologic malignancies. Also, collaborative efforts to provide FISH testing for genital-urinary solid tumors bore fruit with the initial offering for gene rearrangements of *TFE3* and *TFEB*.

Clinical Services
In FY14, the Cytogenetics Laboratory experienced a decrease in overall sample volume for the second consecutive year. A total of 3,774 tests were performed, representing a decrease of 10.8%. Nearly every sample type showed a decline to some extent; new cancer cytogenomic microarray and FFPE FISH testing helped offset some of the decline (see Table 14).

Table 14: Sample Volumes in Clinical Cytogenetics (FY14)

Sample Type	N	Change from FY13
Bone Marrows	1,778	-65 (-3.5%)
Tumor/Lymph Node	294	44 (17.4%)
PB Constitutional	322	-48 (-13.0%)
Prenatal Amnios	70	-16 (-18.8%)
CVS	66	-17 (-21.1%)
Tissues (POC)	99	-1 (-0.7%)
Sub-Total (Chroms)	2,629	-104 (-3.8%)
Tissue Culture Only	7	-4 (-40.0%)
Add Tissue Culture for AM, CV, or TI	12	1 (10.0%)
Sub-Total	19	-3
FISH		
Genetics	102	-5 (-4.3%)
Oncology	824	-396 (-32.5%)
Panels*	129	-30 (-19.1%)
FFPE	17	N/A
Sub-Total FISH Tests	1,072	-414 (-27.8%)
CGMicroarray	54	N/A
Total Tests	3,774	-458 (-10.8%)

*FISH panel = two or more probe sets utilized per sample.

The volumes for both karyotype and FISH tests were lower than the previous year in every category except solid tumor/lymph node karyotypes. Bone marrow samples continued the decline first noted in FY12, but with a slighter decrease of 3.5% (-65 cases). For constitutional karyotypes, prenatal sample volumes (amniocentesis and chorionic villus) also declined again, and this year constitutional blood samples decreased as well, after an uptick last year. The sample volumes for tissues (skin fibroblasts and products of conception) stayed the same (see Table 13).

The decline in prenatal testing (-19.5%, -33 cases) is due to the increasing use of non-invasive prenatal testing and genomic microarrays which are now recommended as a first tier test over karyotype for prenatal testing when ultrasound abnormalities are detected.

The overall number of FISH tests also decreased this year, for the first time since FISH was offered as a clinical test at UM, with a total 27.8% decrease (-414 cases). The decline was due to a significant decrease in oncology FISH requests; especially single probe tests, but also oncology FISH panels. The decrease in single probe test volume was ultimately due to improvements in the quantitative PCR assay for BCR/ABL1, such that fewer FISH tests are required to monitor response to TKI therapy. Constitutional FISH tests remained mostly the same compared to last year.


Rohit Mehra

Two FISH tests newly offered this year are for *TFE3* and *TFEB* gene rearrangements caused by specific translocations in renal cell carcinoma (RCC). These are solid tumor tests that use a protocol for formalin-fixed, paraffin-embedded tissues new to this laboratory. In collaboration with **Dr. Rohit Mehra** and the MCTP, the aim is to develop a clinical testing service for genital-urinary malignancies,

specifically for prostate cancer and renal cell carcinoma. These FISH tests are performed to detect chromosome rearrangements that aid in diagnosis, have known prognostic significance, and/or indicate targeted therapy. The *ERG* break-apart probe set has been validated, and conditions have been optimized for *BRAF*, *RAF1*, and *PTEN*, so more clinical tests are expected next year.

The Microarray Section of the laboratory, under the direction of **Dr. Lina Shao**, began offering clinical testing for hematologic malignances. The microarray results already have provided valuable diagnostic and prognostic information for patients with acute lymphoblastic leukemia and myelodysplastic syndrome. The arrays have more clinical utility than MDS FISH panels and are expected to replace this send-out test. Dr. Shao and Dr. Roulston have attended multiple clinical conferences and meetings to discuss indications for genomic microarray and test requirements. For next development, the test validation for pediatric solid tumor samples is well underway, and assay validation for products of conception using excess clinical material has begun. Cytogenetics technologists have begun to perform DNA extractions to process samples received after-hours and to cover some microarray testing.

Turquessa Brown

With regard to staffing, **Turquessa Brown** was promoted to Senior Technologist to oversee the Blood/Bone Marrow Section, and two more technologists were promoted to Cytogenetics Technologist II. The lab administrators replaced two departing technologists this past year. A new locum tenens service was engaged and has proven extremely helpful for coverage of sign-out duties in director absences.

Other significant activities included participation in department-wide initiatives, including finalizing protocols for the new document control system, adapting and adjusting practices to accommodate the new SCC/Soft LIS, and preparing for the internal CAP inspection. In a renewed effort to address areas identified by the Employee Engagement Survey, Dr. Keren and Human Resources personnel coached the laboratory leadership, held meetings with the entire laboratory, and implemented several changes including a more liberal flex-time practice and activities to improve staff communication and morale.

Education

Graduate students, residents, and fellows from a wide range of specialties performed rotations in the laboratory again last year. These included Genetic Counseling graduate students (7), Pathology residents (11), fellows from training programs in Molecular Genetics in Pathology (2), and Hematopathology (1). The residents and fellows presented brief talks on relevant topics in cytogenetics for the technologists, making a much-appreciated contribution to continuing education.

For regional meetings, three technologists attended the annual Great Lakes Chromosome Conference in Toronto. **Dr. Hong Xiao** presented a talk on her work in establishing FISH testing for translocations in RCC and validating the *TFE3* and *TFEB* break-apart probe sets according to ACMG guidelines. Two other technologists traveled to the national Association for Genetic Technologists conference in Las Vegas.

The laboratory continued to benchmark well and maintained Approved Laboratory status for participation in clinical trials for the Children's Oncology Group (COG); 19 case studies were submitted. Dr. Roulston served on the Cytogenetics Committee for COG, and served as chair of the SWOG Cytogenetics Committee. Dr. Shao performed a review of the clinical microarray validation results for hematologic malignancies and her report has been accepted for an oral presentation at the upcoming national Cancer Genomics Consortium and the Cytogenomics Array Group meeting in Chicago.

FUTURE PLANS

An automated FISH slide processor was recently acquired and staff are eagerly anticipating the labor savings and improvement in productivity. Additional laboratory automation systems, such as slide scanners, are available and recommended as a way to further increase efficiency, so will be investigated further in the coming year.

KUDOS TO OUR ADMINISTRATIVE ASSISTANTS

Finally, a hearty thank you is due to the extraordinary efforts of our Administrative Assistants who provide support to the Director and his colleagues – **Pam Warwashana, Carrie Baker** and **Jessica Shaw**.

Pam Warwashana

Carrie Baker

Jessica Shaw

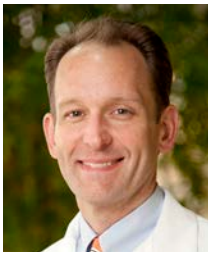
Division of Pathology Education

Barbara J. McKenna, MD
Godfrey D. Stobbe Professor of Pathology Education
Director, Division of Pathology Education

Education is a core mission of the Department of Pathology, and the quality and breadth of its Education Programs reflect this commitment. For decades, the Department has actively participated in the education of undergraduate students and dental students, and has played a major role in the education of medical students, graduate students, residents, and clinical fellows. In addition, many Pathology faculty members 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 2013-14 academic year was marked by significant achievements, as outlined below. The leadership and administrative team consists of the Program Director, **Dr. Barbara J. McKenna;** Associate Program Director, **Dr. Scott Owens;** Fellowship Coordinator, **Marie Sassano**; Residency Program Coordinator, **Pamela Howard**; Medical Student Program Coordinator and Conference Coordinator, **Carrie Scott**; and Academic Human Resources Manager, **Sarah Dudley-Short**. The Residency Program GME Committee includes **Drs. Jonathan McHugh, David Keren, Nathanael Bailey, David Lucas,** and the Chief and Assistant Chief Residents **Megan Alderman** and **Theodore Brown.**



Scott Owens

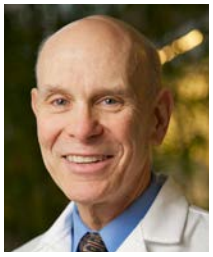
Marie Sassano

Pam Howard

Carrie Scott

Sarah Dudley-Short

Jonathan McHugh



David Keren

Nathanael Bailey

David Lucas

Megan Alderman

Theodore Brown

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 out of 60) by UM in the NRMP match. The group includes all students from the University of Michigan Medical School class of 2014 choosing pathology, and two graduating with M.D., Ph.D. combined degrees. This group hails from Michigan, Ohio, Missouri, Wisconsin, and California.

Achievements
Our residents were very active academically, with a total of 23 publications during 2013-14, 12 of then featuring residents as first authors. The graduating class had accumulated 55 publications and 39 abstracts during the years that they trained here at Michigan. Our residents were also highly involved in quality improvement and patient safety projects, including efforts to improve turnaround times for frozen sections and inpatient biopsies, minimize lost specimens using standardized processes, instituting standardized gross dictations, modifications in emergency department ordering standards for patients with chest pain, and redesigning specimen labels to optimize the clinical information that comes with them.

Board Results
100% of the graduating class of 2013-2014 passed the American Board of Pathology certification examination on the first attempt.

Practice Settings of Graduates
Of the 13 residency program graduates from 2011 and 2012 who have completed fellowships, nine (69%) are situated in academic pathology careers, and four (31%) are in community practices. One additional 2012 graduate is pursuing additional fellowship training.

GRADUATE MEDICAL EDUCATION – FELLOWSHIP PROGRAMS

The fellowship training opportunities continue to grow. With the approval of a Chemical Pathology fellowship and an anticipated new Bone and Soft Tissue Pathology Fellowship, there are now nine ACGME-approved fellowships offering 16 approved positions, and 10 additional clinical fellowship programs offering 12 positions. Interest in these fellowships has grown steadily, with increasing numbers of applications each year. Our fellowship banner and links on Pathology receive between 400 and 600 hits per month, generating traffic to our own department website, and reflecting the interest in our programs.

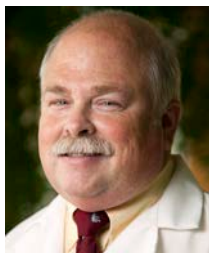
A Fellow Selection Committee continues to monitor and standardize the fellow candidate application, interview, and offer timeline in a way that insures that the best possible candidates are chosen for our fellowships.

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

MEDICAL STUDENT TEACHING

M1 and M2 Teaching


Michael Roh


Paul Killen

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. This M1 Histopathology course is led 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 area of interest, although not exclusively. Altogether, there are 36 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 4.2 to 4.4 (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 2-4 students. 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 under the direction of **Dr. Jon McHugh** has made this an increasingly popular choice for Michigan medical students who 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, 70 senior medical students (greater than 40% of the graduating class) rotated in Pathology. While a few are choosing pathology as a career, most are taking away with them a broader understanding of laboratory medicine and the role of pathologists in clinical medicine.

MOLECULAR AND CELLULAR PATHOLOGY (MCP) GRADUATE PROGRAM

The Molecular and Cellular Pathology (MCP) Graduate Program is under the direction of **Dr. Zaneta Nikolovska-Coleska**. During this past year, nine students (one from the MSTP program) 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 the recruiting for the new 2014 class for the Program in Biological Sciences (PIBS) was finalized and MCP successfully recruited four of the six high quality students (a 67% acceptance rate), indicating the vitality of our 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 two students successfully complete their graduate research careers by defending their thesis.

Zaneta Nikolovska-Coleska

The MCP graduate students produce high quality research that has resulted in publications in top tier journals. In addition, the students have also participated in other academic activities, including mentoring of younger students and undergraduates. Perhaps the most impressive extramural accomplishment that the MCP students perform on an annual basis is the organization of the annual Department Research Symposium that is held in the fall each year, now on its 12th year. This symposium is entirely organized by trainees, and students have selected an outstanding group of visiting investigators to give the keynote address, including Dr. Ralph Steinman, the 2011 Nobel Laureate. Last year's keynote speaker was Dr. Lewis C. Cantley, Director of the Cancer Center at Weill Cornell Medical College and New York-Presbyterian Hospital, a leading cancer researcher in the signaling and metabolic pathways related to cell growth and oncogenesis. During the symposium the research within the program was highlighted through short research talks from faculty, graduate students, and post-docs, including 85 poster presentations. This event has become a true success and highlights the student's enthusiasm, collegiality, and passion for research.

During the 2013 fall semester, the MCP program offered for the first time a new course titled *PATH 862 (Translational Pathology)*, with course masters **Drs. Thomas Wilson, Zaneta Nikolovska-Coleska**, and **Barbara McKenna**. Translational Pathology is an innovative graduate-level course designed to help meet the growing need for scientists and medical professionals who can bridge the gap between basic science and clinical practice. This multidisciplinary course trains both graduate student participants (17 students from MCP and other graduate programs) and clinical residents/fellows in the methods and principles involved in translating basic science findings into clinically useful interventions to improve human disease outcomes. The central objective is to illustrate how basic science, when applied to human disease, can lead to the discovery of pathophysiology and the development of therapeutics and diagnostic tests. The course is taught from the perspective of the pathologist, wherein faculty experienced with successful translational research offer insights spanning the nature and manifestations of human disease, the mechanisms of disease pathogenesis, chemical pathology and drug discovery/development, laboratory diagnostics, clinical trials, personalized medicine, and the newest technologies in these arenas. The target mixture of research and clinical trainees participating in this course enriches the educational experience and makes it a unique learning opportunity. Examples of successful translation were provided in moderated seminars by scientists who have made some of the most significant advances in translational research, particularly in biomarkers and diagnostics (**Drs. Arul Chinnaiyan** and **Scott Tomlins**), personalized medicine (**Dr. Kojo Elenitoba-Johnson**), and drug discovery (**Dr. George Wang**). During their presentations, faculty members share practical insights and perspectives on the importance of cross-disciplinary collaborations and relationship building.

Arul Chinnaiyan

Scott Tomlins

Kojo Elenitoba-Johnson

George Wang

As part of *PATH 862*, students participated in student-led case reports. In this portion of the course, a series of patient-centered case studies were provided to students and residents. These cases were selected to represent a variety of clinical areas and current directions in translational research. Groups were assembled consisting of a clinical resident/fellow and several graduate students to work together on an oral presentation and written document with a focus on identifying potential opportunities and pathways to translation. Since peer review is an important aspect of research, students were asked to provide a short critique of the presentations made by other groups based on the NIH study section format. A final panel discussion session focused on career development in translational research. Participants of the panel were Drs. Bradley Martin, Translational Research and Commercialization; **Bryan Betz**, Molecular Diagnostic Lab; **Scott Tomlins**, faculty; **Zaneta Nikolovska-Coleska**, faculty; and **Thomas Wilson**, faculty. The feedback from graduate students who have taken *PATH 862* was very positive and encouraging with comments that "it is an excellent course which gave them an opportunity to interact and work with clinical colleagues for the first time."

To further improve the training of our graduate students and to prepare them as future leaders in translational research, the Department of Pathology invested in a Pilot Pre-doctoral Training Program in Translational Pathology for students in the Molecular and Cellular Pathology program for two years, 2014 and 2015. Two students are currently enrolled in this program and have received enhanced training including coursework and clinical rotations. These students from the MCP Graduate Program were selected from six eligible second year students. This pilot program will enroll two additional students in September 2014.

Andy Lieberman

Introducing the new course, initiating the Pilot Training Grant, as well as the strong foundation and record of success in translational research of our Department, were the major driving forces for preparation of the training grant in Translational Research, which was submitted May 2014. This training program is designed for pre-doctoral Ph.D. students and aims to address the widely-recognized shortage of rigorously trained scientists who can successfully work together with medical professionals to bridge the gap between basic science and clinical practice. The administrative structure of this training grant is designed to ensure the quality of research and clinical mentorship, including co-Directors who bring complementary and necessary expertise to successfully implement this training program (**Drs. Andrew Lieberman** and **Zaneta Nikolovska-Coleska**) and 60 faculty members affiliated with a dozen departments in the University of Michigan Schools of Medicine and Pharmacy, including Pathology (42 faculty), Internal Medicine (7), Neurology (7), Surgery (1), Obstetrics and Gynecology (1), Pediatrics (1), and Medicinal Chemistry (1). The educational experience will be enhanced and supported by integration of dual-mentors with corresponding expertise in the basic and clinical aspects of the research project. In addition to a curriculum that includes innovative coursework in translational research, students will participate in clinical rotations, interdisciplinary conferences, tumor boards, and grand rounds that will enable the mastery of skills needed for successful translational research. Graduates from this program will have the skills and knowledge to undertake an independent career that features translational multidisciplinary research.

In the next year we will continue with improvements to the training and scientific dedication of our program. In particular we will make appropriate adjustments to the new course, *PATH 862 (Translational Pathology)*, based on the evaluations and suggestions from course participants, students, residents, and fellows. We will also continue with the Pilot Training Grant by enrolling two new students, evaluate the experience of the first two trainees in this pilot program, and make further improvements with the hope that we will successfully secure the funding. We look forward to another productive and outstanding year for our MCP Graduate Program.

PATHOLOGY EDUCATION SERIES

A vibrant and varied morning Pathology Educational Series takes place most mornings at 8:00 am from September through mid-June. In 2013-2014 there were 145 conferences, each offering CME credit. Four were presented by visiting professors, 43 by residents, 18 by fellows, and 15 were part of the *PATH 860, Translational Pathology* course. The remaining 65 were presented by 36 different departmental faculty and staff members. In addition, 10 gross conferences were conducted by surgical pathology faculty and fellows.

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

Division of Pathology Informatics

Ulysses G.J. Balis, MD
Professor of Pathology
Director, Division of Pathology Informatics

The Division of Pathology Informatics, situated as one of the seven autonomous functional units of the overall Pathology Department, serves the tripartite missions of the department including clinical care, research, and education. In addition, the division hosts its own portfolio of research in fundamental information technology as well as imaging and interoperability. Overall, Pathology Informatics operates as a service unit of the department, covering a wide range of operational and strategic functions, with these tied together by a centrally governed team of superbly-trained information technology experts. Compared to many other contemporary pathology departments, the Pathology Informatics Division at the University of Michigan is somewhat unique in terms of both its size and significant degree of autonomy, for both hardware and software stewardship issues. Additionally, the Division has maintained oversight of its two geographically distinct data centers, thus allowing for expedited delivery of new products and services to the department at large.

Perhaps being most important over this prior academic year, the Division has been exclusively responsible for the stewardship and continued development of the new Soft Laboratory Information System (LIS), which was activated on June 1, 2013. At present, we have been active with the new system for over a year's time, with that experience informing our team of both best practices as well as areas where continued configuration adjustments or development are required.

THE NEW SOFT LABORATORY INFORMATION SYSTEM

In terms of sheer hours of effort and the total number of changes that were applied towards the LIS this past year, the numbers only tell part of the story. At the major software version level, the Division installed no less than 14 major software upgrades, each with its own carefully orchestrated change control process and validation protocols. This body of work, taken alone, was monumental in scope, with *each* upgrade cycle requiring over 200 hours of cumulative preparation, followed by a six-hour installation protocol, of which at least 25 lab staff and P.I. staff were participatory. In addition to these monolithic upgrade exercises, the Division carried out over 60 major hotfix installations and minor software upgrade activities, towards the goal of reducing operational deficits in the overall functionality of the application suite.

Continued development effort for SoftPathDX and other lab enhancements is ongoing, with the Division now following a two-year roadmap, by which the far majority of extant deficits in both Anatomic and Clinical Pathology sectors will be resolved by no later than the end of the 2015-2016 academic year. During this period, a number of additional Agile programming sessions in SCC's Poland development facility are anticipated.

COMPLETE REWRITE OF ELECTRONIC BILLING INTERFACES AND SUBMISSION SYSTEM

Recognizing that the department's existing electronic billing solutions were past end-of-life in their functionality and serviceability, the billing office and the Informatics web team formed a working group to address this deficit, by the creation of a fully-automated web-based solution. Development completed in Q4 of this academic year with deployment being scheduled to commence during Q1 of the 2014-2015 year.

MiCHART INPATIENT ACTIVATION – INTERFACE READINESS

Approaching the scope and complexity of the SCC LIS activation was the complex set of electronic interface development and validation efforts carried out by the division in support of the inpatient activation of MiChart, which also took

place during the latter portion of Q4. As a testament to the exceptional level of preparation and testing that the division expended in support of this project, at no time during the daily briefing meetings that took place in the initial two weeks post activation did a pathology-centric IT item surface to the enterprise list of defects requiring team-based mitigation.

WINDOW 7 MIGRATION

Steve Marshall

The health enterprise's 12 year history of successfully leveraging the Windows XP operating system came to an end in Q3, with the deployment of the much-anticipated Windows 7 operating system, for all core-build workstations. As the Informatics Division maintains the approximate 3,200 PCs within the department, it was our responsibility to either update or upgrade all core-build devices. The desktop support team within the Division, under the leadership of **Steve Marshall**, successfully completed this task on time, allowing the department's various laboratory units to continue operating without interruption. This was a substantial effort, given that a fifth of extant hardware needed to be upgraded as part of this overall migration process – an exercise that the desktop team completed in a mere two week period.

MASTER CONTROL SUPPORT AND INTERNAL USE FOR DIVISION DOCUMENTATION NEEDS

The Master Control application was acquired in 2012 to allow for use of electronic policies and procedures. Through the 2013-2014 period, the Informatics Division formalized its support processes for the hardware layer of the application, leveraging fully redundant virtualization technologies and at the same time, made use of the application itself for its internal policy and procedure needs. By Q3, 100% of the division's documentation was successfully ported to Master Control, with this fact validated by the Division's newfound ability to carry out its internal, mid-cycle CAP inspection via use of the electronic documentation exclusively.

INTERIM CAP INSPECTION READINESS AND FOLLOW UP

Being a mid-cycle year for CAP accreditation, the Division carried out a thorough internal review of its policies and procedures, updating documentation and protocols in a number of areas, including: stewardship of virtualization layers, reduction of single points of failure (e.g. dongles), and expansion of digital pathology/whole slide imaging protocols. Such efforts have served the division well in prior CAP inspection cycles, with this fact borne out by the Division's record of not having received a Phase II citation in the past 14 years.

MiCHART INPATIENT PRINTER VALIDATION

In response to increased needs for tighter EMR-LIS integration, in the setting of the MiChart inpatient roll-out, the Informatics Division designed and implemented a new network-based connectivity model, by which a new and expanded cohort of remotely-deployed lab label printers could be deployed in a plurality of time-critical hospital locations (e.g. E.D.), thereby simplifying the process by which providers could obtain lab-ready specimen labels. Besides the immediate time savings provided by having these strategically placed printers, an added benefit enhanced patient safety was similarly realized, owing to the reduction in settings where specimen relabeling (an intrinsically dangerous step with respect to positive patient identification) was required.

REFINEMENT/OPTIMIZATION OF INTRAMURAL ADD-ON TEST ORDERING PROCESS BY LABORATORY STAFF

In response to a request from the MiChart Leadership Team (MLT) to further optimize what was an imperfect and largely manual intramural add-on test ordering process, Informatics worked with the department's lab operations groups to put in place a revised internal add-on protocol. Upon its completion, the new process allowed for greatly expanded results so that closed-loop orders-to-results reconciliation was possible from within the MiChart EMR application.

CONVERTED ALL REQUISITION SCANNING OVER TO SCC SOFTMEDIA

With the sunset of the legacy Freedom Imaging Solution (FIS), the department is now able to benefit from the seamless workflow afforded by use of a native document imaging and management system that is embedded within our LIS.

Already, this has allowed the division to focus support efforts in other areas, as many of the prior recurring support tasks inherent with the use of FIS are no longer an issue.

UPGRADED THE CYTOVISION SERVER AND IMPLEMENTED ISO-NET FOR ALL CYTOVISION RESOURCES

This long-overdue upgrade is now allowing the Cytogenetics Lab to benefit from modern (and fully vendor-supported) software solutions.

ADDITIONAL COMPLETED DIVISION PROJECTS

As most of the following projects, which are smaller in scope, are self-evident by their title alone, they are included here for completeness:

1. Decommissioned the Soft Lab in MSRB.
2. Reviewed, refined, and stabilized the image capture solution for Anatomic Pathology (AP).
3. Completed a major Histotrack application upgrade and completed a new module installation.
4. Completed the AP Reading Room and IT Footprint/Monitor Redesign Project.
5. Completed the Path Stores on-line catalog.
6. Completed new Clinical Pathology brochures.
7. Updated the Path photo image archive infrastructure solution.
8. Facilitated the restoration of the fire-damaged Pathology Imaging Lab.
9. Designed and implemented the IT layer of the new Dermatopathology Laboratory.
10. Completed the RALS Wireless Glucometer server update and deployed hundreds of wireless devices.
11. Planned and tested the Ventana Coreo Imaging system.
12. Planned and implemented the IT support layer of the Sysmex hematology automation line at the Northville Clinic.
13. Provided printer and device support for the opening of the Northville Clinic.
14. Completed the Desktop team restructuring project, creating a new technical desktop team lead model.
15. Evaluated Time to Talk as a candidate vendor for phlebotomy cart power monitoring.
16. Hired and trained a new weekend system operator.
17. Implemented and then improved a new change-control process and associated application.
18. Provided website and conference support for Advances in Forensic Medicine.
19. Provided website and conference support for New Frontiers in Pathology.
20. Support and augmentation of the Pathology On-line Forms System.
21. Migrated current web servers to a new VMware load-balanced server farm.
22. Separated clinical data to specific/partitioned internal servers.
23. Converted legacy web applications to modern support layers, including appropriate HIPAA-compliant database support; provided support during the migration.
24. Provided a major functionality update for the MDRO and Antibiogram services hosted by the Division.
25. Completed network closet switch upgrades for all Pathology-hosted nodes.
26. Initiated the preparation of P7 hardware for the anticipated Soft upgrade in Q4 of calendar year 2014.
27. Continued partnered effort with MCIT to deploy a new generation of network attached storage, in anticipation of transitioning away from our aging EVA solution to a new shared NCDC cluster.
28. Stabilized the University Health Service network connectivity issues.
29. Continued migration of devices from old public-facing IP numbers to private internal-facing IP addresses, thus mitigating cyber infrastructure vulnerabilities.
30. Completed network upgrades and troubleshooting at multiple locations: Traverwood, IHA, PIMA, Botsford Hospital, Room 1, and Microbiology.
31. Re-organized the LIS support team: obtained a new experienced team lead (**Eric Jedynak**) and hired two AP/Gene support staff (**Rachel Roach** and **Steve Eskesen**).

Eric Jedynak

Rachel Roach

Steve Eskesen

PATHOLOGY DATA CENTER INFRASTRUCTURE UPGRADES

The prior year witnessed an exceptionally high turnover of planned data center hardware and infrastructure elements, with multiple large replacement projects allowing the division to replace legacy solutions with contemporary, reliable technology platforms that will appropriately scale with the ever-increasing operational demands placed upon the department's IT backbone. Projects of greatest scope and import are listed below:

EVA (Enterprise Storage Array) Storage Expansion

As the EVA continue to serve as the department's primary method of providing for internal redundant data storage for all departmental IT operations, expanding its total capacity this prior year was essential in allowing the division to provide adequate storage to the many users and labs under our purview. Now with well over a Petabyte of total storage capacity, the current EVA is fully expanded in its storage capacity, with its being scheduled to be replaced in the 2014-2015 operating cycle, predicated upon a $9.3M capital request for block-level storage, which was approved at the Jun 2014 ITSAC (Information Technology Strategic Advisory Committee) and subsequent Capital oversight Group (COG) meetings.

Upgrade of All Blades in VMware Cluster to 16 Core Processors
This expansion of computational cores is now allowing the Division to operate its VMware virtualization layer at maximum efficiency, thus allowing for the hosting of the maximum number of virtual servers per blade. This efficiency, in turn, allows the data center to operate at the highest possible areal density of virtual servers/KW. Essentially, over the past decade, the Informatics Division's strategy of transitioning to near-exclusive use of virtualization technology has allowed the datacenter to expand its areal computational density by a factor of nearly 140, without growth in power consumption, which is quite remarkable.

Expansion of VMware Cluster to 352 Cores and 2048 GB RAM
This scheduled upgrade allowed the division to increase the number of hosted virtualized server environments by a factor of two, which in turn allowed for the hosting of all additional requested clinical virtual servers.

VMware Upgrade to vSphere 5.5
This major software upgrade project now allows the division to take full advantage of the compartmentalized virtualization features included in the latest generation of VMware software, including distributed antivirus detection and de-duplicating block level storage at the virtualization level.

Migration of Systems from Old VM Cluster
With this major scheduled migration, the entire division is now running on a single version of VMware technology, greatly simplifying our stewardship of this important layer of IT infrastructure. The new single cluster is fully redundant and distributed across multiple locations, for added operational continuity.

Installation of P750 Hardware
As part of the expected succession planning of hardware for our primary LIS solution, the Division fully installed and powered up replacement IBM P7 servers, which are anticipated to replace our aging P6 cluster. Clinical transition of the use of the P7 cluster is scheduled to take place in Q4 of the 2014 calendar year, following multiple cycles of performance optimization and LIS software validation, which are each major software projects. It is worth mentioning that the new P7 cluster represents a substantial computational increase in performance over our prior P6 solution, with this enhancement expected to allow for substantial positive impact on LIS system response time.

Creation, Zoning, and Mapping of 52 LUNs to P750
In order to properly attach the above P7 cluster to our EVA storage solution, approximate 500 man-hours of highly technical configuration effort was required to construct 52 separate and redundant LUN virtual mapping connections. This undertaking was completed and subsequently validated by the vendor for correctness.

Upgrade of Entire Tape Backup Enterprise to 12 LTO6 Tape Drives
With the completion of this scheduled hardware upgrade, the Division has the ability, for the first time in 10 years, to backup all clinical storage repositories each evening, without the need for every-other-day scheduling for some data stores, owing to inadequate backup windows.

Virtualization and Decommissioning of 24 Old Servers
Removal of these physical servers and incorporation of the replaced processes into our virtualization layer further allowed the Division to remove single points of failure and benefit from the fully redundant/high availability benefits of our VMware cluster.

New Hardware for Ventana IPOX, Flow Cytometry, Thiopurine Analytics, Cytogenetics, and Photography
Major IT infrastructure upgrades in each of these sectors allow each respective lab or unit to operate at higher levels of performance and availability.

Expansion of Research NAS to 1720 Terabytes Storage
With this expansion, the Pathology Informatics Division hosts upwards of six total Petabytes, making it one of the largest repositories within the health system. The operational experience gained from the division being stewards of such large repositories allows it to continue in its goal of proving contemporary, best-practice IT solutions to the Pathology Department at large.

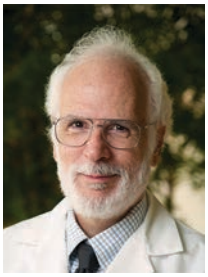
Upgrade of the Research High Performance Cluster to 656 Cores and 5312 GB of RAM
Now in its eighth year of continuous operation under the stewardship of the Path Informatics Data Center, the department's high-performance computational cluster was upgraded to 656 cores with a symmetric infini-band inter-process communication hypercube topology, being further augmented with 5.3 TB of high-performance/low CAS latency memory. This new configuration represents a thoroughly contemporary design, with it expected to provide a minimum of four additional years of continuous service for the department's research computing activities (NGS and proteomic data pipelines). With this upgrade, this resource becomes the eleventh largest cluster computing resource at the University of Michigan and the largest research computing cluster within the medical school.

Division of Sponsored Research

Kathleen R. Cho, MD
Peter A. Ward Professor and Interim Chair

Steven L. Kunkel, PhD
Endowed Professor in Pathology Research
Senior Associate Dean for Research

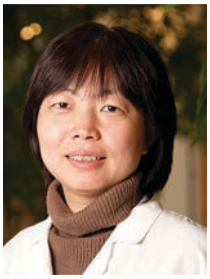
This has been another productive year for research within the department. Despite the departures of **Drs. Jay Hess** and **Cory Hogaboam**, our extramural research funding remained remarkably stable. The outlook for FY15 is very positive as we received funding notices for at least two large grants, one from the Glenn Foundation (PI: **Rich Miller**) and a prostate cancer SPORE from the NCI (PI: **Arul Chinnaiyan**). Furthermore, our new Chair, **Dr. Chuck Parkos**, will add a substantial amount of research funding to our portfolio. Research in the department covers a diverse array of topics, but we have continued to focus extra effort on areas of strength, including biomarker discovery, inflammation, epigenetics, proteomics, drug discovery, and aging. Over the past year our faculty published a wide range of papers in high impact journals.



Rich Miller

Arul Chinnaiyan

Chuck Parkos

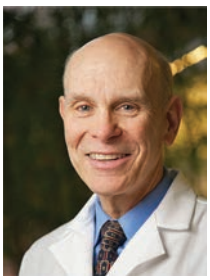


Yali Dou

We are delighted that **Dr. Yali Dou** was named one of two recipients of the 2014 Dean's Award for Basic Science Research. This highly competitive award recognizes scientist(s) identified as having made outstanding contributions to the Medical School in basic biomedical science research.

While this section focuses on the Division of Sponsored Research, this is a somewhat artificial compartmentalization of our research efforts. Almost all of our faculty members contribute to research advances and we make a substantial amount of funding available to support such efforts. The AP Project Research Fund, initiated in 2006, supported many projects in AP this year. **Dr. Andy Lieberman** chairs the departmental committee tasked with reviewing project proposals prior to receiving funds. AP Division faculty published 235 papers in FY14, a 5.4% increase from FY13. Research expenditures by AP faculty also increased (8.1%), totaling nearly $3.5M. AP faculty accounted for nearly 110 abstracts presented at national and international meetings, delivered over 130 invited lectures and visiting professorships, and represented the department on over 30 editorial boards. This year, **Dr. David Keren** initiated the CP Project Research Fund, modeled on the one in AP. **Dr. Michael Bachman** chairs the new committee that reviews CP project applications. The CP faculty also had a very productive year, with 124 publications, 94 abstracts, 120 invited lectures, and representation on 29 editorial boards.

Andy Lieberman



David Keren

Michael Bachman

The Michigan Center for Translational Pathology (MCTP) directed by **Dr. Arul Chinnaiyan** continues to identify molecular drivers and potential therapeutic targets in human cancers through the Michigan Oncology Sequencing Center (MI-ONCOSEQ), which employs high-throughput sequencing for precision cancer therapy. The MCTP continued its remarkable track record of success, with 37 publications including several in high-impact journals such as Nature, Nature Genetics, Nature Communications, Cancer Discovery, and Molecular Cell.

During the eight years of **Dr. Jay Hess'** and **Dr. Kathleen Cho's** tenures as Chair, the departmental Government, Pharmaceutical, and Foundation funding has grown to over $32.7 million, a 48% increase since 2005 (Figure 15). This is a remarkable achievement given the challenging funding environment. As a key indicator of productivity, the Indirect Cost (IDC)/ sq. ft. of the > 67,000 sq. ft. of research space allocated to the department is presently $115/sq. ft. – 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 7th among Pathology departments nationwide.

Dr. Steven Kunkel, Professor of Pathology and Senior Associate Dean for Research, continued to lead the FastForward intiative, the goal of which was to make informed decisions about how to invest Medical School resources to accelerate research and clinical translation at Michigan. Several Pathology faculty members are actively engaged in FastForward programs, including **Drs. Andy Lieberman** and **Kojo Elenitoba-Johnson** (Protein Folding), **Gabriel Nunez, Naohiro Inohara, Michael Bachman** and **Duane Newton** (Microbiome), and **Maria Figueroa** (Epigenetics Core).

Kojo Elenitoba-Johnson

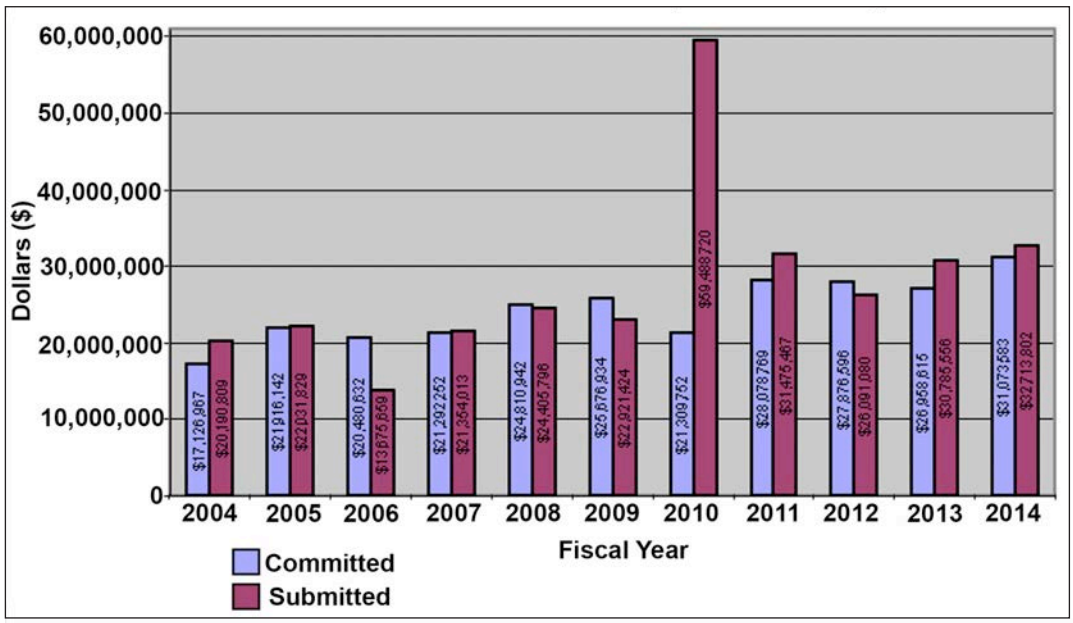
Gabriel Nunez

Naohiro Inohara

Duane Newton

Maria Figueroa

Figure 15. Committed Total Awards and Submitted Competitive Dollars by Fiscal Year



Division of Translational Research

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

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

PROTEOMICS RESOURCE FACILITY (PRF)

The PRF is a resource service that supports the research needs both within and outside the Department and University. The PRF is led by **Dr. Kojo S.J. Elenitoba-Johnson,** (Director), **Dr. Venkatesha Basrur,** (Lab Manager), **Kevin P. Conlon** (Senior Research Lab Specialist), **Dr. Damian Fermin,** (Proteome Informatics Specialist).

Venkatesha Basrur

Kevin Conlon

Damian Fermin

Progress Report
The PRF, located in the Medical Science 1 building, houses state-of-the art instrumentation to meet the proteomic requirements of researchers both in and outside of the University of Michigan.

Instrumentation
Thus far the PRF has utilized the following instruments to fulfill its mission.

Table 15:

Instrument	Year of Acquisition
LTQ XL ETD	2004
LTQ Orbitrap XL	2008
LTQ Quantum Ultra	2008
HPLC/Autosamplers (3)	2004/2008

Over the past six years, the PRF has catered to the needs of over 60 Principal Investigators. During the same period, approximately 17,000 samples/fractions have been analyzed. More importantly, data generated at the PRF has resulted in 31 peer-reviewed publications in several high impact journals including *Cancer Cell, Nature, Nature Cell Biology, Molecular Cell, Proceedings of National Academy of Sciences, Neuron*, and *Oncogene*. Many more are currently under consideration for publication. The PRF has also supported the research mission by contributing significantly to the securing of several R01 grants. The PRF is also funded through the Leukemia and Lymphoma Society for the 5th year running.

Just recently the PRF was designated as the "Post-translational Modification Core" with the mission to support the Protein Folding Disorders (PFD) initiative, one of the two key areas supported by the University's Strategic Research Initia-

tive. Through PFD funding, the PRF acquired several new instruments, listed below, to serve the needs of over 50 PFD investigators.

Table 16:

Instrument	Year of Acquisition
Orbitrap Fusion Tribrid with ETD	2014
Nano-UPLCs (3)*	2014

* Two older HPLC/autosamplers were traded-in to secure an attractive discount on the new LC systems.

The new Orbitrap Fusion Tribrid mass spectrometer combines the best features of the quadrupole, Orbitrap, and dual-cell linear ion trap technologies. The sophisticated software control system and the unique geometry of the instrument allows multiple, independent processes, such as ion injection, precursor isolation, gragmentation, and mass analysis, to be performed in parallel resulting in unprecedented depth and quality of proteomic datasets. High resolving power of Orbitrap Fusion (FWHM > 400,000, mass accuracy of < 3 ppm) in combination with electron transfer dissociation (ETD) is also essential for top-down proteomics which is becoming a method of choice for quantitatively mapping post-translational modifications on proteins, especially epigenetic modification of histones.

All new nano-LCs acquired are ultra-high pressure rated (~12,000 psi) and two of these are capable of 2D-LC. These are in-line with Orbitrap XL, Orbitrap Fusion, and Quantum ultra mass spectrometers.

All the new instruments are installed and are being tested currently to establish optimized experimental methods.

Services

The services offered by the PRF have not changed.

- Protein identification by LC-MS/MS sequencing – *In-gel* and *in-solution* processing
- Identification of post translational modifications (PTMs) – Phosphorylation, acetylation, methylation, ubiquitination etc. Minimum protein amount required for this service is higher than regular protein ID by LC-MS/MS. This service will be charged as protein identification by LC-MS/MS sequencing. Any specific reagents needed (such as IMAC column for Phosphopeptide enrichment) will be supplied by the user.

The above services include cutting the gel slices (if needed), protease (trypsin) digestion, desalting/fractionation (where applicable), LC-MC/MS analysis, and database search (X!Tandem/TPP). Results are delivered via an e-mail link (internal users) and/or Excel file format (external users). In-solution digestion includes a SCX fractionation (three 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
    - SILAC – Stable Incorporation of Labeled Amino acids in Culture

Rates

The rates mentioned below are for internal (UM researchers) and external users (non-UM researchers). A 30% surcharge is added for all external users.

Table 17:

		Internal Users		External Users	
Service		Unit Cost (USD)		Unit Cost (USD)	
Protein ID by LTQ-ETD	In-gel digestion	99.99/gel slice*	1199.88/lane	129.99/gel slice*	1559.85/lane
Protein ID by LTQ-ETD	In-solution digestion	124.99b		164.484b	

Protein ID by LTQ-Orbitrap XL	In-gel digestion	107.12/gel slice	1285344/lane	139.25/gel slice	1671.07/lane
Protein ID by LTQ-Orbitrap XL	In-solution digestion	132.12		171.75	
Relative Quantitation (Orbitrap XL)	In-solution digestion	137.12/fraction		178.25/fraction	

Projects and Clients

The majority of the projects submitted to the PRF deal with the identification of interacting proteins, post-translational modification, and determining the relative quantitation of differentially expressed proteins. To accomplish these analyses, the 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.

For FY14, PRF has provided services to 39 Principal Investigators, both from within and outside of the University of Michigan Hospital and Health Systems.

Table 18:

Principal Investigator	**Affiliation**	**Billed**
Megan Lim	University of Michigan	564
Kojo Elenitoba-Johnson	University of Michigan	426
Jean-Francois Rual	University of Michigan	179
Jay Hess	University of Michigan	24
Henry Paulson	University of Michigan	23
Gabriel Nunez	University of Michigan	140
Subramaniam Pennathur	University of Michigan	56
Dipankar Ray	University of Michigan	9
David M. Lubman	University of Michigan	23
Tomasz Cierpicki	University of Michigan	30
Yifan Liu	University of Michigan	20
Peter Ward	University of Michigan	12
Henriette Remmer	University of Michigan	5
Lois S. Weisman	University of Michigan	54
Yali Dou	University of Michigan	2
James Ferrara	University of Michigan	22
Puneet Garg	University of Michigan	52
Richard Auchus	University of Michigan	4
Peter Todd	University of Michigan	2
Sharlene Day	University of Michigan	3
Yatrik Shah	University of Michigan	3
Bishr Omary	University of Michigan	30
Ryan Wilcox	University of Michigan	9
Marc Peters-Golden	University of Michigan	6
Marina Mata	University of Michigan	72

Michael Wang	University of Michigan	4
Duxin Sun	University of Michigan	117
Malini Raghavan	University of Michigan	2
Mary Lee	University of Michigan	36
Joseph Holoshiz	University of Michigan	4
Billy Tsai	University of Michigan	6
David Ginsburg	University of Michigan	15
Jason Gestwicki	University of Michigan	20
Mark Day	University of Michigan	3
Antonio Iavarone	Columbia University	45
Venuprasad Poojary	Baylor University	48
Ashok Kumar	The University of Toledo	2
Sudhir Jain	The University of Toledo	2
William Maltese	The University of Toledo College of Medicine	4

Publications

Following are recent manuscripts that were published with the proteomic data generated at the PRF:

1. Shukla S, Allam US, Ahsan A, Chen G, Krishnamurthy PM, Marsh K, Rumschlag M, Shankar S, Whitehead C, Schipper M, Basrur V, Sourthworth DR, Chinnaiyan AM, Rehemtulla A, Beer DG, Lawrence TS, Nyati MK, Ray D. KRAS protein stability is regulated through SMURF2:UBCH5 complex-mediated b-TrCP1 degradation. Neoplasia 16(2):15, 2014.
2. Rolland D, Basrur V, Conlon K, Wolfe T, Fermin D, Nesvizhskii AI, Lim MS, Elenitoba-Johnson KS. Global phosphoproteomic profiling reveals distinct signatures in B-cell non-hodgkin lymphomas. Am. J. Pathol. 184(5):1331-42, 2014.
3. Nakamura Y, Oscherwitz J, Cease KB, Chan SM, Munoz-Planillo R, Hasegawa M, Villaruz AE, Cheung GY, McGavin MJ, Travers JB, Otto M, Inohara N, Nunez G. Staphylococcus-toxin induces allergic skin disease by activating mast cells. Nature 503(7476):397-401, 2013.
4. Conlon KP, Basrur V, Rolland D, Wolfe T, Nesvizhskii Al, MacCoss MJ, Lim MS, Elenitoba-Johnson KS. Fusion peptides from oncogenic chimeric proteins as putative specific biomarkers of cancer. Mol. Cell Proteomics 12(10):2714-23, 2013.
5. Chiruvella KK, Liang Z, Birkeland SR, Basrur V, Wilson TE. Saccharomyces cerevisiae DNA Ligase IV supports imprecise end joining independently of its catalytic activity. PLos Genet. 9(6):e1003599, 2013.
6. McDonnell SR, Hwang SR, Rolland D, Murga-Zamalloa C, Basrur V, Conlon KP, Fermin D, Wolfe T, Raskind A, Ruan C, Jiang JK, Thomas CJ, Hogaboam CM, Burant CF, Elenitoba-Johnson KS, Lim MS. Integrated phosphoproteomic and metabolomics profiling reveals NPM-ALK-mediated phosphorylation of PKM2 and metabolic reprogramming in anaplastic large cell lymphoma. Blood 122(6):958-68, 2013.

FLOW CYTOMETRY CORE LABORATORY AND VIRTUAL SLIDE SCANNING SERVICE

Lloyd Stoolman

Ronald Craig

Joshua Jacques

The Flow Cytometry Core Laboratory consists of **Dr. Lloyd M. Stoolman,** (Director), **Dr. Ronald Craig,** (Operator/Manager), **Joshua Foster** (Operator, scanning and flow core), and **Joshua Jacques** (application development, IT support).

Flow Cytometry Core Laboratory

The Laboratory provides access to a Becton-Dickinson LSR-II (3-laser, 10-color, 13-parameter; plate-loader), networked data storage, and web-based scheduling system. More than 60 undergraduates, graduate students, post-docs, research associates, and principal investigators from 17 laboratories used the instrument in FY14. The instrument operated a total of 2,093 hours – 2,005 hours were for departmental use, 31 hours for non-departmental use (recharged), and 57 hours of downtime

for service/maintenance.

Visit the Flow Cytometry Core Laboratory's website at pathology.med.umich.edu/pathflowcore/.

Table 19 shows usage by investigator and the cost of an equivalent level of service at the UM Core facility for unassisted ($60.00/hour) instrument operation (Cancer Center rates).

Table 19:

PI	Hour Used	UM Core $60.00/Hr.	% Usage
Bachman, Michael	21	$1,260	1.0
Cierpicki, Tomasz	28	$1,680	1.4
Dou, Yali	90	$5,400	4.4
Figueroa, Maria	90	$5,400	4.4
Grembecka, Jolanta	47	$2,820	2.3
Hess, Jay	197	$11,820	9.6
Hodgin, Jeff	6	$360	0.3
Hogaboam, Cory	74	$4,440	3.6
Kunkel, Steve	373	$22,380	18.1
Lukacs, Nicholas	327	$19,620	15.9
Muntean, Andy	71	$4,260	3.4
Nemzek, Jean	43	$2,580	2.1
Nikolovska-Coleska, Zaneta	138	$8,280	6.7
Nunez, Gabriel	121	$7,260	5.9
Phan, Sem	60	$3,600	2.9
Varani, James	106	$6,360	5.1
Ward, Peter	213	$12,780	10.3
Service	57	$3,420	2.8
TOTAL	**2,062**	**$123,720**	**100.0**

Pathology Virtual Slide Scanning Service

The Pathology Virtual Slide Scanning Service generates diagnostic quality (200-1,000x) digital slide scans using a Leica Biosystems (Aperio) AT2 (upgraded in November 2013 after fire destroyed Aperio XT scanner). In April 2014, the core image server was upgraded to an HP D2600 running 64-bit Windows Server 2008. The scanning service also maintains a Zwiss Axiomat computer-controlled photomicroscope with "mosaic" stitching software for applications that require fluorescence microscopy or high magnification (up to 1,000x). ~5,400 slides were scanned during FY14, a year-over-year increase of 8%, despite the disruption caused by the fire. Scans for education and clinical support (63% of scans) exceeded those for research projects (35% of scans) with 2% non-departmental (recharged).

The Virtual Slide Scanning Service maintains both vendor provided (Leica/Aperio Biosystems, Spectrum software) and custom design databases (see below) that support educational, clinical, and research application. The core HP D2600 image server has 38 terabytes of dedicated storage and currently hosts ~23,000 virtual slides (~14 terabytes) with capacity for 40,000+ slides. Virtual slides can be (1) transferred to portable media (flash drives, DVDs), (2) accessed and managed online via the Spectrum database, or (3) accessed through a variety of custom tools designed and maintained by Joshua Jacques and Lloyd Stoolman. The custom applications support educational, research, and training missions (see Specialized Virtual Microscopy Applications below).

The following usage table (Table 20) shows project, attending or PI, number of slides, percentage of scans that required manual set-up or stitching (adds 30 minutes to several hours/slide of operator effort), the cost at commercial rates ($60/slide), and the percentage of total slides scanned.

Table 20:

Project/PI Education, Clinical	**Slides**	**% Manual**	**Cost at $60/Slide**	**% of Total**
Resident and Fellows	45	100	$2,700	0.8
Hematopathology/Consults	147	100	$8,820	2.7
Lymphoma Conference	1163	100	$69,780	21.5
DermPath	75	100	$4,500	1.4
A. Andea	99	100	$5,940	1.8
H. Appelman	1	100	$60	0.02
S. Camelo-Piragua	212	50	$12,720	3.9
M. Chan	24	100	$1,440	0.4
D. Fullen	180	100	$10,800	3.3
P. Harms	3	100	$180	0.1
A. Lieberman	12	100	$720	0.2
R. Lieberman	140	100	$8,400	2.6
M. Lim	9	100	$540	0.2
D. Lucas	83	100	$4,980	1.5
P. McKeever	25	100	$1,500	0.5
B. McKenna	54	100	$3,240	1.0
J. Pang	2	100	$120	0.0
S. Ramsburgh	981	100	$58,860	18.2
J. Vergilio	2	100	$120	0.04
Fritzemeier - Surgical Path	79	100	$4,740	1.5
Total for Education, Clinical	3336		$200,160	61.8
Meetings				
J. Myers New Frontiers	60	100	$3,600	1.1
Research				
U. Balis	1	100	$60	0.02
A. Chinnaiyan	120	0	$7,200	2.2
G. Dressler	14	0	$840	0.3
T. Giordano/D. Thomas	263	100	$15,780	4.9
J. Hodgin	1021	20	$61,260	18.9
J. Nemzek	30	10	$1,800	0.6
G. Nunez	87	0	$5,220	1.6
R. Patel	1	100	$60	0.02
L. Stoolman	20	0	$1,200	0.4
J. Varani	344	100	$20,640	6.4
Total for Research	1901		$114,060	35.2
Non-Department		**Charge/Slide**		
Veracyte	103	$36.60	$3,770	1.9
TOTAL	5400		$321,590	100

Specialized Virtual Microscopy Applications Developed by the Slide Scanning Service Team

The UM Virtual Slide Box is a major new initiative by Joshua Jacques, Dr. Ron Craig (Pathology Informatics) and Dr. Lloyd Stoolman. This application streamlines access to online slide collections for residents, fellows, and interested parties outside the institution. It currently contains 3,500 virtual slides covering a growing number of areas in hematopathology and surgical pathology. It is accessible from computer workstations, tablets (including iPads), and smartphones. It provides an intuitive user interface that allows for (1) slide search based on diagnosis, (2) side-by-side image viewing for A-B comparisons, and (3) creating of "unknown sets" and "teaching sets" from the online collection. We currently have the server capacity to grow the collection to 10,000+ slides. The only ingredient needed to accomplish this ambitious goal is continued buy-in from the faculty and support for virtual microscopy personnel and infrastructure (detailed below).

You can visit the Virtual Slide Box website at pathology.med.umich.edu/slides/. The application works best on Chrome and Firefox internet browsers or Lecia/Aperio e-Path viewer (available from the Apple App Store, free download).

The relatively simple user interface belies the complexity of the infrastructure required to deliver the application. The hardware includes (1) the slide scanner and core virtual slide server in the Department of Pathology, (2) 10- MCIT/MSIS virtual servers running the web services element of the Spectrum software (under software license negotiated by Dr. Stoolman in exchange for early beta testing of Aperio hardware/software), and (3) custom software written by Joshua Jacques.

The custom code written and supported by Joshua Jacques performs the following activities in a semi-automated fashion: (1) strips patient identifiers from designated slide files on the core image server, (2) moves a "stripped" copy of the file to the sub-directory on MCIT/MSIS server, (3) links the virtual slides on the MCIT/MSIS server to a custom database that contains diagnoses and supports the specialized functions of the website described above, and (4) provides a simple, intuitive, and useful universal Web interface.

The MCIT/MSIS virtual slide servers were developed with MSIS originally to support medical, dental, and graduate students slide-based teaching activities. Slide-based laboratory exercises in the medical and dental curriculum are likely to diminish as priorities change. However, the clinical and post-graduate training missions of the UM Hospitals and the professional stature of the Department of Pathology are well-served by providing online access to the wealth of teaching material hiding in our slide libraries.

The searchable Hematopathology slide library is linked to Hematopathology reports, flow cytometry reports, and the frozen cells/tissue repository via Portal software used for case sign-out. It is used by Ron Craig, Joshua Jacques, Denise Sulavik, and trainees.

Ron Craig, Denise Sulavik, and trainees attended the Lymphoma Conference.

Faculty members made presentations at the New Frontiers in Diagnostic Pathology Conference, and presented courses on CAP and AJCP.

The virtual microscopy support for medical campus teaching initiatives encompasses a collection of virtual slide servers, teaching laboratory websites, and personnel that jointly support 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 includes websites in Medical Histology, Medical Histopatholoyg, Medical Organ Systems Pathology, Dental and Graduate Student Histology, and Histopathology.

Michigan Center for Translational Pathology

Arul M. Chinnaiyan, MD, PhD
S.P. Hicks Endowed Professor of Pathology
Professor of Urology
Director, Michigan Center for Translational Pathology

The Michigan Center for Translational Pathology (MCTP) was formed in 2007 as a focused initiative to bring basic research discoveries from molecular medicine to clinical applications for the identification of biomarkers and therapeutic targets for cancer diagnosis and treatment. This endeavor was supported by the Department of Pathology, the University of Michigan Health System, the Medical School, and the University President's Office. The goals of MCTP were not only to improve clinical care for cancer patients, but also to complement the academic goals of the University of Michigan Medical Center.

MCTP's overarching mission is to: 1) 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, and 2) establish a new paradigm of bringing personalized medicine to routine clinical care through the use of high throughput sequencing. In parallel with the UMHS, MCTP also has four core components to their mission: research, education, patient care, and service. Our specific goals are as follows:

- 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 the next generation of 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.

MCTP continues to expand and evolve and a solid foundation has enabled us to become well-positioned to pursue cutting-edge research to advance the discovery of important biomarkers of cancer as well as novel therapeutic targets. We have established strong partnerships with industries such as Agilent Technologies, Ventana, and GenProbe to translate basic research discoveries into clinical applications.

Recently, in collaboration with Dr. John Wei and the Early Detection Research Network, we developed a newly released clinical-grade assay, Mi-Prostate Score (MiPS), an early detection test for prostate cancer that incorporates three specific markers – TMPRSS2:ERG (T2:ERG) gene fusion, PCA3 (prostate cancer antigen-3), and PSA (prostate specific antigen). Two genes, TMPRSS2:ERG and PCA3, are specific for prostate cancer, and they are rarely present at high levels in the urine of men without prostate cancer. The MiPS test was developed by measuring serum PSA, urine T2:ERG, and urine PCA3 in men immediately before prostate biopsy. Models were then generated that optimally combine these three biomarkers to predict the presence of prostate cancer, or high-grade cancer, on biopsy. The MiPS test was developed and validated in almost 2,000 patients. MiPS is designed to help doctors and patients make a decision after PSA testing about whether to monitor PSA levels or pursue a prostate biopsy.

Our clinical sequencing study, Michigan Oncology Sequencing Center (MI-ONCOSEQ), has experienced a tremendous rate of growth since its inception in 2011. We have now sequenced over 400 adult and 80 pediatric (under PEDS-ONCOSEQ study) cancer patients in a CLIA-certified sequencing facility. Recently, from the MI-ONCOSEQ cohort, we analyzed nine ER-positive treated metastatic breast cancer patients. The samples were subjected to integrative sequencing including whole exome and transcriptome analysis that allows a mutational landscape of coding genes including point mutations, indels, amplifications, deletions, gene fusions/translocations, and outlier gene expression. We discovered non-synony-

mous mutations in the ligand binding domain (LBD) of the estrogen receptor, ESR1 in four index patients. All had been treated with anti-estrogens and estrogen deprivation therapies. A survey of The Cancer Genome Atlas (TCGA) identified 4 endometrial cancers with similar mutations of ESR1. The five novel LBD mutations of ESR1 we identified were shown to be constitutively active and continue to be responsive to anti-estrogen therapies *in vitro*. Taken together, our studies suggest that activating mutations of ESR1 are an important mechanism of acquired endocrine resistance in breast cancer therapy (*Nat Genet*. 2013 Dec;45(12):1446-51).

The translational successes outlined above are powered by the basic discoveries from the bench that continue to advance the field of cancer research. Our major research discoveries over the past year include:

1. The critical interactions between BET bromodomain protein 4 and androgen receptor that can be inhibited by the compound JQ1 to block androgen receptor signaling, and circumvent the acquired resistance related to hormone therapy during treatment of castrate-resistance prostate cancer (*Nature*. 2014 Jun 12;510(7504):278-82).
2. Prostate cancer-associated long non-coding RNA, SChLAP1 contributes to the development of lethal cancer at least in part by antagonizing the tumor-suppressive functions of the SWI/SNF complex (*Nat Genet*. 2013 Nov;45(11):1392-8).
3. The role of EED, a core component of polycomb repressive complex (PRC) 2, as an epigenetic exchange factor coordinating the activities of PRC1 and 2 (*Nat Commun*. 2014;5:3127. doi: 10.1038/ncomms4127).

Overall, we published over 40 papers from 2013 to present, seven of which were in journals with an impact factor of greater than 20 (*Nature*, *Nature Genetics*, *Cancer Cell*, and *Molecular Cell*). Our publications are highly cited with an overall h-index of 91 for Dr. Chinnaiyan (Web of Science®).

MCTP researchers continue to engage in both national and international collaborations with other research groups and industry partners. MCTP has a longstanding collaboration with the Early Detection Research Network (EDRN) and more recently with 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. To date, approximately 200 patients have been enrolled across the clinical sites. Other collaborations include Metabolon, Ventana, GenProbe, GenomeDx, and WaferGen to develop clinical testing platforms. Joint collaborations on research projects with industry partners include Armune Bioscience, to develop autoantibody cancer diagnostics, and Oncofusion Therapeutics, to design and optimize a new class of highly potent and specific BET bromodomain inhibitors for treatment of castrate-resistance prostate cancer.

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 *Bloomberg Business Week*, *Science Daily*, and *The Scientist*, among others. An improved, streamlined website that is easy to navigate in order to find critical information by the public, as well as treating physicians and researchers, was released in June, 2013.

Our publications in high impact journals and media exposure were coupled with the recognition of MCTP scientists by their scientific peers. Dr. Arul Chinnaiyan, an Investigator for the Howard Hughes Medical Institute and an American Cancer Society Research Professor, was the recipient of the Clifford Prize for Cancer Research from the Centre for Cancer Biology, Australia. He was also named the United States and Canadian Academy of Pathology (USCAP) Kaufman Timely Topics Lecturer, and most recently he was elected Member of the American Academy of Arts & Sciences.

Many of MCTP's researchers were also recognized for their achievements this past year.

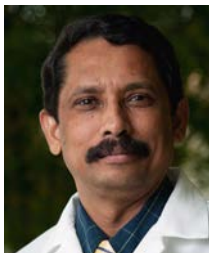
- **Anirban Sahu** was the recipient of the Rackham Travel Award to attend the 2014 Keystone Symposia "Long Noncoding RNAs: Marching Toward Mechanism" in Santa Fe, NM. He also received the NIH F32 individual predoctoral fellowship award.
- **John Prensner** was the recipient of the 2014 Dean's Award for Research Excellence and Graduation with Distinction in Research Honors. He also received the PCF Young Investigator award entitled, "Biological and Clinical Roles for the SChLAP1 Long Noncoding RNA in Aggressive Prostate Cancer".
- **Dr. Nalla Palanisamy** was awarded the NIH R21 entitled, ""Functional Characterization of Pseudogenes as New Biomarker in Prostate Cancer".
- **Dr. Irfan Asangani** won 1st prize for the poster entitled, "Therapeutic Targeting of BET Bromodomain Proteins for Castration-resistant Prostate Cancer" at the 2014 Prostate SPORE retreat. Dr. Asangani also received the highly com-

petitive and prestigious NCI Pathway to Independence Award (K99/R00).

- **Dr. Marcin Cieslik** received the PCF Young Investigator Award entitled, "Clinical Implications of Expressed Pseudogene Transcripts in Metastatic Castration-resistant Prostate Cancer."
- **Dr. Rohit Malik** received the PCF Young Investigator Award entitled, "Characterization and Therapeutic Targeting of Androgen Receptor Co-activators in Castration Resistant Prostate Cancer."
- **Dr. Scott Tomlins** was the winner of the inaugural Martin and Rose Wachtel Cancer Research Award presented by the American Association for the Advancement of Science and Science Translational Medicine. He has also been awarded a NIH R01 entitled, "Exploiting Drivers of Androgen Receptor Signaling Negative Prostate Cancer for Precision Medicine."
- **Dr. Shaomeng Wang** was named 2014 Distinguished University Innovator.

Anirban Sahu

John Prensner

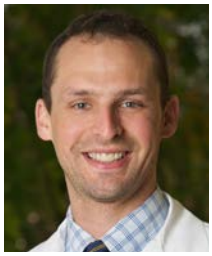


Nalla Palanisamy

Irfan Asangani

Marcin Cieslik

Rohit Malik



Scott Tomlins

Shaomeng Wang

Students, postdoctoral, and clinical fellows that trained at MCTP have successfully obtained employment as either independent faculty or in industry positions. **Dr. Chad Brenner**, a former graduate student and postdoctoral fellow, joined the faculty at the University of Michigan's Department of Otolaryngology. **Dr. Shanker Kalyana-Sundaram**, who obtained his Ph.D. jointly with MCTP, was recruited by GlaxoSmithKline as a Research Analyst Senior. Former bioinformatics graduate student **Alejandro Balbin** joined Novartis as an investigator in their Bioinformatics division.

Chad Brenner

Shanker Kalyana-Sundaram

Alejandro Balbin

MCTP funding continues to be strong despite the challenging funding climate. This past fiscal year, we obtained $12,579,104 in committed awards. In addition, MCTP discoveries generated $3,621,007 of royalties to U-M in FY14. Fundraising efforts through the Medical School's Office of Development were productive this year. MCTP received a total of $276,322 in gifts directly from donors in FY14.

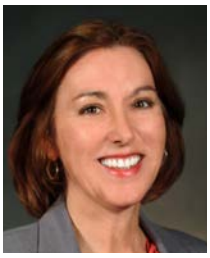
Total gross charges continue to increase each fiscal year for our CLIA testing. FY14 saw total gross charges of $3,369,682. The majority of the charges were due to the PCA3 technical component ($2,338,990).

MCTP continues to be successful on all fronts with making progress towards our goal of translating basic laboratory discoveries into clinical applications. We strive to remain at the forefront and continue to make a significant impact on cancer biology, bioinformatics, and the emerging field of precision medicine. With sustained efforts, we anticipate exciting new discoveries that impact patient health in the coming year, particularly as our clinical sequencing program experiences increasing demand.

MLabs Outreach Program

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

MLabs, established in 1985, serves as a portal to ensure that those from outside the University of Michigan Health System (UMHS) have easy access to the expertise and sophisticated testing of the Department of Pathology faculty, staff, and laboratories. As we celebrate our 29th anniversary in the reference laboratory business, we are a recognized leader for advanced diagnostic testing, anatomic and hematopathology consultations, and exceptional customer service. Our ability to establish long term relationships with our clients is built on the promise of *Expertise Delivered Personally* and our commitment to service excellence.



Sue Valliere

Sue Valliere has served as Manager of our MLabs program since its inception in 1985 and continues to play a central role in our collective successes. With our successfully recruiting an Operations Manager (Dierdre Fidler) in FY14 she is now increasingly focused on strategic partnerships and business development.

GROWTH

MLabs' client portfolio includes over 500 accounts. We provide referral laboratory testing in several specialized fields (e.g., molecular diagnostics, renal biopsy, nerve and muscle biopsies, and anatomic and hematopathology consultations) to most hospitals in Michigan, and many other hospitals nationwide. We have major hospital clients that utilize MLabs as their primary reference laboratory; two of which have large outreach programs and complex referral laboratory services. Our Molecular Diagnostic Laboratory provides an extensive menu of qualitative and quantitative analysis for the diagnosis of inherited genetic abnormalities and hematologic and solid tumor malignancies to several national commercial reference laboratories. In addition to our hospital and reference laboratory clients, we provide laboratory services to over 125 physician offices in our geographic service area. Having the direct experience in serving the needs of our physician community helps us understand the unique challenges in the physician office market, thus allowing us to better support our hospital clients as they manage their own outreach business. Finally, MLabs provides phlebotomy and laboratory services to the nursing home/acute care facilities in our area in an effort to provide continuum of care for these patients, many of whom have been discharged from our hospital to these facilities.

MLabs continues to experience consistent growth. Working together, the MLabs team acquired 85 new clients during FY14. While we do not anticipate large volume from each of them, collectively they represent growth opportunities in FY15. We successfully responded to three RFPs for renewal business and have one outstanding RFP waiting for decision.

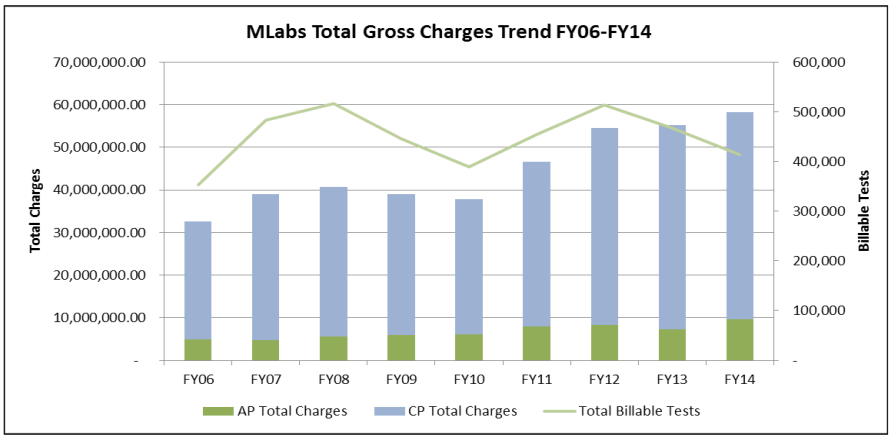


Figure 16: MLabs Total Gross Charges (Professional and Technical) Trend FY06-FY14

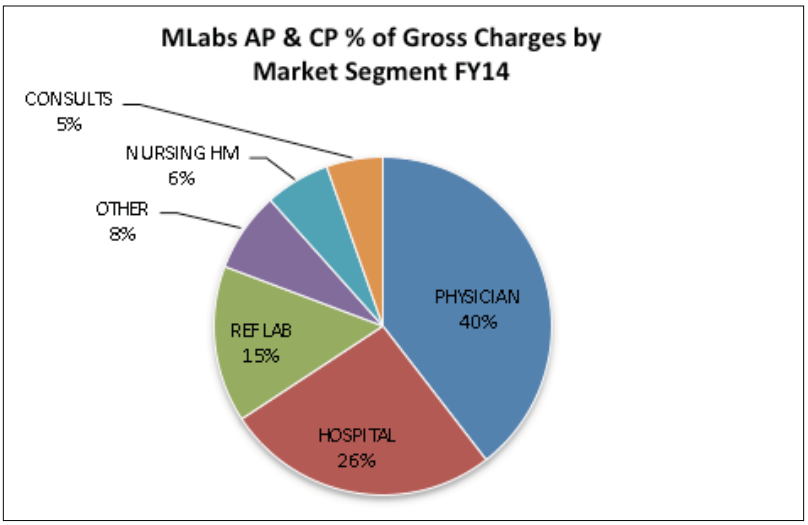
FY14 Total Gross Charges increased over FY13 by approximately $3M, allowing MLabs to make significant contributions to the margin that supports all of the missions of UMHS and the Department.

MARKET SEGMENTS SERVED

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

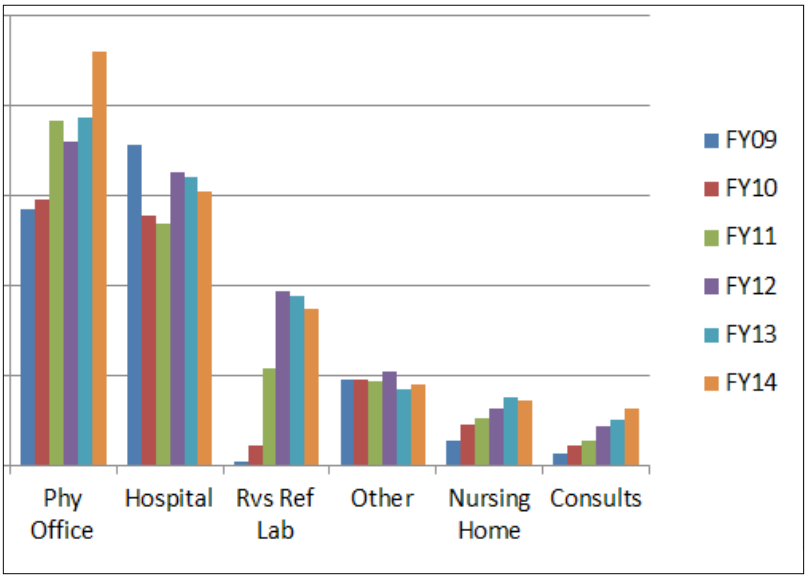
MLabs categorizes its business into six market segments. Understanding the percentage of total business by market segment provides useful information to guide strategic planning and allocation of resources to support the unique needs of each book of business.

Figure 17: MLabs AP & CP % of Gross Charges by Market Segment FY14



Physician Office – all Specialties
Hospital – both full service and those sending specialized testing
Reverse Reference Laboratories – commercial/ independent labs
Consultations – includes HemePath
Nursing Home – extended nursing and acute care facilities
Other – Miscellaneous 'catch all' category (REFR)

Fig 18: Total Gross Charges Trend by Market Segment FY09-FY14

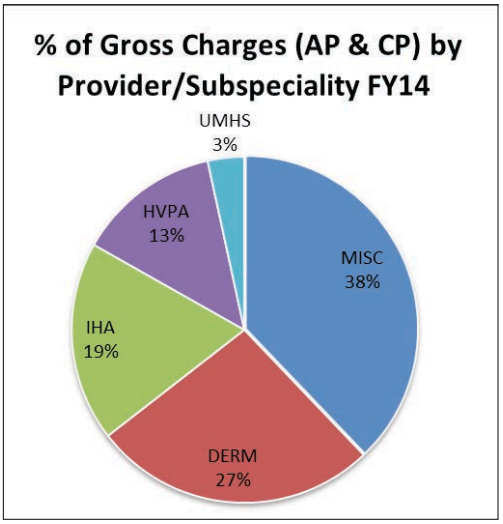


MLabs' physician office market continues to grow organically; hospital market fluctuates with acquisitions/mergers; reverse reference lab remains strong; the segment with the most potential for growth, nursing home accounts, are purposely limited to UMHS strategic goals; and continued growth in consult cases allow opportunities to provide other services.

MARKET SEGMENT IN DETAIL

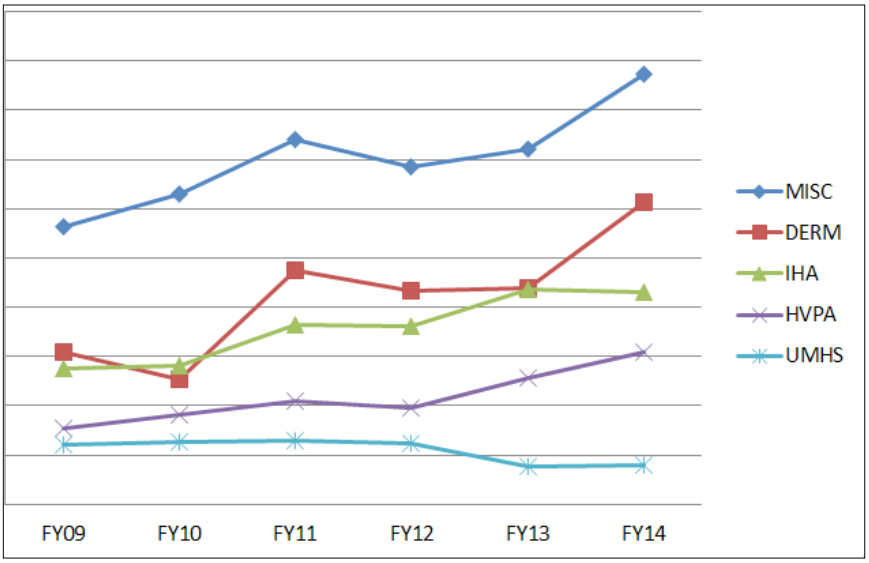
Physician Office Market Segment (40% of Total Gross Charges)

Figure 19: Physician Office Market Segment by Provider/Subspecialty FY14



MLabs provides laboratory testing to over 150 individual offices in the greater Washtenaw County service area. In addition, we provide services to 54 Integrated Health Associates (IHA) offices (over 300 physicians), 55 Huron Valley Physicians Association (HVPA) (over 500 physicians), as well as 25 dermatology offices and numerous independent practices. MLabs has a bi-directional interface with the IHA practices (electronic orders in and results out) required to support their interest. We are interfaced with several common EMRs allowing us to meet some of our physician office clients' result reporting interface needs, but many remain in the queue. The number of interface requests continues to outpace our ability to respond expeditiously. We experienced significant growth in this market, especially dermatology, and anticipate this to continue provided that we focus increase IT effort on interfacing to these offices.

Figure 20: % Total Gross Charges Trend FY09-FY14



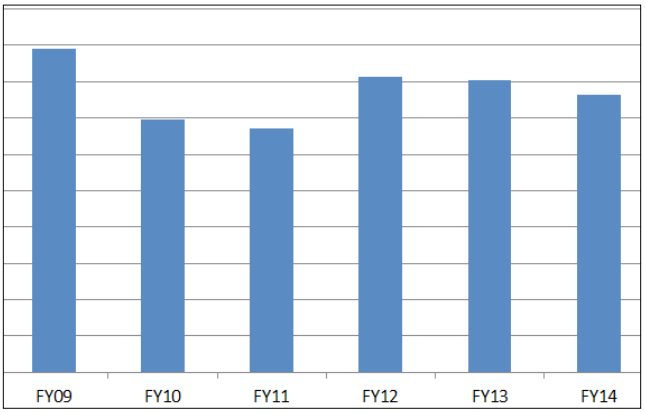
Intentionally transitioning 'UMHS' (various UM run clinics previously handled as MLabs) to UM/MiChart, non-MLabs accounts.

Physician Office Market % of Total Gross Charges	FY09 36%	FY10 39%	FY11 41%	FY12 33%	FY13 35%	FY14 40%	% Change FY13 vs. FY14 = 12%

Hospital Market Segment (26% of Total Gross Charges)

MLabs is a primary reference laboratory and provides full esoteric testing to three 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 60 + hospital clients around the country that routinely seek us out for referral testing.

Figure 21: Hospital Market Total Gross Charges Trend FY09-FY14

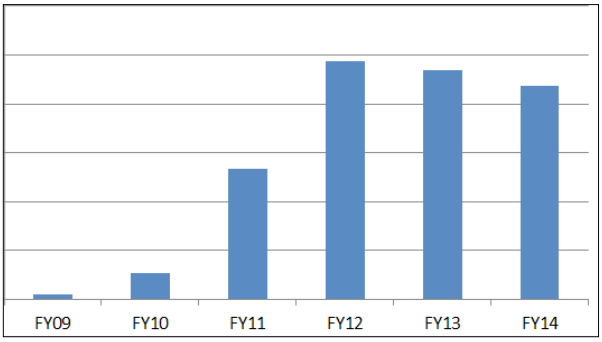


Hospital Market % of Total Gross Charges	FY09 46%	FY10 37%	FY11 28%	FY12 30%	FY13 29%	FY14 26%	% Change FY13 vs. FY14 = 11%

Reverse Reference Lab Market (15% of Total Gross Charges)

The sustained success in the Reverse Reference Lab market segment reflects the outstanding combined effort of the Molecular Diagnostic Laboratory, MCTP, and MMGL, combined with MLabs focused sales and marketing effort, its Client Services Staff, and Pathology Informatics efforts toward supporting the challenging IT requirements. With increased competition in the marketplace and advances in technology, we see smaller commercial laboratories offering a larger test menu and some molecular diagnostic testing being 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.

Figure 22: Reverse Reference Lab Total Gross Charges Trend FY09-FY14

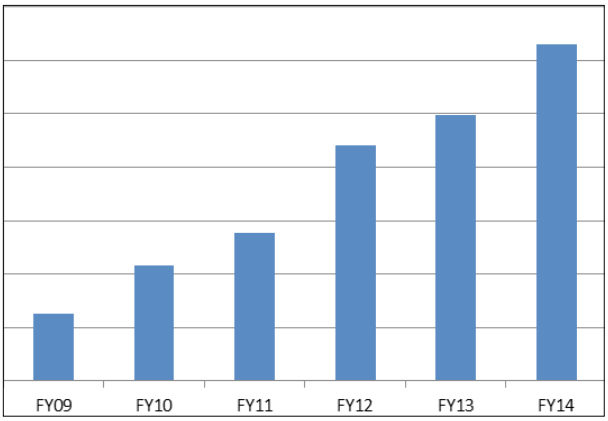


Reverse Reference Lab % of Total Gross Charges	FY09 1%	FY10 3%	FY11 11%	FY12 18%	FY13 17%	FY14 15%	% Change FY13 vs. FY14 = -13 %

AP Consultations (5.4% 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 85 established clients referring consult cases to us. Most diagnosis is rendered within 24-48 hours of receipt with result reporting primarily by facsimile. Referral consultations demonstrate consistent year-over-year increases in percentage of total MLabs gross charges.

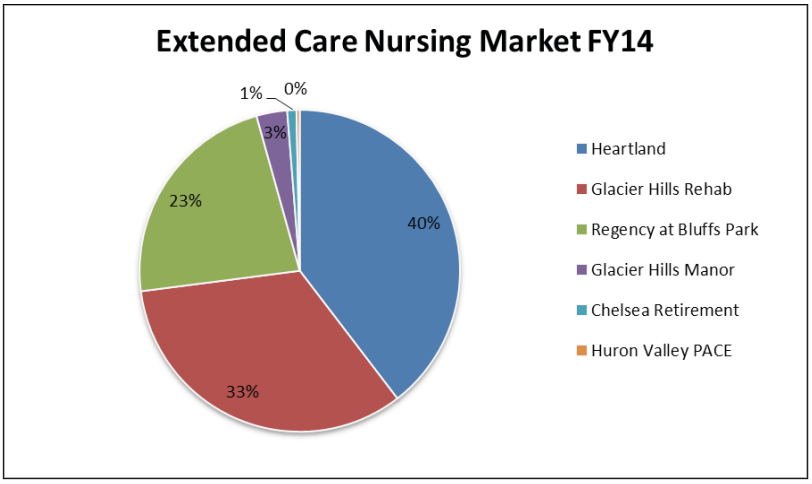
Figure 23: Consults – Total Gross Charges Trend FY09-FY14



Consults % of Total Gross Charges	FY09 2.0%	FY10 2.8%	FY11 3%	FY12 4%	FY13 4.5%	FY14 5.4%	% Change Gross Charges FY13 vs. FY14 = 16.7 %

Extended Care Nursing Facilities (6.0 % of Total Gross Charges)

Figure 24: Extended Care Nursing Facilities



MLabs provided laboratory and phlebotomy services to five regional nursing homes and acute care facilities. The percentage of MLabs total business this market segment remains consistent with our desire to limit this to those facilities with an UMHS strategic interest.

FY14 INITIATIVES

MLabs Website and Social Media

A continued, dedicated effort supports our MLabs website that serves as 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 is a 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 contract an outside agency to manage this activity. Preliminary data indicates that we are being seen, heard, and followed.

Informatics

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 many of our clients receive results

electronically via multiple interface platforms and secure delivery systems. The demand for IT connectivity challenges our abilities to deliver. We continue to explore information technology solutions 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's 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. During FY14, MLabs exhibited at four national meetings (USCAP, CAP, AMP, 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.

Our partnership with Paradigm has allowed for collaborative sales and marketing initiatives with prospective clients as well as planned joint exhibits at national meetings in 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 (GLLN) is a network of hospital laboratories geographically located primarily on the western side of the state. MLabs became a member of GLN in 1996 but does not participate in managed care contracts through GLN. MLabs plays an advisory role through representation on the Steering Committee.

MLabs helps facilitate departmental issues pertaining to contractual obligations as a member of JVHL and GLLN. MLabs serves as a resource for UMHS' Managed Care Operations Office with lab related issues.

ACKNOWLEDGEMENTS

MLabs 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.

VA Ann Arbor Healthcare System

Stephen W. Chensue, MD, PhD
Professor of Pathology
Chief, Pathology and Laboratory Medicine Service
VA Ann Arbor Healthcare System

The VA Ann Arbor Healthcare System (VAAAHS) 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 VAAAHS Pathology and Laboratory Medicine Service (PALMS) maintain a close relationship with the UM's Department of Pathology at every level. All pathologists in the VAAAHS have medical school appointments and participate in university activities in a manner similar to other departmental sections. Recruitment for VAAAHS pathologists is a joint activity and candidates are selected on the basis of academic performance and potential, as well as professional competence similar to any departmental candidate. There are currently four full-time pathology staff positions plus a consultant dermatopathologist. Three resident training positions in the Department's program are supported with funds from the Department of Veterans Affairs. All residents serve monthly rotations in Surgical Pathology and Autopsy Pathology, with access to special study programs in Surgical Pathology, Cytopathology, and Digital Imaging. The VAAAHS laboratory retains full accreditation by the College of American Pathologists. The VAAAHS satellite laboratory at the Toledo 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 four 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, MI and Jackson, MI. The VAAAHS PALMS provides specimen testing for these sites and oversees all ancillary testing. All sites are fully accredited by the College of American Pathologists (CAP).

ANATOMIC PATHOLOGY

Surgical Pathology

In addition to serving its local hospital and clinics, the VAAAHS PALMS is currently performing all surgical pathology for the Aleda E. Lutz VA Medical Center in Saginaw, MI and VA facilities in Battle Creek, MI and Grand Rapids, MI. The Ann Arbor PALMS also performs all gynecologic cytopathology for Saginaw, MI; Battle Creek, MI; Detroit, MI; and Toledo, OH and affiliated CBOCs. Beginning FY14, the department began providing Telepathology services to the VA Northern Indiana Healthcare System.

Case Load

14,040 surgical cases were accessioned and reported during this reporting period, this represents a 9.9% increase over last year. This continues the trend of steadily increasing workload.

Quality Assurance

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

Surgical pathology diagnosis under 48 hr:	98.4%
Average surgical pathology report turn-around-time:	1.4 days
Case concordance (internal and external second reviews):	95.8%
Average frozen section turn-around-time:	9.0 min.
Frozen section to permanent section concordance:	99.0%

Informatics, Infrastructure, and Automation

In FY14, the VAAAHS PALMS instituted a digital telepathology program using whole slide imaging. In February 2014, VAAAHS started providing telepathology consultation services to the Northern Indiana Healthcare System.

Autopsy Pathology

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

Case Load

13 autopsies were performed during the reporting period.

Quality Assurance

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

Autopsy completion turn-around-time average:	7.6 days
Percent less than 30 days:	100%

Cytology

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

Case Load

5,197 cases were examined and diagnosed during this period. This is a 4.5% 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.

Non-gyn cytology diagnosis under 48 hrs:	98.8%
Average non-gyn and gyn turn-around-time:	4.46 days
Cytology PAP diagnostic concordance:	100%

CLINICAL PATHOLOGY

During the period of this report 1,933,146 clinical pathology tests were performed in the Ann Arbor laboratory with the following breakdowns:

Chemistry	1,638,576
Hematology/Coagulation/Urinalysis	178,826
Microbiology	62,898
Blood Bank	23,893
Other	28,953

A total of 124,897 phlebotomies were performed. Our affiliated community-based outpatient clinic laboratory in Toledo, OH performed 313,913 tests.
Residents may participate or observe clinical pathology procedures when this activity is appropriate in relation to their rotations. Drs. Chensue, Bieliauskas, and Chamberlain oversee the clinical laboratory and make interesting and pertinent clinical laboratory information available to residents as desired. Clinical Pathology and medical historical data is available to pathology residents via CPRS in surgical pathology, autopsy pathology, and elective rotations.

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

Informatics, Infrastructure, and Automation
The VAAAHS clinical laboratories have continued to incorporate as much automation as possible employing state-of-the-art analyzers. In FY14, new Hematology, Coagulation, and Microbiology analyzes were installed.

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 specimens grossly and microscopically under close one-to-one mentoring by the staff pathologists. The resident interacts with the clinical teams. A weekly Urology Case Review Conference is held by Dr. Murphy. 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. Because of the closeness of various sections of the laboratory, there is frequent consultation among the pathologists and the residents are involved throughout. Since the VAAAHS is physically close to the University, the residents are expected to attend the appropriate teaching conferences at the University. VAAAHS pathologist staff contribute to teaching of medical and graduate students at the University of Michigan. Through his research program, Dr. Chensue also mentors post-doctoral fellows, graduate students, and undergraduate students.

RESEARCH

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

ADMINISTRATION

Dr. Chensue has served as Chief of Service since March 2001. He serves on the VA/UM Affiliation Council, as well as local and national VA oversight committees. Staff pathologists at the VAAAHS 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, and teaching faculty for post-graduate courses in the medical school. At the VAAAHS, the pathology staff members serve on all major committees involved with institutional policies and procedures.

SUMMARY

The VAAAHS PALMS 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 veteran patients. This is evidenced by continuing accreditation by external review agencies such as CAP, the Joint Commission for hospital accreditation, and the Food and Drug Administration. 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 improve-

ment 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 as well. The VAAAHS PALMS is positioned to continue delivery of high quality service to veteran patients as demand for medical care continues to mount in the next decades.

Figure 25:

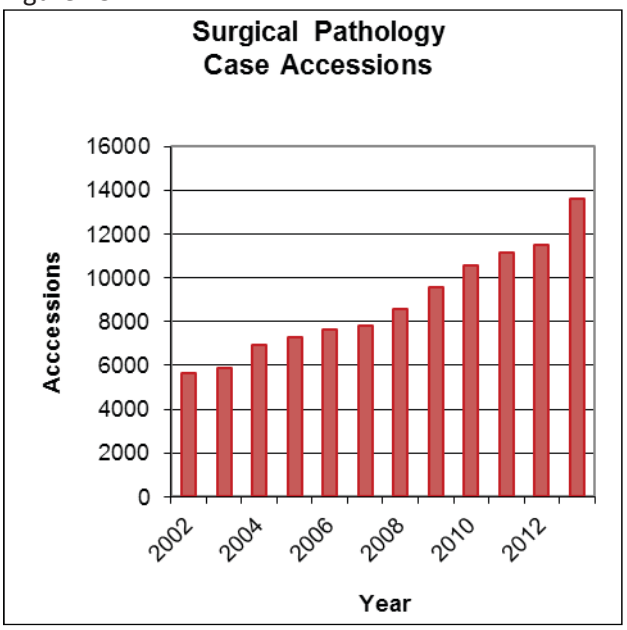


Figure 26:

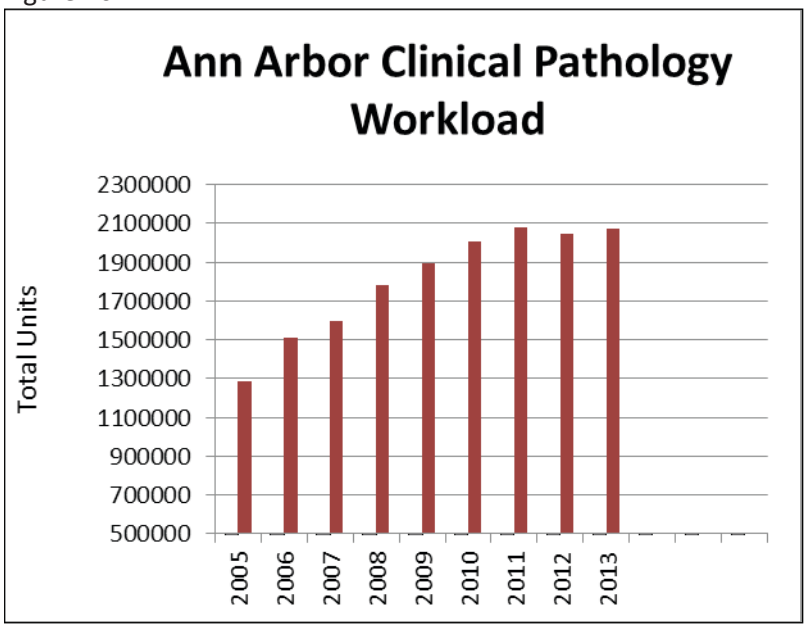
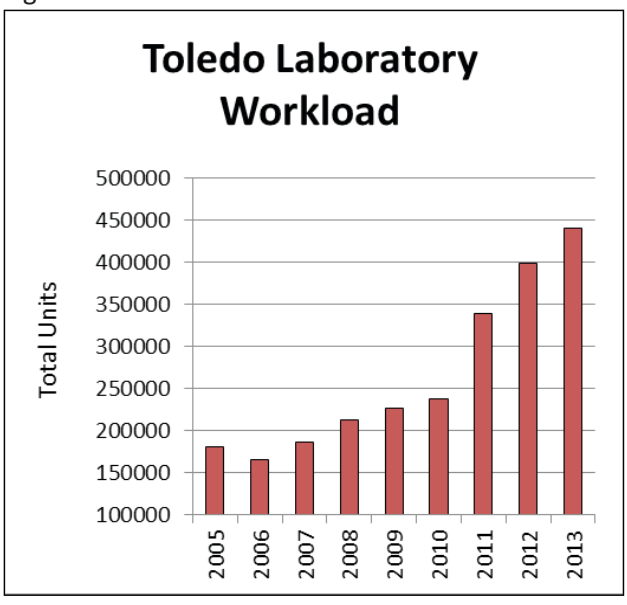


Figure 27:



Division of Finance and Administration

Martin Lawlor
Director, Division of Finance and Administration

The Division of Finance and Administration is under the Office of the Chair and directed by **Martin A. Lawlor**, Department Administrator. Marty is responsible for the business, operational, and fiscal affairs of the Department of Pathology as mandated by the policies of the Chair, University of Michigan Health System (Medical School and Hospitals), and the University of Michigan. In addition to directing this Division, Marty serves on various departmental, Health System, and University committees, including the Financial Advisory Committee and the Cancer Center Ambulatory Care Coordinating Group. He 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 Medical School. Marty 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.

Some key divisional highlights orchestrated by Finance and Administration this academic year include:

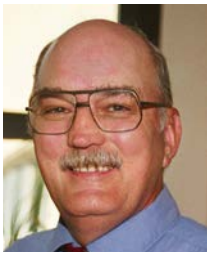
- Managing the Wayne County Medical Examiner's Office contract (through September 2014) and Washtenaw County Medical Examiner's Office contract (through September 2015), which has allowed us to add eight new faculty positions and two new fellowships; and negotiating a new contract through 2017 that will integrate all Wayne County Medical Examiner activities with UMHS.
- Continuing to support the non-profit joint venture with Paradigm for personalized medicine and incorporating it into our workflow.
- Planning space solutions for NCRC Buildings 30, 35, 36 and 60.
- Assisting the Department with the transition of the Interim Chair and helping to orient the new Chair.

We saw our professional revenues increase once again this year. Pathology began professional component billing for Clinical Pathology outpatient services in the 4th quarter of 2010, resulting in a new revenue stream of $1,470,744. UMHS Department of Pathology is the first group to institute professional component billing in the State of Michigan. We have also seen the benefit of three years of work on blood product negotiations with the Red Cross and utilization reductions that resulted in a savings of over $2 million from FY 2010.

ADMINISTRATIVE SUPPORT CENTER

Administrative Support Center/Pathology Laboratories

The Administrative Support Center for Pathology Laboratories is responsible for the preparation and monitoring of all Hospital laboratories' revenue, expense, capital budgets, and personnel and payroll systems. During this period, total laboratory expenditures were $101,141,386. Pathology is responsible for 10% of total Hospital Gross Revenue and 4.5% of total expense. As detailed below, **Tom Morrow** is responsible for administration of the Clinical Pathology Laboratories, **Christine Rigney** for the administration of the Anatomic Pathology Laboratories, and **Suzanne Butch** for maintaining licensure and accreditation for our laboratories.



Tom Morrow

Christine Rigney

Suzanne Butch

Tom Morrow oversaw the Clinical Pathology Laboratories. Clinical pathology laboratory activity was above last fiscal year's levels, as was Clinical Pathology revenue. Tom 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, such as Mayo Medical Laboratories, Ventana, and Atlas Medical Systems, were re-negotiated under Tom's supervision this past year.

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 Pathology Operations meetings and coordination of subsequent projects resulting from these discussions. Kristina also serves as the department liaison with nursing.

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, Central Accessioning, and the Administrative Assistant team supporting AP Faculty. Services are provided in the University Hospital, Cardiovascular Center, Children's and Women's Hospital, and East Ann Arbor Ambulatory Surgery Center. Chris is the department lead for many building and renovation projects which include future laboratory space planning. She 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.

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

David Golden

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.

David managed the UMHS and All Funds expenditures and forecast processes. Total Medical School All Funds expenditures for FY 2014 (Pathology and MCTP) were $59,949,013 and Hospital expenditures were $101,141,386. He also developed the 2015 forecast for the Hospital, Pathology, and the MCTP; and managed the pre- and post-award research enterprise for both Pathology and the MCTP. There were 167 research proposals submitted to external sponsors this year. 56 of these proposals were submitted to the NIH. Committed awards for FY 2014 were $31,563,730. An increase of 17.1% over FY 2013 committed awards. Actual sponsored research revenue was $31,341,919. A 4.4% increase over FY 2013 actual research revenue. Overall, the academic side of the Department saw a 1.7% increase ($879,802) in the following revenue components: net patient care, federal and non-federal research, and other revenue (Washtenaw and Wayne County contracts, royalties, rebill activities, and operating transfers) from FY 2013 to FY 2014. Overall gross charges for Pathology's group practice were up 11.3% ($6.2M). David and his billing team played a pivotal role in the launch of the new Soft Laboratory Information System (LIS). They successfully transitioned all professional and technical billing to the new LIS with minimal impacts to revenue capture. He continues to manage and mentor Cindy Benedict, Karen Giles, Mary Green, John Harris, Laura Labut, Jenny Mattson, Nancy Parker, Thad Schork, and Christine Shaneyfelt in their analytic and managerial roles.

Nancy Parker is responsible for all front-end (charge capture) billing operations. Hospital technical gross revenue for FY 2014 was $600,997,172, compared to $538,957,092 in FY 2013, an increase of 11.5%. Professional fee gross charges were $61,143,603. Nancy 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.

Nancy Parker

John Harris

John Harris is responsible for oversight of the accounting and financial staff supporting our research programs and the daily management of the post award process. Extramural sponsored expenditures for FY 2014 amounted to $31,388,197. John manages a staff of two accountants and two procurement specialists. This year, he 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.

Thad Schork

Christine Shaneyfelt

Thad Schork is responsible for pre-award activities for the Department of Pathology's research program. 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.

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

Human Resources, Faculty Affairs, and Education

Katie Adams

Karyn Procter-Wicks

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 **Katie Adams** with support from **Karyn Procter-Wicks** and **Audrey Morton-Dziekan**. 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 230 FTEs).

Sarah Dudley-Short

Faculty Affairs is the responsibility of **Sarah Dudley-Short**, who coordinates appointments, reappointments, and promotions for our faculty (125.68 FTEs). Sarah is responsible for the Education Office activities including the Residency and Fellowship Training Programs (28 residents and 18 fellows in seven ACGME and seven non-ACGME programs) and the Medical Student Education Teaching Programs for the M1 and M2 laboratories and the M4 Clerkship Program. Sarah also maintains our online Academic HR Tool to track all faculty, fellows, and residents.

Laura Labut

Laura Labut is responsible for administration of the Molecular and Cellular Pathology PhD program with 31 students actively pursuing their doctoral degrees. 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. Laura is the administrator for the department's two NIH training grants

(PIs Steven Kunkel, Ph.D. and Nicholas Lukacs, Ph.D.) which support four pre- and eight post-doctoral trainees. Laura performs the human resource functions for the department's graduate students (41 including 12 non-MCP students with Pathology mentors) and training grant trainees (four).

Office of the Chair

Angela Suliman

Angela Suliman provides support to the Department Administrator, including scheduling, travel arrangements, data collection, and event planning, in addition to supervising and managing all staff and activities in the Chair's office. She has been the facilitator for the Administrative Modernization Research Subcommittee, the Cancer Center Ambulatory Care Coordinating Group, the Post-Award Implementation Team, and the Diabetes Working Committee. She oversees the reconciliation of the department P-Cards, the renewal of medical licenses, and payment of all CME requests for faculty and house officers. Angie also serves as the conference coordinator for the Advances in Forensic Medicine & Pathology Conference, which was held for its fifth year.

Laura Zaborski

Liz VanderElzen

Laura Zaborski provides support to the Chair of the Department including management of calendars, travel arrangements, preparation of correspondence, and all materials related to the many committees chaired by Dr. Cho. Laura has led the efforts for the development of an annual departmental alumni newsletter, as well as working with the Office of Development to create an online giving page.

Liz VanderElzen is responsible for processing all of the CME requests for the faculty and house officers in addition to reconciling the P-cards for the Chair and Administrator. Liz worked with a team to look at how we track CME funds while providing the most up-to-date balance. In addition, she also manages the conference room calendars and provides back-up support for Laura and Angie.

Pathology Professional Fee Billing Office

Holly Daul

Holly Daul continues 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. Holly serves on several physician professional fee committees and is one of the Process Owners for MiChart.

For information, questions, or permission requests, please contact:
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