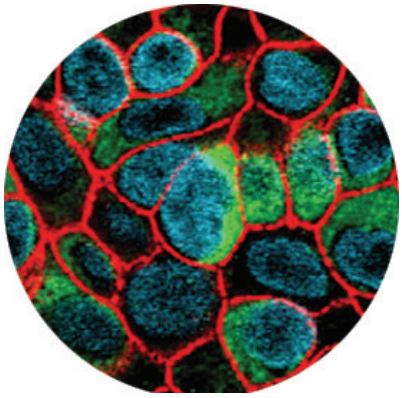
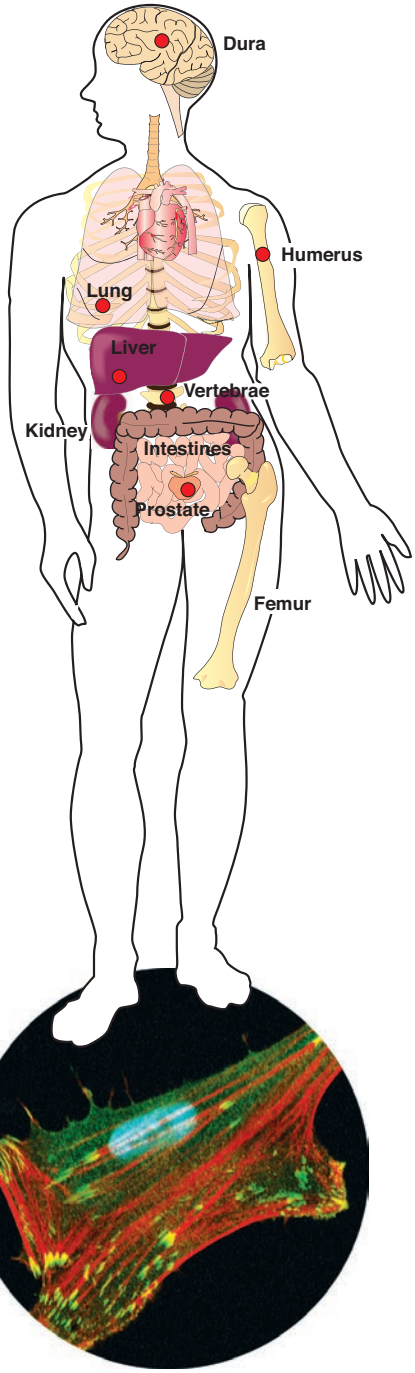
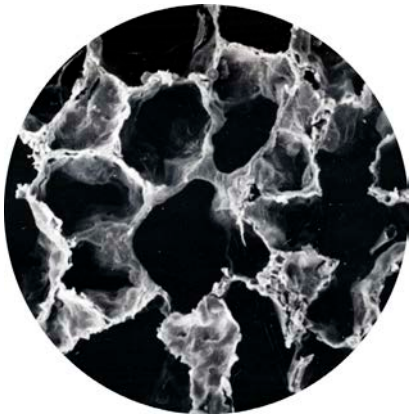
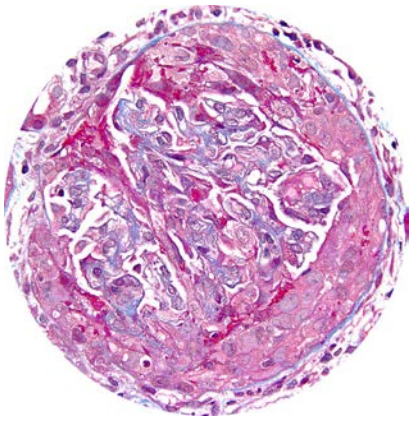
DEPARTMENT OF PATHOLOGY
UNIVERSITY OF MICHIGAN HEALTH SYSTEM

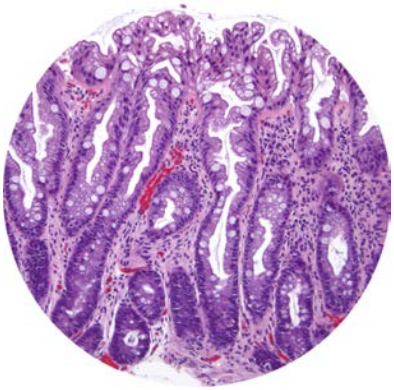
Annual Report
2014 - 2015

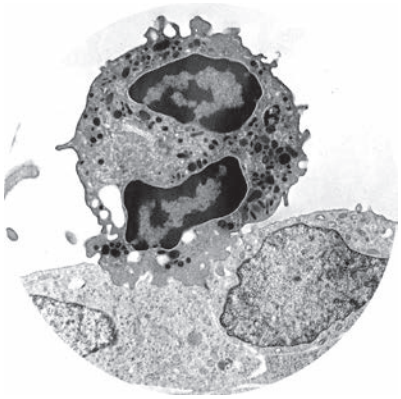












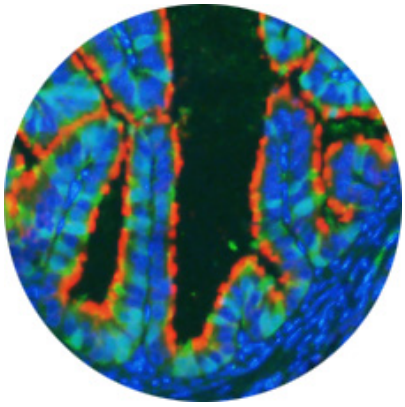


Table of Contents:

Chair's Report.....1-5
Anatomic Pathology.....6-14
Clinical Pathology.....15-37
Education.....38-43
Experimental Pathology.....44-45
Informatics.....46-52
MLabs.....53-57
Michigan Center for Translational Pathology 58-60
Molecular and Genomic Pathology.....61
Quality and Health Improvement.....62-65
VA Ann Arbor Healthcare System.....66-69
Finance and Administration.....70-73

Cover (clockwise)

Upper R:	*SEM of normal rat lung (by R. Kunkel for P.A.Ward)*
Mid R:	*Typical colonic hyperplastic polyp (H. Appelman)*
Lower R:	*Mouse oviduct showing red tubulin expression post tamoxifen (by Rong Wu in K. Cho lab)*
Lower Center:	*Fibroblast showing red actin fibrils (by M. Dame in J. Varani lab)*
Lower L:	*TEM of PMN adhering to endothelium (by R. Kunkel for P.A.Ward)*
Mid L:	*Ductal carcinoma in situ expressing E-cadherin (red) and AMACR (green) (C. Kleer)*
Upper L:	*Rapidly Progressive Glomerulonephritis (P. Killen)*
Center Art:	*Investigating pancreatic tumor metastases (by R. Kunkel for C. Kumar)*

1. Charles Parkos, MD, PhD
2. Jeffrey Myers, MD
3. David Keren, MD
4. Kathleen Cho, MD
5. Kathryn McFadden, MD
6. Charles Ross, MD
7. Hemamalini Ketha, MD
8. Madelyn Lew, MD
9. Celina Kleer, MD
10. Zaneta Nikolovska-Coleska, PhD
11. William Carson, PhD
12. Arul Chinnaiyan, MD, PhD
13. Sriram Venneti, MD, PhD
14. Jolanta Grembecka, PhD
15. Andrew Lieberman, MD, PhD
16. Jonathan McHugh, MD
17. Marie (Ken) Figueroa, MD
18. Tomasz Cierpicki, PhD
19. Jean-Francois Rual, PhD
20. Yifan Liu, PhD
21. Scott Tomlins, MD, PhD
22. Roland Hilgarth, PhD
23. Monique O'Leary, PhD
24. Jennifer Brazil, PhD
25. Robert Penny, MD, PhD
26. Michael Garratt, PhD
27. David Lombard, MD, PhD
28. Asma Nusrat, MD
29. Veronica Azcutia Criado, PhD
30. Shuling Fan, MD
31. Lauren Smith, MD
32. Jeffrey Hodgin, MD, PhD
33. Richard Millller, MD, PhD
34. Ulysses Balis, MD
35. Tom Wilson, MD, PhD
36. Jeffrey Jentzen MD, PhD
37. Scott Owens, MD
38. Aleodor Andea, MD
39. Nathanael Bailey, MD
40. Barbara McKenna, MD
41. Jiaqi Shi, MD, PhD
42. Bertram Schnitzer, MD
43. Paul Killen, MD, PhD
44. Kristine Konopka, MD
45. Evan Farkash, MD, PhD
46. Daniel Boyer, MD, PhD
47. Rajan Dewar, MBBS, PhD
48. Donald Giacherio, PhD
49. Michael Roh, MD, PhD
50. John Frederiksen, MD, PhD
51. Amer Heider, MD
52. Anuska Andjelkovic-Zochowski, PhD
53. Paul Harms, MD, PhD
54. David Gordon, MD
55. Michael Bachman, MD, PhD
56. Martin Lawlor
57. Peter Ward, MD
58. Henry Appelman, MD
59. Andrew Muntean, PhD

2014-15 Department of Pathology Faculty*

* In all there are 181 Department of Pathology faculty members, including Emeritus and Adjunct professors. A fraction are pictured here on the steps outside the Medical Science Building II in the fall of 2015.

Charles A. Parkos, MD, PhD
Carl V. Weller Professor and Chair

Chair's Report

It has been an honor to lead this department since September 2014, and my first year has been nothing short of a fantastic experience that has been marked by many significant changes. During this time, Dr. Mark Schlissel completed his first year as President of the University of Michigan which began on July 1, 2014. As a physician-scientist, he has begun tackling many important issues including expanding diversity and improving basic science education and research here at the University of Michigan. While Dr. Schlissel was on-boarding, Dr. Ora Pescovitz stepped down from her role as Executive Vice President for Medical Affairs (EVPMA) and Emory's Dr. Michael Johns was appointed as interim EVPMA while a search took place. On March 1, 2015, Dr. Marschall Runge, a highly accomplished physician-scientist, was appointed as our new EVPMA. Dr. Runge comes from University of North Carolina's School of Medicine, where he was Executive Dean and Chair of the Department of Medicine in addition to principal investigator and director of the NIH-funded North Carolina Translational and Clinical Sciences Institute. With his appointment, a new organizational structure with new leadership will be put in place in 2016. This new structure will involve merging the positions of Dean and EVPMA with Dr. James Woolliscroft stepping down in his capacity as Dean, as well as creating new positions including a Chief Academic Officer, Chief Scientific Officer and Executive Vice Dean for Clinical Affairs. While the recruitments to fill these positions are not complete at the time of this report, I am both optimistic and enthusiastic about these changes and look forward to working with the new leadership moving forward.

During this past year, I have had the pleasure of congratulating our faculty, residents and staff on many outstanding awards/accomplishments on a national/regional level, some of which include:

- Dr. Ulysses Balis - Elected to Fellow status of the American Institute for Medical and Biological Engineering
- Dr. Noah Brown - Association for Molecular Pathology, Young Investigator Award 2014
- Dr. Kathleen Cho – election into Academy of Medicine (formerly the Institute of Medicine)
- Dr. Gregory Dressler - Elected as AAAS Fellow
- Dr. Jeffrey Hodgin – recipient of Gloria Gallo Research Award, given by the Renal Pathology Society.
- Dr. David Keren – recipient of American Board of Pathology's Life Trustee Award
- Dr. Hemamalini Ketha – 1st place oral presentation at the American Association of Clinical Chemistry.
- Dr. Richard Lieberman – industrial partner with U-M's Society of Women Engineers, winning 1st place for its Automated Tissue Slicer, in the Boeing Team Tech Competition (Los Angeles, Oct. 24, 2014)
- Kristina Martin - elected as the President-elect for the Michigan Society of Clinical Laboratory Scientists (MSCLS)
- Dr. Duane Newton – elected as a Fellow by the Infectious Disease Society of America
- Dr. Steven Pipe –recipient of the Leadership in Research Award from the National Hemophilia Foundation
- Dr. Mark Kiel – awarded Benjamin Castleman award at USCAP
- Dr. Peter Ward - Society of Leukocyte Biology Honorary Lifetime Award for Excellence in Leukocyte Biology Research

Similarly, the University of Michigan rewards faculty and administrative staff for many accomplishments. Some of these awards include the Dean's Administrator of the Year Award, given to Mary Lawlor and the Dean's Basic Science Research Award, given to Dr. Yali Dou, both in November 2014. Drs. Yali Dou, Jolanta Grembecka and Celina Kleer were inducted into the University of Michigan Medical School's League of Excellence, an honorary society established in 2011 to recognize faculty who have made significant contributions to the school's research enterprise. I am very pleased to announce that our own Dr. Henry Appelman is the recipient of the prestigious Lifetime Achievement Award in Medical Education, just presented in November 2015.

FY15 brought new growth to our faculty, in part to keep up with increased clinical demands and to expand our research mission. During this time, we bade fond farewells to Jo-Anne Vergilio, Kojo Elenitoba-Johnson and Megan Lim.

We recruited 20 new faculty members since July 1, 2014, including:

- Allecia Wilson, MD, (Forensics and Assoc Director of Residency Training Program)-7/1/2014
- Noah Brown, MD, (Molecular Pathology)-7/1/2014
- Lee Schroeder, MD, PhD (Chemistry)-9/1/2014
- Rohit Malik, PhD (non-coding RNAs)-10/1/2014
- Sriram Venneti, MD, PhD (Neuropathology)-10/20/2014
- Jennifer Brazil PhD (Mucosal immunology)-12/8/2014
- Shuling Fan MD (Epithelial Pathobiology)-3/1/2015
- Roland Hilgarth PhD (Epithelial Pathobiology)-3/9/2015
- Asma Nusrat, MD (Epithelial Pathobiology and GI Pathology)-3/15/2015
- Kristine Konopka, MD (Pulmonary Pathology)-7/01/2015
- Hemamalina Ketha, PhD (Chemical Pathology (MS testing) - 7/01/2015
- Jiaqui Shi, MD, PhD (GI Pathology) - 7/01/2015
- Young-Tae Lee, PhD (Epigenetics)-7/1/2015
- Kathryn McFadden, MD (Neuropathology)-8/01/2015
- Catherine Ptaschinksi, PhD (Immunology)-9/1/2015
- Rajan Dewar, MBBS, PhD (Hematology) – 9/08/2015
- Muhammad Aslam, MBBS (GI Biology)-10/1/2015
- Veronica Azcutia Criado PhD (Mucosal immunology)-10/1/2015
- Monique O'Leary PhD (Epithelial Pathobiology)-10/15/2015
- Marcin Cieslik, PhD (Translational Pathology)-11/1/2015

Other highlights that I am very proud to acknowledge are the multiple new leadership appointments and professorships to our Faculty:

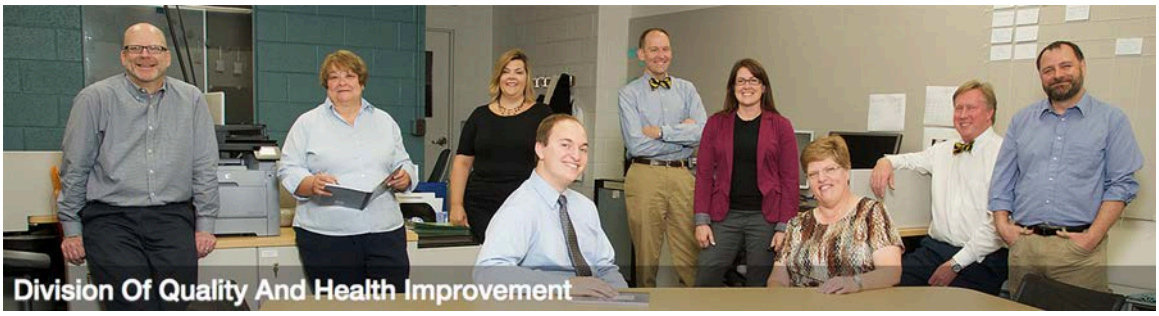
- Kathleen Cho M.D., Vice Chair for Academic Affairs
- Jeffrey Myers M.D., Vice Chair for Clinical Affairs and Quality
- Asma Nusrat M.D., Director of Experimental Pathology
- Scott Owens M.D., Director of Quaity and Health Improvement (DQHI)
- Thomas Giordano M.D, Ph.D. Director of Molecular and Genomic Pathology
- David Lucas M.D., Director of Anatomic Pathology
- Lee Schroeder M.D., Ph.D., Director of Point of Care Testing
- Lina Shao Ph.D., Director of Cytogenetics
- Allecia Wilson M.D., Associate Residency Program Director
- Madelyn Lew M.D., Director, Medical School Pathology Education Curriculum
- Noah Brown M.D., Associate Director, Molecular and Oncologic Diagnostics (MOLDX)
- Dan Boyer M.D., Ph.D., Director of (Clinical) Flow Cytometry Lab

With these new additions, our faculty now is the largest it has ever been and is the third largest at U-M. Given the size and complexity of our department, even before I arrived, I began to reflect on how to best lead the department with a team of experienced colleagues. After a lot of thought and consideration of the needs of such a large and diverse department, I appointed Drs. Jeff Myers and Kathy Cho as Vice Chairs to help oversee Clinical and Academic Affairs respectively. With the appointment David Lucas as Director of Anatomic Pathology, effective December 1, 2015, Jeff will step down as AP Director to focus on his role as Vice Chair for Clinical Affairs and Quality. He will continue to direct MLabs. Dr. Myers' vision, extensive experience in clinical operations and longstanding interest in quality and safety make him exceptionally well qualified for this senior leadership position. Likewise, Dr. Cho's experience as a remarkably successful physician-scientist and as interim Chair for fourteen months prior to my tenure, coupled with a strong commitment to faculty and trainee mentoring, strongly position her as Vice Chair for Academic Affairs.

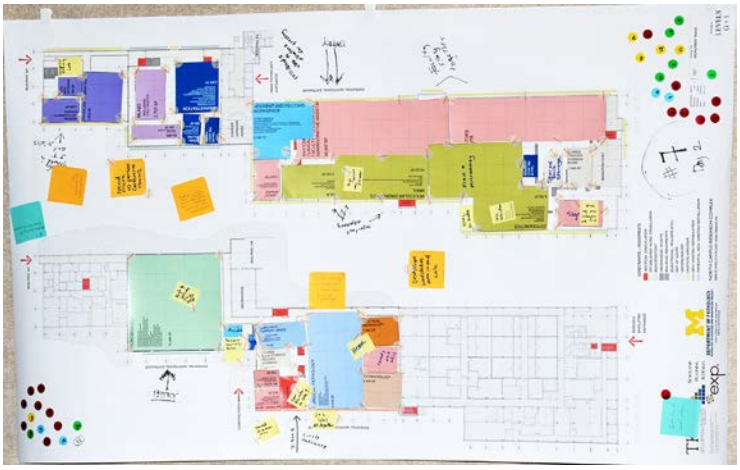
Leadership of our departmental Faculty Affairs has expanded and now includes Drs. Henry Appelman, Joel Greenson and Nick Lukacs. These three, in addition to Drs. Duckett, Fullen and Newton, comprise our departmental committee on appointments, promotions and tenure. This committee continues to do a fantastic job in

providing thoughtful reviews and advice to our faculty as they are being considered for promotion. I thank them for all of their hard work put into this vital departmental function.

In terms of new programs and leadership moving forward, I am pleased to announce the creation of a new Division of Quality and Safety that was funded in partnership with the hospital and University of Michigan Medical Group. The goal of this new division will be to enhance value in the department and larger health system through identification and solution of problems related to quality and safety. Dr. Jeff Myers has appointed Dr. Scott Owens as the Director of our new Division of Quality and Safety. As of this fall, all of the staff appointments are in place. Strategic planning to include goals and milestones will occur in the upcoming months. I look forward to ground-breaking advances that set new standards in value-added healthcare from our Division of Quality and Safety!


Division Of Quality And Health Improvement

This year's annual report would not be complete without an update on plans for new clinical laboratory space. After several failed attempts to identify new space for our clinical operation prior to my tenure, I am delighted to report that the University Regents approved funding for renovation of 140,000sf within four large connected buildings at the North Campus Research Complex (NCRC) on April 16, 2015. This $160M renovation project will include space to house non-stat clinical activities for both Anatomic and Clinical pathology as well as Informatics, MLabs and Administration. Offices for most of our faculty and suites for our trainees will also be located at NCRC. Space will also be renovated at the University Hospital to house a new Core Laboratory as well as specific hospital-based functions. The move will co-locate a large portion of the University of Michigan Health System's clinical pathology teams and educational programs. This venture will greatly facilitate the ability of Pathology to provide the highest level of support to UMHS patients and providers. Moving into laboratories at NCRC that incorporate Lean design principles will not only align capacity with demand, but will provide an environment that fosters collaboration among staff, trainees and faculty. The move to NCRC reduces Pathology's current geographic dispersion from 10 locations to 5, and positions Pathology to better support strategic UMHS services, such as transplantation and oncology. Co-location with the UMMS Biorepository will also facilitate activities central to the goal of positioning UMHS as a leader in precision medicine.



The Department of Pathology remains in a very strong financial position; current assets will continue to enable us to recruit new faculty and support the outstanding academics that separate U-M from the rest. Our contributions to the health system continue to be robust. In particular, Pathology accounted for 10.3% of total hospital gross revenue, but only 4.3% of total expense in FY15. Our surgical pathology service continues to grow with an increase of 7.5% in specimens and nearly 6% in consult cases. In the clinical laboratories, there were over 5 million billed tests resulting in a 6% increase in gross charges. In addition to obtaining Regents' approval of funding for 140,000sf of new clinical lab space at NCRC, other notable successes in the clinical service arena include a remarkably successful CAP inspection this past spring, departmental leadership (Drs. Keren and Owens) of a Collaborative Quality Initiative (CQI) between Michigan laboratories with genetic testing menus and Blue Cross Blue Shield of Michigan (BCBSM) termed The Genetic Testing Resource and Quality Consortium, and significant continued progress on SOFT implementation led by Dr. Ul Balis, Kathy Davis and the rest of our IT Division.

The Department of Pathology, working with Wayne County, received approval from the Board of Commissioners to manage all activities of the Wayne County Medical Examiner's office effective Oct.1, 2014. The Wayne County Medical Examiner's Office is led by Chief Medical Examiner, Dr. Carl Schmidt. Other key members of this team are:

- Carl Schmidt M.D., Chief Medical Examiner
- Leigh Hlavaty M.D., Deputy Chief Medical Examiner
- Francisco Diaz M.D., Assistant Medical Examiner
- Kilak Kesha MBBS, Assistant Medical Examiner
- Chantel Njiwaji M.D., Assistant Medical Examiner
- Leonardo Roquero M.D., Assistant Medical Examiner
- Lokman Sung M.D., Assistant Medical Examiner

Dr. Jeffrey Myers wears many hats, one which is Director of our MLabs outreach program. Now in its 30th year, MLabs has shown continued growth that now includes over 700 accounts providing service to over 300 physician offices, Nursing Home and Acute Care facilities and reference laboratory services to hospitals throughout Michigan. Dr. Myers has done an outstanding job integrating MLabs into our tripartite mission as a leader in the areas of molecular diagnostics and precision medicine.

The department also entered into its fourth year of major financial support of Paradigm, the nonprofit startup company that offers state of the art, next generation sequencing-based genomics analyses of human tumors. In partnership with the Michigan Health Corporation and International Genomics Consortium, our department has been actively engaged in soliciting investment partners that would transition Paradigm into the for-profit space.

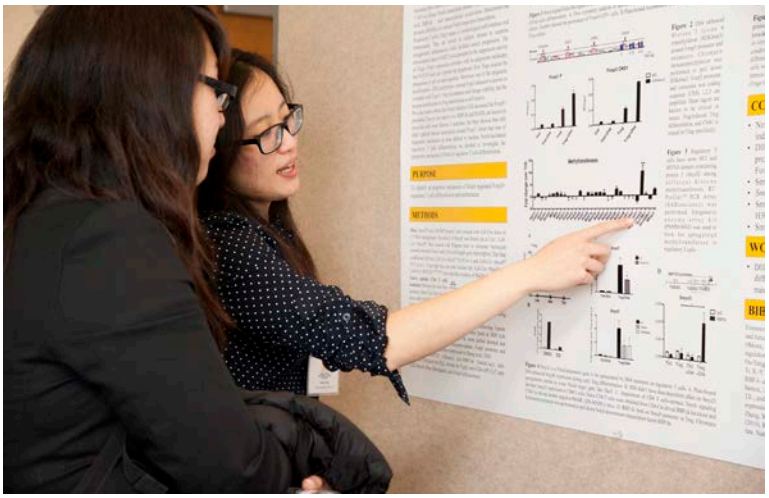
Pathology's basic, translational and clinical research programs continue to thrive and funding remains very strong, despite the continuation of a challenging funding climate. I am delighted to welcome Dr. Asma Nusrat, who was recruited to our Department from Emory University to lead a new Division of Experimental Pathology. Dr. Nusrat was named the Warthin Professor of Experimental Pathology and, in addition to having a robust research program and being a practicing GI pathologist, will focus efforts on integrating research programs and mentoring faculty in research. As highlighted in our Academic and Business Affairs report, departmental external research support increased 4.1 percent in committed awards and 1% in total research revenue for FY 15 despite very a challenging funding environment. Given our strong performance and recent recruitment efforts, I am optimistic that our national rankings in research funding will improve this year. Several Pathology faculty members remain actively involved in the Medical School's Fast Forward Initiative, led by Senior Associate Dean for Research, Dr. Steven Kunkel, which began its third year in July, 2015. These include Drs. Andy Lieberman, Alexey Nesvizhskii and Kojo Elenitoba-Johnson (protein folding diseases), Drs. James Varani, Naohiro Inohara, Gabriel Nunez, and Michael Bachman (host microbiome) and Maria (Ken) Figueroa (epigenetics core). 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. Notable large research awards and new investigator grants include fifteen NIH grants totaling over $16M; two Department of Defense grants totaling nearly $695K; and foundation, society and private grants totaling over $5.7M. Dr. Nick Lukacs has been named the Scientific Director of the Mary H. Weiser Food Allergy Center which has received $10M as the first installment of a $30M+ endowment. Recruitment efforts are underway to identify established mid- to senior-career mucosal immunologists.

The Michigan Center for Translational Pathology (MCTP), 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). Great progress has been made in development of new next generation sequencing-based molecular testing platforms to help identify targetable pathways for treating cancer patients.

I am pleased to announce the new Division of Molecular and Genomic Pathology. The new Director, Dr. Thomas Giordano, the Henry Clay Bryant Professor of Pathology, will seek to create a broad vision across all of the molecular pathology labs. He will set department strategy for future test development, a critical goal as

the department prepares to move to new facilities at NCRC amidst a complicated landscape within the hospital system. In addition, he will seek and consult with others within Pathology to leverage the department's substantial efforts for research for broader use by pathology faculty.

Our educational programs in pathology are among the best in the country (#1 among large public universities, and #7 overall.) thanks to an outstanding leadership team lead by Drs. Barbara McKenna and Scott Owens. During my first year in the Department, I had the pleasure of meeting residency applicants in small groups as they came for interviews and was impressed with their quality, accomplishments and diversity of backgrounds. Our match results were nothing less than spectacular, filling all eight available residency positions with excellent trainees. A flagship of our department is the availability of a diverse portfolio of competitive clinical fellowships. We offer 16 ACGME-approved slots in 10 accredited fellowships, including a recently approved fellowship in Clinical Chemistry, as well as several non-ACGME fellowship positions. We anticipate great things next year in our Educational division with the recent appointment of Dr. Allecia (Lisa) Wilson as Associate Director of the Pathology Residency Program. She will replace Dr. Scott Owens in this role, as he takes on leadership of the new Division of Quality and Health Improvement. Scott will continue to provide his advice to the administration of the residency program, especially as we pilot a new Quality Improvement Curriculum this year. Furthermore, Dr. Madelyn Lew has been appointed Director of the Medical School Pathology Curriculum. She has already been involved in teaching M1 and M2 students in the existing curriculum, is engaged in planning groups for the new Medical School curriculum, and is part of the group of pathology faculty working to revise the M4 rotation to prepare for the new curriculum. Dr. Paul Killen will continue to coordinate the M2 curriculum until it is fully merged into the new curriculum. 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" last year which received a commendable score. They worked with Departmental leadership to submit a revised application this September. 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 Tom Wilson will direct for the second time our highly successful course in Translational Pathology to meet the need for scientists and medical professionals who can bridge the gap between basic science and clinical practice. Graduate students and pathology residents are jointly participating.



With all of the changes in UMHS leadership, the financial performance of the health system in FY15 remained strong compared to FY14. The Hospital and Health Centers (HHC) ended FY15 with an operating margin of $100.8M and finished well above the budgeted and forecasted amount of $79.0M. Ambulatory care continues to be a major and increasing source of revenue, with an operating margin of $185.6M compared to $125M in FY14. While the Medical School budgeted a predicted loss of $25.9M, recent one-time royalty payments catapulted the year end budget to a $68.4M gain. Overall, improved performance is attributable to strong patient care revenues, margin sharing, and philanthropy.

I would like to thank the faculty, trainees, and staff for helping to make my first year in this department a big success. Without all of their support, none of this would have been possible. A major reason I came to this Department is because of the wonderful spirit of collegiality and collaboration. Despite the departure of a few valued faculty members, our leadership team remains outstanding. The two new vice chairs, Jeff Myers and Kathy Cho as well as our group of Division Directors (Drs. Keren, McKenna, Owens, Balis, Kunkel, Nusrat, Giordano, Lucas and Marty Lawlor) are second to none and I look forward to working closely with all of them moving forward. I am also fortunate to have an outstanding Finance and Administration team and thank Marty Lawlor and David Golden for all of their hard work in managing a complex Division of Administration and Finance. Finally, I'd like to thank Vashni Santee, Angie Suliman, and Liz VanderElzen, who have done an outstanding job providing administrative support in the Chair's office.

Division of Anatomic Pathology

Jeffrey L. Myers, M.D.
A. James French Professor, Pulmonary Pathology
Vice Chair of Clinical Affairs and Quality
Director, Divisions of Anatomic Pathology and MLabs
Director, Pulmonary Pathology Fellowship

Anatomic Pathology had an extraordinarily successful year across all missions. Demand for clinical services remains strong across the practice. Research productivity hit record levels measured across multiple metrics. Our educational programs continue to reflect our collective passion for teaching a diverse group of learners with sustained investments in the University of Michigan Medical School as well as graduate, post-graduate and continuing medical education.

Dr. Allecia ("Lisa") Wilson rejoined the faculty in July 2014 as Assistant Professor in the clinical track 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 having completed our pediatric pathology fellowship in June 2014. Dr. Sriram Venneti joined our neuropathology team in the second quarter of FY2015 as Assistant Professor in the instructional track 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 nearly 50% with a corresponding 31% increase in effort recovery compared to FY14 despite the unfavorable national funding climate. The number of published abstracts and invited lectures reached record highs 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 neuropathology hosted strong candidates and recruited additional candidates for FY16. AP faculty continued to play key roles in medical school teaching and post-graduate education, contributing nearly 800 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 continue to realize strong year-over-year growth, increasing from a total of 90,703 specimens in FY2014 to 97,543 in FY2015, an annual growth rate of 7.5%. Our extramural consultation practice continued to be a key area of practice growth with 11,245 consultation cases signed out in FY2015 compared to 10,619 in FY2014, an annual increase of 5.9%. The total number of work-relative value units (RVUs), the measure by which Medicare and other payers recognize and reimburse professional activity, remained level despite growth in accessioned cases in large part attributable to devaluations of key, high volume CPT codes (88305 and 88342) that affect pathology practice. As a consequence, faculty productivity, measured as RVUs/FTE/month, fell to 525 (-11.0%) in June 2015 expressed as a 12 month rolling average compared to 590 in June 14.

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 service which grew at an annual rate of just over 9% (see Table 1).

Table 1: Surgical Pathology Clinical Activity, FY11 – FY15

	FY11	FY12	FY13	FY14	FY15	YOY % change
breast	1,960	2,220	2,330	2,346	2,513	7.1%
gastrointestinal	17,431	16,857	17,570	18,144	19,787	9.1%
genitourinary	2,537	2,387	2,304	2,381	2,515	5.6%
gynecological	6,274	5,988	6,166	6,013	6,217	3.4%
surg path– Room 1	9,412	9,318	9,686	10,658	11,157	4.7%
transfer cases	4,968	5,067	5,885	10,214	10,375	1.6%
TOTAL	42,582	41,837	43,941	49,756	52,564	13.2%

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 while also supporting appropriate selection of tissues for molecular testing and interpretation of immunostains for Paradigm.

Pediatric and Perinatal Pathology

Dr. Allecia (“Lisa”) Wilson finished one-year fellowship training in our accredited fellowship program and joined the faculty on July 1, 2014 as a member of our pediatric and perinatal pathology team with primary responsibilities in our autopsy and forensics service.

The pediatric and perinatal pathology practice continued to flourish in FY2015. As summarized in Table 2 the pediatric surgical service grew at an annual rate of 22.7%, with just over 3,400 cases from the CSMott Hospital ORs. In addition, there were 1,756 placentas from the Von Voigtlander Women’s Hospital reflecting a 2.4% annual increase over FY2014.

Table 2: Pediatric Pathology Clinical Activity, FY11 – FY15

	FY11	FY12	FY13	FY14	FY15	% change
Peds (IP)	1,794	2,177	2,191	2,793	3,426	22.7%
Placentas (PL)	1,474	1,456	1,650	1,715	1,756	2.4%
Pediatric autopsies		29	25	37	32	(13.5%)
Fetal examinations		36	115	129	149	15.5%

In addition to surgical cases and placentas, the pediatric team covers all pediatric autopsy cases from Mott Hospital. Thirty two autopsies were performed this year and most of them were reviewed in grand rounds and morbidity/mortality meetings with different pediatric/perinatal subspecialties. The team participated in over 125 multidisciplinary and teaching conferences at Mott and Women’s Hospital at which 696 patient’s cases were discussed.

Dermatopathology

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

Table 3: Dermatopathology Clinical Activity, FY13-FY15

	FY13	FY14	FY15	YoY % change	% change (FY13 - FY15)
ID	13,461	13,906	14,562	4.7%	8.2%
MD	7,418	8,199	8,836	7.8%	19.1%
Consults	2,205	2,416	2,491	3.1%	13.0%
Transfer	3,732	3,843	3,923	2.1%	5.1%
TOTALS	26,816	28,364	29,812	5.1%	11.2%

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 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 FY2013.

The past academic year has been a period of stability in the Dermatopathology Section without any personnel changes to the service. Under Dr. Aleador Andea's directorship, the Dermatopathology Molecular Research Laboratory (DMRL) successfully completed a CAP inspection and is now fully operational in support of clinical service and 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. Patel has committed increased effort in support of the Sarcoma SPORE. Dr. Alexandra Hristov continues to provide invaluable hematopathology expertise, as well as broad diagnostic dermatopathology, to the service and primary support for the Cutaneous Lymphoma Tumor Board. Dr. Paul Harms is transitioning to clinical assistant professor with increase to 50% in clinical service, with the remainder of his effort devoted to basic science research pertaining to cutaneous neoplasia under the mentorship of Dr. Arul Chinnaiyan and support of molecular testing in the DMRL.

This was an extremely productive academic year for the dermatopathology faculty with high visibility of our faculty at national and international meetings. Dr. Lori Lowe was inducted into the League of Clinical Excellence at University of Michigan. Dr. Doug Fullen completed his term as Chair of the Mentorship Committee of the American Society of Dermatopathology. Dr. Harms continues his research with renewal of his Dermatopathology Research Career Development Award (7/13-7/16) from the Dermatology Foundation. Dr. Patel received a Mentorship Award from the American Society of Dermatopathology in November, 2014 to serve as mentor of a research project to a pathology resident from Emory University. The dermatopathology faculty has demonstrated increased academic productivity from last year in nearly all metrics, despite the high volume on the clinical service. Collectively, the dermatopathology faculty had 64 peer-reviewed publications or articles in press (up 15 from last year) and 60 abstracts (up 22 from last year) presented at national or international meetings during the past academic year. Eight research grants (1 external and 7 departmental) were awarded to dermatopathology faculty serving as principal investigator on the studies. Dermatopathology faculty members were invited speakers at departmental, institutional, national or international meetings on 30 occasions, which was only slightly lower than 32 in the past academic year. Three dermatopathology faculty members served on editorial boards.

Neuropathology

Paul McKeever, Sandra Camelo-Piragua, Sriram Venneti, Connie D'Amato and Andrew Lieberman contributed to the neuropathology service. **Dr. Sriram Venneti** joined our neuropathology faculty as a physician-scientist in the 2nd quarter of FY15.

There were 1,332 neurosurgical cases examined this year compared to 1,381 in FY14 reflecting a year-over-

year decrease of 3.5% (see Figure 1). UMHS surgical patients comprised 58% of the accessioned cases and dropped 1.4% with 776 cases in FY15 compared to 787 in FY14. The nerve and muscle biopsy service is staffed by Drs. McKeever and Camelo-Piragua and recovered from the minor dip seen in FY14, showing year-over-year growth of 2.7%. Consultation cases dropped 21.3% from 225 in FY14 to 177 in FY15. An additional 143 transfer cases were signed out by neuropathology faculty and were not included in the 1,332 total. Neuropathology faculty staffed the following conferences: twice weekly neuropathology case conference; monthly neurosurgery CPC; weekly brain cutting conference; weekly nerve and muscle conference; weekly brain tumor board.

Ninety-four cases were examined at brain cutting conference. Of these, 38 were UH hospital cases, 22 were ME cases, and 34 were acquired through the UM Alzheimer's Center and required a more extensive evaluation.

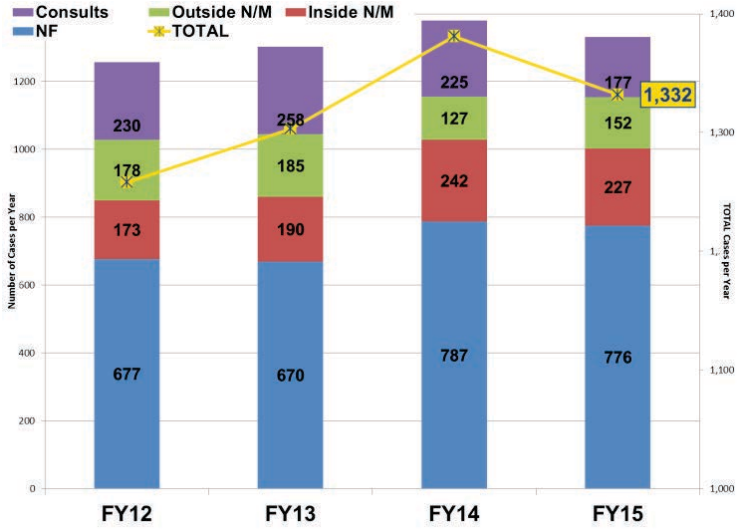


Figure – Neuropathology Case Volumes, FY12-FY15
Neuropathology case volumes showed a year-over-year decrease of 3.5% due to decreases in UMHS and extramural consultation cases. Outside nerve and muscle biopsies great at an annual rate of 19.7%

Medical Renal Pathology

Drs. Paul Killen (Director), Jeffrey Hodgin, Evan Farkash and Kent Johnson (active emeritus) supported our renal biopsy service in FY2015.

Our renal biopsy practice continued to stabilize in FY15, accessioning 1,121 cases compared to 1,194 in FY14 reflecting a 6.1% year-over-year decline (see Table 4 and Figure 2). This is the fourth consecutive year in which annual volumes have been above 1,100 cases. 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

FY12	FY13	FY14	FY15	YoY % change	% change (FY10 – 15)
1,166	1,370	1,194	1,121	(6.1%)	81.4%

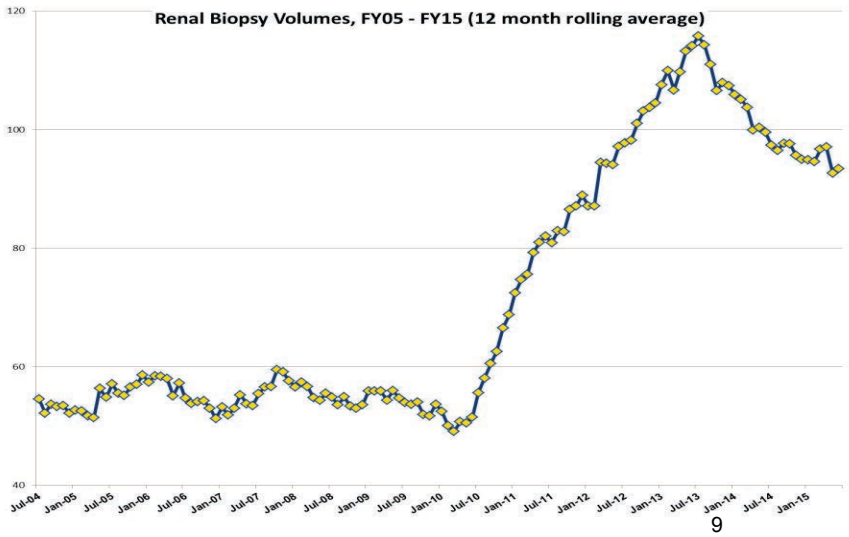


Figure . *The strong growth realized from FY11 through FY13 stabilized in FY14 and FY15*

Cytopathology

FY2015 saw a fully staffed cytopathology service comprising Robert Davenport, Amer Heider, Xin Jing (fellowship program director), Madelyn Lew, Judy Pang, Mike Roh (service chief and medical director, cytopathology laboratory). Our cytopathology fellows, Julie Dueber and David Moons, performed admirably and successfully completed their fellowship in cytopathology. The cytopathology laboratory performed exceptionally well in this year's CAP inspection with no citations.

Table 5: Cytopathology Clinical Activity, FY11 – FY14

	FY12	FY13	FY14	FY15	% change
Gyn Total	32,866	26,928	26,078	24,092	(7.6%)
Non-Gyn Exfoliative	7,034	7,357	8,808	8,392	(4.7%)
ASP Total	2,630	2,962	3,245	2,853	(12.1%)
ASP 1	862	826	670	665	(0.7%)
ASP 2	1,526	1,802	2,345	1,987	(15.3%)
ASP 3	242	208	230	201	(12.5%)

As indicated in the above table, non-gynecologic cytology specimens numbered 11,245, a 6.7% decrease from last year. Fine needle aspirations (FNAs) totaled 2,853, a 12.1% decrease from last year. FNAs performed by pathologists at the Cancer Center dropped from 230 in FY14 to 201 in FY15, representing a year-over-year decrease of 12.5%. This was compounded by declines in assisted FNAs (ASP2) and aspirates performed by clinicians without our assistance (ASP1) resulting in an overall decrease of 12.1% in FNAs. Over the long term this represents a substantial increase in FNAs compared to FY12 and earlier and continues to be a key driver of demand for laboratory personnel, cytotechnologists, fellows and faculty to provide the needed service across a geographically dispersed clinical care environment. The value of pathologist-performed ultrasound-guided fine-needle aspirations in the Cancer Center clinic was reported in a recent publication authored by our cytopathology fellow, Julie Dueber (Dueber *et al*, *Value of ultrasound guidance in cytopathologist-performed fine-needle aspirations of palpable lesions.* J Am Soc Cytopathol, 2015).

Summary of Service Initiatives and LEAN Activities in Cytopathology

- Mobile telecytology carts have been constructed and successfully employed during this past year to assist with staffing of ASP2 FNA procedures. Brian Smola, Bill Solinski, Tom Peterson, and Oliver Bichakjian were especially helpful in overcoming the barriers to successful and efficient delivery/ implementation of this technology. Efforts to continuously improve the quality and implementation of this technology are ongoing.

- The cytopathology laboratory staff and faculty continue to optimize and continually improve the utilization of our laboratory information system, SoftPathDX. Their patience, engagement, and eagerness to continuously devise creative solutions to optimize workflow is appreciated and applauded.

- 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. For instance, cytopathology staff actively participated and presented at AP QA meetings. One of the service improvement initiatives presented was a collaboration between Kalyani Naik, Nancy Fritzmeier, Katie Hayes, Jeanette Gohl, and Dr. Roh along with Cancer Center staff to improve communication regarding scheduling of patients requiring pathologist-performed FNAs in Cancer Center Room 32.

- 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 sign-out room. This serves to minimize unnecessary movement of blocks in and out of the slide library and provide easy access to histotechnologists and the AP Service Center who can easily pull the blocks when a request for molecular testing is received.

- Cytopathology continues to collaborate with the Molecular Diagnostics Laboratory in their development of new assays. 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 4 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.

- Kalyani Naik, Dr. Pang, and Dr. Roh have been a part of the MiP3 leadership group.

- The cytopathology staff and faculty are actively involved in the NCRC relocation planning process.

Autopsy and Forensic Services

The autopsy section provides faculty and resident coverage for autopsies performed at UH and VA hospitals. The section also provides forensic pathology coverage for the Washtenaw County and Wayne County medical examiners' offices. The section has two forensic fellowship positions. Residents complete three one-month rotations on the autopsy service to comply with ACGME autopsy requirements. Medical students receive exposure to autopsies on an elective basis. A one-month rotation dedicated to forensic medicine is offered to senior medical students. Educational conferences in autopsy pathology include a weekly autopsy gross conference, a monthly extended gross conference emphasizing clinicopathological correlations, and presentations in mortality conferences serving the clinical services within the hospital. A monthly didactic forensic pathology conference and multidisciplinary forensic sign-out conferences are also provided by the faculty.

A total of 601 autopsies were completed at the UMHS morgue in FY2015, reflecting an annual decrease of 2.6%. The total included 253 UMHS hospital cases and 348 cases performed on behalf of the Washtenaw County Medical Examiner's office including 311 full autopsies, 35 external examinations and 2 limited autopsies.

Wayne County in FY2015 accounted for an additional 2,699 examinations including 2,009 complete autopsies, 33 limited and 657 external inspections.

The current initiatives of the section continue to revolve around improvements in autopsy turnaround time and communication with the clinical care teams. Gross pathological diagnoses are routinely communicated to clinical providers immediately following completion of the autopsy. The section performs all Washtenaw County medical examiner autopsies and examination in the UMHS morgue. This has added an additional 311 autopsies available for resident education. The administrative and investigative functions of the medical examiner are located in offices in North Ingalls building, which allows for centralization of all medical examiner functions. Senior students will have the option of taking a one-month rotation dedicated to forensic medicine with rotations to Wayne County Medical Examiner Office in Detroit.

The service supports two forensic fellowship positions. The fellows will obtain training and experience in all aspects of forensic medicine including toxicology, criminology, forensic anthropology, forensic pathology, and courtroom testimony. The forensic autopsy experience will be augmented with cases from the office of the Wayne County medical examiner in nearby Detroit.

The administrative staff supports two annual conferences: *Advances in Forensic Medicine and Pathology* and the *Wayne County Death Investigation Seminar* sponsored by UM intended for physicians, death investigator, attorneys and healthcare workers involved in the support of families.

RESEARCH ACTIVITIES

Anatomic Pathology faculty, staff and trainees were remarkably productive despite the demands of patient care, setting records in virtually every measure of research productivity (see Table 6). Individual faculty reported authoring or co-authoring 301 peer-reviewed publications in print or in press in FY2015 compared to 245 in FY2014, a 22.9% percent year-over-year increase and an increase of 35.0% compared to FY2013. In addition, faculty reported the results of their work in abstract form on 187 occasions. Thirty-seven faculty served as invited lecturers, speakers or visiting professors on 187 occasions, for an overall average of 5.1 (median 3) per participant. Clearly our faculty members remain top-of-mind when looking for cutting edge speakers in anatomic pathology. In addition twenty-one different faculty reported being members of 46 editorial boards.

Table 6: Academic Productivity in AP, FY12 – FY14

	FY13	FY14	FY15	% change
publications	223	245	301	22.9%
abstracts	125	120	168	40.0%
invited lectures	150	157	187	19.1%
editorial boards	36	33	46	39.4%
FTEs funded	4.0	5.4	7.0	31.0%
research expenditures	$3,235,470	$3,449,157	$5,028,517	43.8%

Research expenditures grew by just over $1.5 million, reflecting a year-over-year increase of 43.8% compared to FY2014 and a record level of extramural research support in anatomic pathology (see Figure 7). This was attributed in large part to the collective successes of nine faculty who realized a combined year-over-year increase in research expenditures of $1.7 million. Four faculty, including three in the instructional track (Andrew Lieberman, Scott Tomlins and Sriram Venneti) and one in the clinical track (Lakshmi [“Priya”] Kunju), accounted for nearly 80% of the total. This more than offset minor year-over-year losses experienced by other AP faculty. Research expenditures in FY2015 were more than double those in FY04 and speak to the vitality of our research mission. The total number of FTEs funded through extramural sources grew to 7.0, the highest level of effort recovery in the division’s history. 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 Evan Farkash, Paul Harms, Jeff Hodgin, Rohit Mehra, Scott Tomlins, and Sriram Venneti 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.

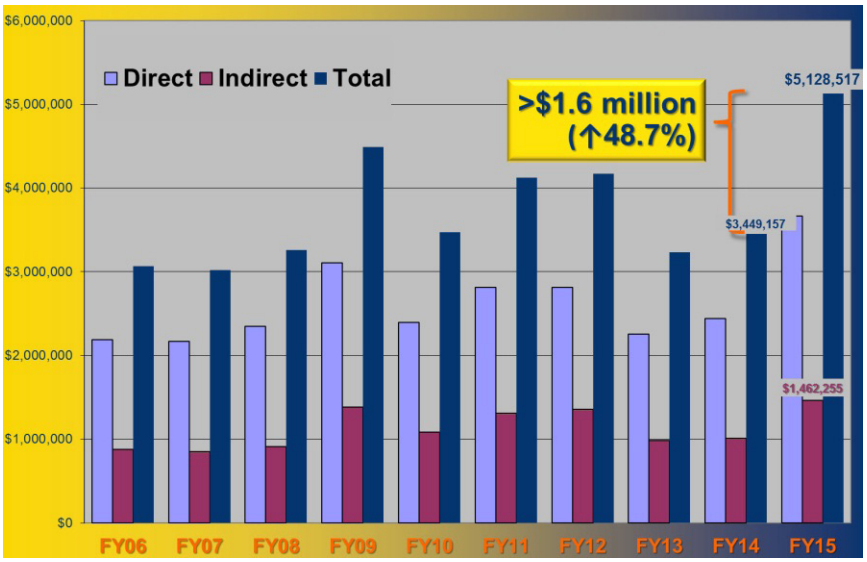


Figure – AP Research Expenditures, FY06-FY15

Research expenditures grew by 48.7% ($1.6 million) compared to FY2014.

AP funding accounted for an additional $121,474 allocated in support of projects in which AP faculty and trainees served as primary investigators (see Figure below). This reflects a 76.2% year-over-year increase and was a record high for intramural dollars spent in direct support of research projects.

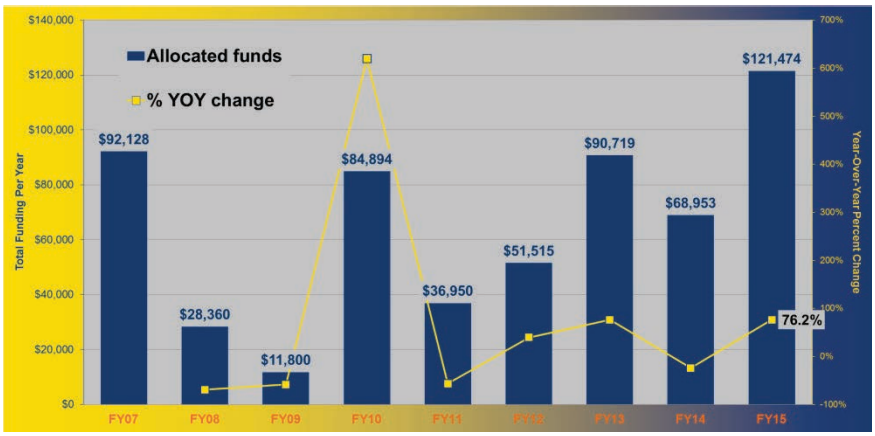


Figure – AP Project Funding, FY07-FY15

Funding for AP Projects grew in FY15 compared to FY14 to a total of $121,474, the highest allocation in the 9 year history of the program.

We hosted our 6th Annual Research Day on February 21, 2015 in collaboration with Hematopathology and Molecular Pathology. The day included 42 abstracts presented as posters (34) and platforms (8). Our Keynote Speaker was Dr. Christopher French from Harvard Medical School and Brigham and Women's Hospital. The target audience was departmental trainees and faculty with the goal of increasing collaboration and projects.

The Molecular Pathology Research Laboratory (MPRL), under the direction of Tom Giordano, continues to be an important asset for faculty in AP. Since the last annual report work performed in the MPRL has supported publication of 20 manuscripts in high impact journals, in addition to 4 abstracts presented at USCAP (3) and ASCO (1).

Drs. Xin Jing and Michael Roh were promoted to Associate Professor, and Andrew Lieberman to Professor effective in the first quarter (September 1, 2014) of FY2015.

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, residents and fellows served as first authors for 22 different abstracts presented at the 2015 annual meeting of the USCAP in Boston, MA.

Fellowships in breast (1), cytopathology (2), dermatopathology (2), forensic (1), gastrointestinal (1), genitourinary (1), gynecologic (1), neuropathology (1), pulmonary (1) and surgical pathology (3) were filled by competitive candidates in the 2014-2015 academic year.

Active and emeritus faculty in Anatomic Pathology continued to play significant roles in the medical school, accounting for nearly 800 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 continued 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 270 contact hours recorded by the University of Michigan Medical School. Multiple additional faculty participated in laboratory-based educational experiences for 2nd year students and in teaching dental and

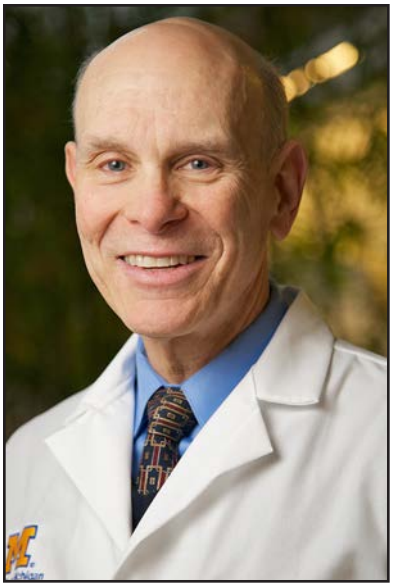
graduate students.

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

Four Visiting Professors visited our department through the *A. James French Visiting Professorship*, each presenting a lecture and slide seminar, including Drs. Lester Thompson (Southern California Permanente Medical Group), Steven Billings (Cleveland Clinic), Caterina Giannini (Mayo Clinic), Linda Ferrell (University of California at San Francisco) and Rupert Langer (Bern University, Switzerland).

Multiple faculty participated in our eight CME workshop, *New Frontiers in Pathology,* presented in collaboration with the A. James French Society. The 2014 course was held at Rackham Auditorium and again yielded very strong attendee evaluations for the quality and content of the program. Dr. Volkan Adsay from Emory University and served as guest faculty and the A. James French Lecturer.

Our CME offerings included the fifth year of *Advances in Forensic Medicine and Pathology*, hosted in collaboration with the Washtenaw County Medical Examiner's Office in May 2015 at Kensington Court in Ann Arbor, MI setting 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, M.D.
Professor, Chemical Pathology
Director, Division of Clinical Pathology

Dr. Newton serves as the Associate Director of the Division of Clinical Pathology and as the Director of Microbiology.

FACULTY UPDATES
New Faculty

Dr. Noah Brown (Assistant Professor) joined the faculty on July, 2014 as an Associate Director of the Molecular Diagnostics Laboratory.

Dr. Lee Schroeder (Assistant Professor) joined the faculty on September 1, 2014 as an Associate Director of the Clinical Chemistry Laboratory. On November 1, 2014, he was also approved as having the additional title of Director of Point of Care Testing.

Two other recruitments were successful during the last two quarters of FY2015. Dr. Hemamalini (Hema) Ketha (Clinical Instructor) will join us as an Associate Director of the Clinical Chemistry and the Director of Toxicology in July, 2015. Dr. Raj Dewar (Associate Professor) will join us as the Director of Clinical Hematology within the Hematopathology Section in September, 2015.

MAJOR FY14 EVENTS

Clinical Pathology in the Pathology Relocation and Renovation

This year was highlighted by a major effort to move from the planning stage to the approval of a 160,000 square foot Pathology Building to be located in the North Campus Research Complex (NCRC). Because the new Pathology Building will house Molecular Testing, the recently formed Molecular Test Committee (MTC) was used as a model to create a working space that joins several laboratories currently lodged in separate locations too distant to allow collaboration or efficiencies. To plan the new Molecular space, a Molecular Administrative Group was formed, consisting of faculty and staff (Noah Brown, Bryan Betz, Jennifer Bergendahl, Jeff Innis, Marwan Tayeh, Todd Ackley, Lina Shao, Beth Cox, Leslie Ernst, Priya Kunju, Javed Siddiqui, Debbie Snyder, Daniel Ramon, Kathryn Daavettila, Cynthia Shall, Aleodor Andea, and Min Wang) who direct the daily operations of these laboratories.
Planning has also begun on the extensive renovations needed for our Core Laboratory on site at University Hospital. The Core Clinical Pathology Laboratory will include Chemistry, Hematology, Blood Bank/Transfusion Medicine, Point of Care Testing and Phlebotomy.
The staff and faculty of the Clinical Pathology laboratories continued to work with upgrades and challenges of coordinating the University of Michigan Health System MiChart (EPIC), the ongoing Soft laboratory information system and the upgrade to the our MasterControl system.
Kellen Kangas was appointed to transition into the role of Compliance Coordinator under the mentorship of Suzanne Butch and as Director of the Master Control Program under the mentorship of Kristina Martin.
Suzanne Butch (CPQA Coordinator) and Kellen Kangas organized the certifications of the 39 CLIA certificates managed by the Department of Pathology. This year, in addition to our successful CAP external self-inspection and external inspections from outside agencies, we performed a CAP inspection of another facility. This provided us with another learning opportunity.

We successfully retained our accreditations and maintained our California and Florida licenses for this past year.

Molecular Test Committee

Last year, the Molecular Test Committee (MTC) was formed by hospital leadership and the Chairs of the Department Pathology and the Department of 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 quarterly meetings held this year by MTC allowed them to share data and anticipate conflicts of testing. A key offshoot of this effort is the establishment of the Molecular Administrative Group that has had extensive involvement in planning the new Molecular Laboratory at the NCRC.

Genetic Testing Resource and Quality Consortium (GTRQC)

The Genetic Testing Resource and Quality Consortium is a Collaborative Quality Initiative (CQI) between Michigan laboratories with genetic testing menus and Blue Cross Blue Shield of Michigan (BCBSM). Drs. David Keren and Scott Owens are Co-Directors and Ms. 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. This year the GTRQC has established its website (www.gtrqc.org) and has participation from hospitals across the state. The kick-off meeting will be on November 10, 2015.

Clinical Pathology Quality Assurance (CPQA) Quarterly Staff Meetings

Four CPQA quarterly staff meetings were held this year as a mechanism to improve employee engagement and to enhance involvement of staff with Lean projects. John Perrin transitioned his role as the coordinator to Suzanne Butch during the past year. At the meetings, 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 Lean techniques.

Formulary Committee

The Lab Formulary Committee, originated in 2008 by Jeff Warren, continues to meet monthly to review evidence-based medicine supporting the use of new laboratory testing.

THE LABORATORIES

The University of Michigan Health System (UMHS) Clinical Pathology Laboratories encompass Specimen Processing and the Sendout Laboratory; more than twenty UMHS off-site limited function laboratories associated with ambulatory care units, phlebotomy stations and point-of-care testing facilities; a 24 hours per day/7 days per week inpatient Phlebotomy Service; and full service hospital-based laboratories that include: Blood Bank/Transfusion Medicine Service (which encompasses the Therapeutic Apheresis/Hematopoietic Progenitor Cell (HPC) Procurement Unit, and FDA-approved Good Manufacturing Process-compliant HPC Processing Laboratory, and an Immunohematology Reference Laboratory); Chemical Pathology (which encompasses Special Chemistry, Automated Chemistry, Immunology, Toxicology-Therapeutic Drug Monitoring, Endocrinology); Point of Care Testing; Cytogenetics (which encompasses routine Cytogenetics, Microarray Cytogenetics and Fluorescence In-Situ Hybridization (FISH) testing); Hematology (which encompasses Special Hematology, Automated Hematology, Flow Cytometry and Coagulation); Histocompatibility; Microbiology/Virology (which includes Molecular Microbiology); and Molecular Diagnostics.

Clinical Laboratory personnel provide extensive testing capacity and consultative/logistical support to the

MLabs Program. Pathology Informatics, Specimen Processing and Pathology Administration continue to provide logistical, operations, and regulatory support for the Pediatrics Michigan Molecular Genetics Laboratory (MMGL), Pediatrics Blood Gas Laboratories, and 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 (Table1) are complicated by changes in billing as well as in charges. The decrease in Billed tests recorded for Clinical Pathology in FY2014 reflects a significant change in the billing process. In 2013, molecular testing billing was done by using "stacking" codes rather than individual test codes. 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 FY2013, the billed tests were part of the previous system which inflated the number of actual tests performed. Because of their timing, these changes altered some aspects of the financial report for FY2013 and FY2014. These effects are not present for FY2015 which will become the baseline year for future comparisons. Notably, however, one can follow our gross charges that increased by over $30,000,000 between FY2014 and FY 2015 and our expenses that increased by only $2,000,000 in the same period. This extraordinary performance is occurring at a time when both the volume and complexity of new testing is increasing. To provide safety and accuracy for our patients, the increase in volume and complexity of testing cannot continue without increasing our FTE numbers in FY2016.

Table Clinical Pathology Laboratories FY2013-2015

	FY2013	FY2014	FY2015	% Change
Billed Tests	5,109,497	5,015,219	5,101,062	1.7
Gross Charges	$490,563,953	$546,966,965	$579,988,161	6.0
Expenses	$72,163,336	$73,655,845	$75,673,407	2.7
Total FTEs	517.46	534.68	534.8	0

Quality Management Team

The clinical laboratories are led by our Clinical Pathology Laboratory Operations Coordinator, Kristina Martin. She is joined by our Clinical Pathology Quality Assurance Coordinator, Suzanne Butch, who transitioned this year from her role as Compliance Officer and Manager of the Blood Bank/Transfusion Medicine service. Together they oversaw the arrangements for our internal and external CAP inspections this year. 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.

Education, Research and Innovation

The Division of Clinical Pathology has produced several highly successful educational efforts. Quarterly joint Hematopathology-Anatomic Pathology case review evenings were attended by Pathology residents, fellows and faculty.

In October, 2014, the Clinical Pathology Symposium provided two half-day grouping of laboratory medicine presentations featuring discussions on Next Generation Sequencing (Dr. Mark Kiel), Newborn Screening: Over 50 Years of Preventing Disabilities, Saving Lives (Dr. Frances Downes), an Ebola Roundtable (Drs. Duane Newton, Sandro Cinti and Terri Stillwell), Celiac Disease and Testing (Dr. David Keren), Langerhans Cell Histiocytosis (Dr. Noah Brown) and a knowledge test on laboratory safety (Ms. Suzanne Butch).
The Current Topics in Blood Banking Conference, May, 2015, celebrated the 75th year of Blood Banking and Transfusion Medicine at the University of Michigan. The featured speaker was Connie Westhoff, SBB, PhD

Director of Immunohematology, Genomics and Rare Blood, New York Blood Center. She presented the annual Harold A. Oberman, M.D. Memorial Lecture on "The Conundrum Over D." In addition, there were presentations by Pamela Cornwell, MT(ASCP) on "Panels I have Known and Loved," Teresa Downs, MT(ASCP)SBB on "Changes in Blood Use," Sean Li MD, Sheri Hugan, MLS(ASCP)CM,SBBCM, and Kelly Anderson, MLS(ASCP)CM,SBBCM "Transfusion Service Case Studies, Jeffrey Myers, MD "Huddles and Communication," and Suzanne Butch, MA, MLS(ASCP)CM "Safety Quiz."

RESEARCH ACTIVITIES

In FY2015 the University of Michigan Department of Pathology Clinical Pathology Division was well represented at National and Regional meetings. The twenty-five faculty averaged 3.4 publications (median 3) with 86 peer-reviewed publications in press or in print. In addition, the faculty reported their work in 66 abstracts with 24 faculty serving as invited lecturers, speakers or visiting professors 116 times, for an average of 4.8 (median 4) per faculty. Finally, our faculty reported service on 16 Editorial Boards including: American Journal of Pathology, Laboratory Investigation, FASEB Journal, Journal of Hematopathology, and Clinical Chemistry.

Clinical Pathology Faculty Research Annual Report

Overview

The Clinical Pathology Faculty Research grants provide funds to faculty members for projects that will lead to peer-reviewed publications, and in turn, advance their academic career. The committee is chaired by Michael Bachman and includes Nathanael Bailey, Bryan Betz, Robertson Davenport, Donald Giacherio, Steven Pipe, and Lauren Smith. Statistical support is available from biostatistician Lili Zhao PhD, with partial salary support provided by the Clinical Pathology Division.

Status Report

In the first year, the committee awarded four grants to CP faculty. In the coming year, we can measure the success of these grants by monitoring expenditure of funds and acceptance for peer-reviewed publication. Dr. Yamada used the statistical support from Dr. Zhao in her successful application, and Dr. Bachman collaborated with Dr. Zhao on a MICHR-funded project and peer-reviewed publication. The availability of a biostatistician is important to promote high-quality research in the division. With the departure of Dr. Elenitoba-Johnson, a change to a UM PI will be required (Drs. Betz, Brown and Bailey are collaborators), or the project will be terminated. Projects are limited to $10,000 in direct costs.

Four projects were funded in FY2015. One to Principal Investigator Chisa Yama, two to PI Nathanael Bailey, and one to PI Kojo Elenitoba-Johnson. The total commitment was $31,195 and there has been $4,450 in expenditures to date.

As part of her support for faculty research in the division, Dr. Zhao has assisted Dr. Bachman in multiple projects on bacterial pathogenesis of *Klebsiella pneumoniae*. This collaboration has led to a peer-reviewed publication and multiple grant proposals.

CLINICAL PATHOLOGY FELLOWSHIPS

Clinical Pathology has fellowships in blood banking (Sean Li), chemical pathology (fellow to begin in 2015-16 session), hematopathology, (Rashi Singhal, Juan Gomez-Gelvez, and Mary Dhesi, and John Frederiksen) histocompatibility (no fellow for FY2015), and molecular genetic pathology (Mark Kiel).

HEMATOPATHOLOGY LABORATORY

Hematology, Bone Marrow, Flow Cytometry, and Coagulation

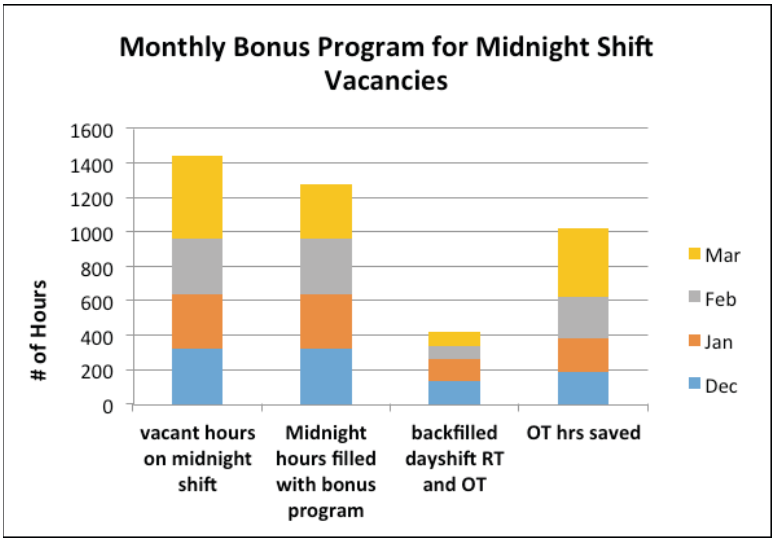
This year there was a transition in leadership from Dr. Megan Lim serving as Director from July 1, 2014 to Dr. Lauren Smith serving as Interim Director. A search for a Director of the Clinical Hematology/Bone Marrow Laboratory culminated with Dr. Raj Dewar from Beth Israel Deaconess Medical Center and Harvard Medical School.

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 FY2014. The volume of CBC testing has increased to more than 600,000 in FY2015. 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

Dr. Lauren Smith served as Interim Director of Clinical Hematology for most of 2014-15. The Hematology Laboratory continues to offer 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, pathologist review of blood and body fluid smears). The volume of complete blood count (CBC) testing, a key benchmark of laboratory activity, exceeded 600,000 for FY2015.

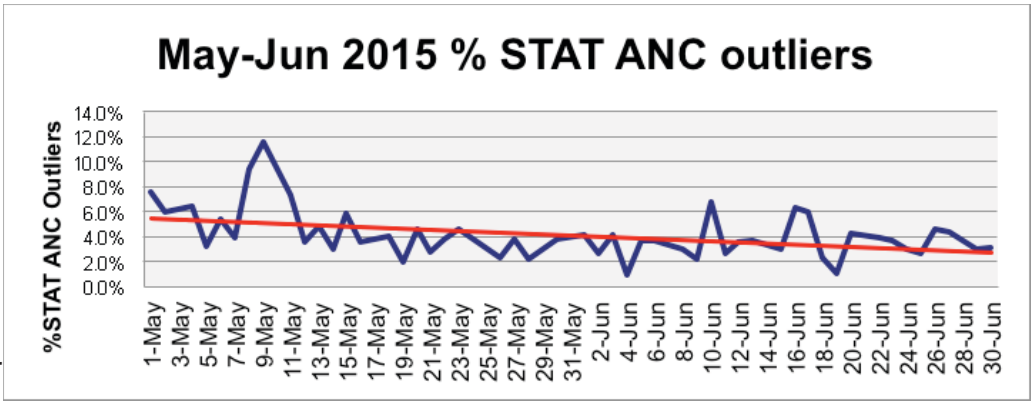
Staff shortages due to retirements, relocations and internal promotions have provided additional challenges as staff are struggling to complete clinical work with the associated quality/competency measures such that little time has been able to be devoted to process improvement and/or test development.



Despite these challenges, several key collaborations occurred with other Departments. The Hematology Laboratory worked with Pathology Informatics to prepare for Soft hardware upgrade in the fall. Jerry Davis built testing and interface codes for the new Northville Laboratory. Further, he worked with Dr. Newton for promoting improved collection of urine cultures from the CCMU Unit. The laboratory had a successful CAP inspection with only one phase I deficiency that was easily fixed. We completed migration of all procedures and policies to MasterControl and trained all staff in its use. The entire competency program was aligned with CLSI guidelines for a 6 point competency for every test system.

A midnight bonus program was instituted to help deal with a shortage of staff. The plan moved 2 dayshift personnel to midnights (with bonus pay) to avoid inconsistent overtime help on these shifts that cannot go unfilled. While this added to shortage on days, that work was largely absorbed by reducing office time and putting projects on hold. Importantly, we kept patients safe by not overworking staff and reducing the carousel of staff that would have been rotating onto midnight shift otherwise.

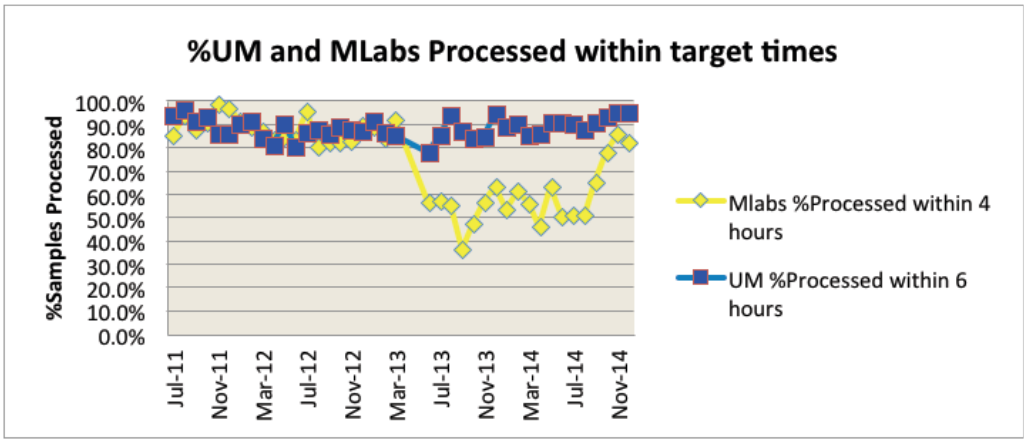
During the past year, we achieved our goal of <5% of absolute neutrophil counts (ANC) exceeding the 60-minute established turnaround time. The downward trend reflected several initiatives, including but not limited to better training, labeling, fewer service calls leading to fewer interruptions in workflow, better marrow scheduling, using a float position to help with diffs, and better awareness of potential problems by staff.



The laboratory acquired Cellavision was validated and is now live on dayshift.
Through a Lean project, the lab optimized requests for Pathologist's interpretation of blood/body fluid smears.

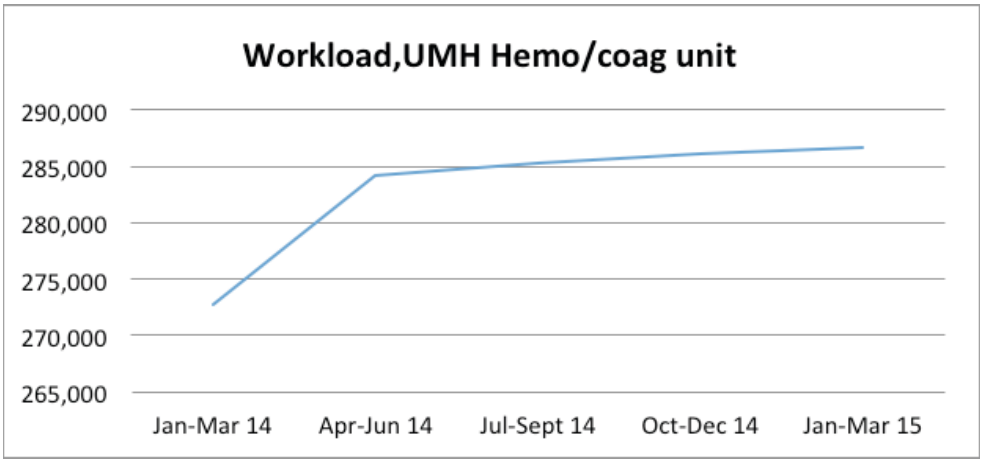
The laboratory has also reduced unnecessary Path Revs by removing the ability to create standing orders for path revs on inpatients, eliminating the requirement for technologists to confirm positive urine crystals with pathologists, and changing the procedure for dealing with low MCVs.

Finally, the laboratory was able to improve M-labs processing turn around times late in 2014 by adding 8 incremental hrs/wk in flow so processing could start sooner. As a result, the laboratory is back to our target of 80% of MLabs cases processed within 4 hours of receipt in the laboratory.



Coagulation Section

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:



Cost Reduction

A research study was completed in partnership with the Pharmacy Department to compare the dose of argatroban when monitoring aPTT versus a novel in-house developed indirect anti-IIa assay for patients on continuous argatroban infusion. The study showed that therapeutic argatroban anticoagulation with anti-IIa level monitoring resulted in lower argatroban dosing requirements compared to aPTT monitoring.

Quality Improvement/Clinical Practice Guidelines

The Coagulation Laboratory continued participation on the Anticoagulation Subcommittee for the P&T Committee which has been highly productive in establishing a full complement of CPGs for UMHS. In addition they initiated a retrospective evaluation of use of anti-Xa assays compared to PTT for monitoring heparin in the Children's Hospital with Pharmacy.

A Chromogenic Factor VIII assay was implemented.

An anti-Xa method was begun for the new anticoagulant Rivaroxaban.

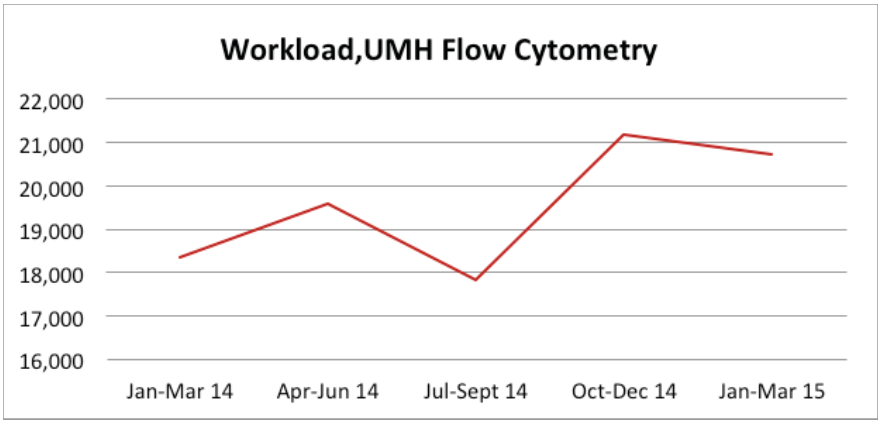
The Laboratory completed a major initiative to facilitate the use of ROTEM analyzers in the CVC ORs to support the Cardiovascular surgery program. Technology has successfully launched in January 2015 and are now used for ~100 OR procedures per month. A second machine has been launched to support other programs (organ transplant, trauma etc.). We have plans to establish a third machine within the Special Coagulation Laboratory to support diagnostics.

Clinical Research

The Coagulation Laboratory has been designated a Center of Excellence by Siemens which has resulted in our selection as a clinical site for a multi-year study of their new coagulation analyzers toward FDA approval in the US market. This led to our relocation into the Woodson clinical research space in UH South and hiring of a research technician to support these studies. We have completed Wave A and just started Wave B of these research studies. We were also funded to evaluate a new INNOVANCE Heparin assay.

Finally, the Laboratory completed two field studies for aPTT and chromogenic factor VIII assays on new bioengineered factor VIII products from Baxter and CSL Behring.

Clinical Flow Cytometry Laboratory



The Clinical Flow Cytometry Laboratory this year transitioned from Dr. Lloyd Stoolman to Dr. Dan Boyer. The Laboratory purchased an additional Gallios flow cytometer this year. The division averaged 4.75 FTEs/week drawn from a group of 11 cross-trained technologists shared across the Consolidated Hematology Laboratory. This represents a decrease of approximately 0.5 FTEs/week in flow cytometry compared to FY2014.

Specimens

The laboratory projects a year-over-year increase of ~15% in complex cases (Pathologist verified), a 10% increase in antigen (Ag) "tests" (CDM), a 12% increase in revenue, and a 21% increase in Ag tests/FTE. Cost/test increased slightly from $11.56 to $12.33 (7%).

1. The increased test volume was accommodated despite a 0.5 FTE decrease in staffing, a testament to the bench technologists and lab manager.
2. Pathologist verified cases make up 53% of the volume (~5300 cases). These high-complexity tests require review of clinical records, specimen triage, panel selection and integration with other laboratory data for diagnosis.
3. Technologist-verified quantitative tests include lymphocyte subset analysis, stem cell counts, immunodeficiency testing, CD4 counts, CD4:CD8 ratio determination and PNH-testing (~4800 cases).
4. The major driver of increased costs was a 37% increase in expenditures on laboratory reagents, which was mainly due to purchasing new antibodies for development of 10-color assays. However, the development of 10-color assays will result in long-term savings because of a decreased number of tubes used per assay and decreased redundancy of antigens examined per assay.
5. Turn-around time for pathologist verified tests was virtually unchanged from the previous year (after stabilization of TAT post SoftFlw implementation).

Goals and Progress (highlights)

A. Modernize panels: Most panels in the laboratory consist of 3-5 color cocktails of monoclonal antibodies. These are sufficient for most diagnostic tests but the growth in minimal residual disease testing, cost benefits derived from consolidating panels into the fewest cocktails possible and the increased diagnostic power of "polychromatic" cocktails fueled interest in 8-10 color panels.

B. B-ALL MRD assay: We plan to implement a standardized MRD assay for B-ALL in collaboration with the Children's Oncology Group (COG).

C. Flow cytometry supervisor search: The lab has not had a general supervisor since Usha's promotion to hematology lab manager. The lack of a designated supervisor has been an impediment to development of new assays and balancing the flow workload among a group of technologists who frequently rotate among different areas of the hematology lab and often divide their time between flow and other tasks within the same day. In addition, as part of our reference lab work, we would like to offer technical-component-only flow cytometry, which will require a senior technologist to oversee client support.

D. Upgrade specimen preparation assist devices: The lab currently uses two PrepPlus instruments from Coulter; however, these instruments can only make cocktails with a maximum of 7 antibodies, while our newer panels use 9 – 13 antibodies. We are testing a newly developed instrument from a Norwegian company (InstruNor), which can cocktail up to 100 antibodies and automates the entire stain-lyse-wash-fix procedure for up to 18 patient samples at a time. We are currently one month into a two-month testing period. Our technologists have been pleased with the instrument so far, especially the cocktailing capabilities.

E. Refine triage criteria for CSF: Most CSF specimens that we receive for flow cytometry are paucicellular and low volume (less than 5 ml received for >70% of specimens; 40% of specimens contain 2 ml or less). These specimens are rarely positive, and we would like to develop criteria for cancelling specimens that are likely to be inadequate.

Chemical Pathology and Clinical Immunology Laboratory

The Chemistry Section, under the leadership of Dr. Donald Giacherio, and the administrative management of Sue Stern, experienced an approximate 3.7 % increase in overall testing volume this year. CRP and alpha 1 anti-trypsin (A1AT) testing was moved from the Cobas Integra to the Siemens LabCell automation track sys-

tem, simplifying sample handling. Urine ethylglucuronide testing was moved to the automation line, dramatically improving turn around times. Urine free cortisol testing was moved from the RIA area of the lab to the Centaur analyzers, freeing up technologist time to devote to the rapidly growing tests in Special Chemistry, Quantiferon TB and 1,25 dihydroxy Vitamin D. Finally, the automation area evaluated and implemented allergen testing for three major peanut component proteins to help Allergists gain additional specificity in the evaluation of patients with potential serious peanut allergies.

In the Special Chemistry section of the laboratory, significant effort was devoted to the selection, evaluation, validation, and implementation of a core of instruments to provide STAT testing for potential Ebola virus infected patients. The Special Chemistry and Point-of Care groups identified and acquired 4 analyzers (Abbott i-STAT, Abaxis Piccolo, Sysmex pocH-100i, and Helena Cascade) to be used for suspected Ebola patients. This project was led by David Harro and John Alfsen.

The lab validated and implemented a new Tosoh G8 analyzer for Hemoglobin A1C testing. Three new IL Gem Premier 3500 analyzers were put in service to perform ionized calcium testing, and will clearly enhance patient safety. The lab also implemented ADNA testing by the Inova ELISA methodology and the Special Chem area validated SHBG testing on the Beckman Access 2 platform.

The Drug Analysis and Toxicology section of the laboratory focused on LC-MS assay development this past year. A new Waters LC-MSMS analyzer was purchased and installed in the fall of 2014. Senior Clinical Technologist Larry Clayton, developed, validated, and put into production, an assay for 17-hydroxyprogesterone which will benefit congenital adrenal hyperplasia patient diagnosis and monitoring. The lab validated an LC-MS assay for testosterone that will be utilized for samples from children and women to provide a far more accurate measurement than the current immunoassay methodology. The lab also participated in the validation of a point-of-care urine drug screen cartridge based assay that was implemented at multiple health care centers as an aid in the compliance monitoring of patients on potentially addictive pain medications.

The Immunology section of the laboratory under the Direction of Dr. Jeff Warren and administrative supervision of Mary Lou Erber acquired a 2nd BioRad BioPlex analyzer and were able to move testing for both cardiolipin antibody panel and beta-2 glycoprotein 1 antibody panel to the automated BioPlex multiplex assay. Preliminary work on the validation of CCP antibody and a treponemal antibody assays was completed. Contract negotiations to acquire a new capillary electrophoresis analyzer and an automated ANA fluorescent microscope slide reader were completed as well. Dr. Lee Schroeder and Dr. David Keren developed a new method for quantitation of beta migrating monoclonal antibody peaks on the Sebia Capillarys that will dramatically improve the accuracy and precision of reporting values for small monoclonal spikes.

The laboratory completed several lean projects aimed at improving efficiency. Eric VasBinder and Merry Muilenberg led a project to standardize the printing of barcode labels from remote blood draw station label printers and improve the placement of barcode labels on sample tubes, leading to a dramatic reduction in barcode read failures from the automation line. The lab participated in 2 different projects with biomedical engineering students. Both helped make best use of technologist time. One by developing a data plan on ideal batch size, the other by developing a program for the special chem area that will help scheduling ELISA assay start times.

The lab welcomed the addition of Dr. Lee Schroeder to the chemistry faculty. Lee has devoted his efforts to Point-of-Care testing.

Point of Care Section of Chemical Pathology and Satellite Support

The Point of Care Section and Satellite Support, under the leadership of Dr. Lee Schroeder, and the administrative management of Sue Stern (onsite services) and Sue Clark (offsite Satellite Support services), oversee ~5,000 users performing ~1 million tests annually over 19 analytes and panels, drawing 300,000 samples offsite for M-Labs, and consist of 35.5 medical technologist FTE, 58 phlebotomist FTE, operating over the 33 UMHS CLIA sites.

Table : Current UMHS POC tests in use

Basic labs	Cardiovascular	Endocrine	Hematology	Microbiology	Maternal/ Child	Toxicology
BMP	Lipid profile	Glucose	Hb/Hct	HIV	Pregnancy	Drugs of abuse
Blood gas	Troponin	HbA1c	PT/INR/ ACT	Group A Strep	PROM	
	BNP	UMA	ROTEM	Infectious Mono		
				Trichomonas		
				Urinalysis		

Administrative

Onsite, UMHS invested in Point of Care services through funding 2 incremental medical technology positions. This consisted of a supervisor position and an information technologist position filled by the prior medical technologist and senior clinical technologist. Also accomplished this year was the conversion of procedures into Master Control and creation of smart links to the Point of Care webpage where users can now access Master Control procedures and policies. To accommodate after hour support, we have established a 24 hour hotline, in the C&W Emergency Department laboratory, for questions from users. Finally, we have gone live with an LIS interface for the Clinitek urinalysis testing from the main Emergency Department laboratory through our RALS middleware.

Offsite, there was funding of an incremental quality assurance medical technologist position to assist in assuring quality testing in a continually expanding UMHS Ambulatory Care Service. This year the prior quality assurance technologist was replaced and the two new medical technologists are undergoing training by Sue Clark with extensive rounds over 28 physical locations and 71 clinics. Additionally, offsite there were 14 phlebotomy positions created to accommodate expanded services. These services included additional Pathology Blood Draw stations at the following clinics: Wound Care, Pre-Op at Dominos Farms, Northville Health Center (blood draw and Hematology lab), Livonia Health Center, and Dexter Family Medicine. Also, hours were expanded at the following clinics: Dominos Farms Family Medicine, Livonia Health Center, West Ann Arbor Health Center, and Briarwood Family Medicine. Sue Clark provided primary planning from Satellite Support for the following in-progress renovations or new builds: Dexter (renovations set to be completed August, 2015), Howell (renovations set to be completed Spring, 2016), West Ann Arbor (set to open Spring 2017), Brighton (set to open 2018), Livonia (renovations in progress), and Canton (remodel for port draws; still under consideration). Additionally, port draw services were initiated at Northville Health Center, a new service for Satellite Support. Finally, 20 replacement phlebotomists were hired.

Compliance

A substantial component of Point of Care and Satellite Support consists of assuring compliance with CLIA regulations. This is ever more the case as CMS and accrediting agencies are requiring 6 point competency assessments of all non-waived testing. This year we have implemented 6 point compliance requirements of

operating room point of care testing, particularly blood gas and coagulation testing. In addition to increased requirement of moderate complexity compliance, due to a CMS memorandum this year, off-label use of glucose meters in critically ill patients required the adoption of high complexity compliance requirements. This involved several high level meetings to establish a hospital-wide policy crafted by the Point of Care section and Nursing and approved by the Critical Care Committee. This decision involved many stakeholders as 6 point competency assessments by Pathology staff were required for over 1000 users (managed by Denise Twarkowksi and involving recruitment of several part-time employees) and workflow in several areas of the hospital, including critical care units, was changed to ensure only registered nurses were performing glucose meter measurements.

This year we also worked with Ambulatory Care Services leadership to establish a workable plan for compliance of provider performed microscopy. This is a particularly difficult problem as providers are scattered throughout numerous locations and are not accustomed to compliance requirements for their procedures, which are typically granted as a consequence of medical licensure. The plan involves direct observation performed by providers on each other, an M-Learning module taken annually, and biannual proficiency testing. Proficiency testing has already been initiated and the M-learning module is in development.
In addition to the CAP inspection onsite, 8 inspections were passed this year in Satellite Services: COLA (Northville), CAP (East Ann Arbor Surgery Center twice – initial in November, biannual in April), CLIA COW (Briarwood Center for Children and Women, Addiction Treatment Services, Dominos Wound, Dominos Cardiology, and Physical Medicine and Pain Management).

Point of Care Testing Expansion

In collaboration with Connie Standiford in Ambulatory Care Services, we developed and conducted a survey on priorities in the expansion of point of care testing in Ambulatory Care Units. Expansion of point of care testing could play an important role in patient-centered care and especially in the context of value-based medicine, where there is a priority placed on efficient use of UMHS resources and getting the right patients the right treatment at the right time. After two circulations of the survey we received 287 completions. Overall, the most requested tests included the CBC, the basic metabolic panel, and influenza testing. When broken down by service, other tests were rated with high priority (see attached POC expansion white paper). Service Chiefs were interviewed by Point of Care to better understand the requests and two common themes emerged. First, to improve the ability of Ambulatory Care Service clinicians to assess patient acuity, thereby getting the right patients to the ED without delay and reducing unnecessary ED referrals. Second, to improve efficiency of Ambulatory Care Services health care delivery. A significant amount of time is spent by medical assistants, nurses, and providers in what often develops into multiple follow up phone calls, phone call attempts, and prescription changes to address abnormal central laboratory test values and subsequent alterations in patient management. These additional activities remove health workers from supporting the patients that are currently in the clinic. An interdisciplinary team has been assembled by the Point of Care section to choose an initial set of instruments to roll out, and to identify the most useful implementation, that is, who will perform the testing and where.

In addition to preparing for a future expansion in point of care testing, several instruments were rolled out in 2015. To improve workflow in pain management clinics, a large implementation of point of care drug/tox testing occurred at 14 locations, including validation and training. This is a relatively complicated test with numerous pitfalls in interpretation will likely require continued refinement of training approaches.

This year also marked the offering of ROTEM thromboelastography to UMHS. ROTEM management is being conducted in a novel way. Instead of a single Division taking responsibility for the instrument, there is a collaboration between the Point of Care Section of the Chemical Pathology Division, and Hematology. Oversight of interpretations is being provided by the Director of Coagulation, Dr. Steve Pipe. ROTEM is being used currently for cardiac procedures in the CVC OR as well as for liver transplant patients in Main OR. Trauma services at UMHS requires thromboelastography for level 1 accreditation and therefore Point of Care Services is facilitating development of a hospital-wide plan to provide thromboelastography to providers with patients who would benefit, including trauma.

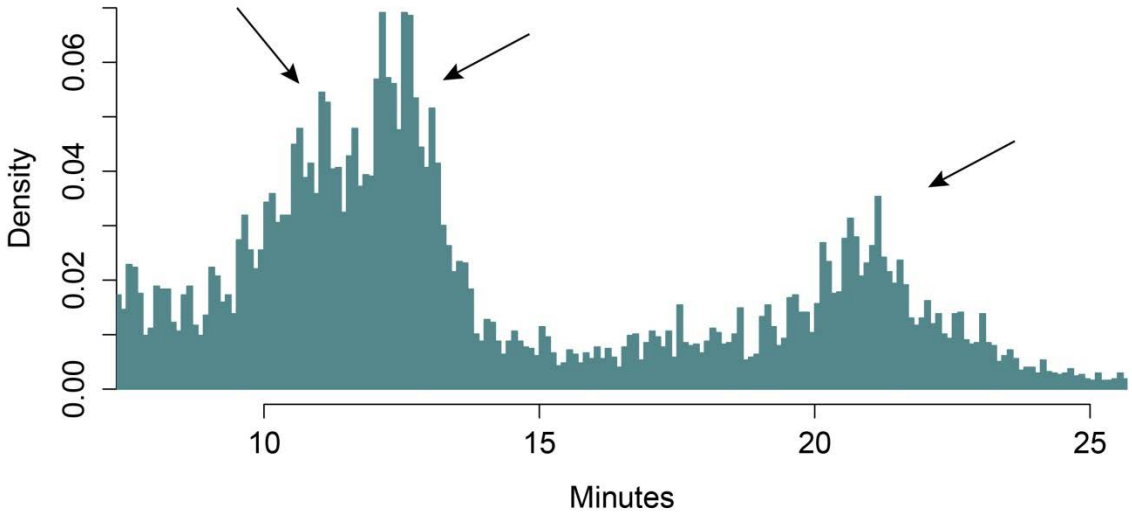
The Department of Pediatrics requested that hemoglobin testing be available for 12 month well checks. Satellite Support services changed policy to allow fingersticks on 12 month old children, lowered from the prior 18 month old minimum age, implemented Hemocue testing at Pediatric and Family Medicine clinics, and trained phlebotomists on testing and new dermal puncture equipment.

In addition, an Alere B-type natriuretic peptide device was provided to a provider conducting a multi-site clinical trial on UMHS patients, the operating room Coulter complete blood count instrument was replaced with a Sysmex instrument. And, the Medtronic HMS plus (ACT and heparin concentration testing) is being trialed in the CVC OR.

Quality/Service improvement

Of the Point of Care section's 19 instruments, the Roche glucose meter has the largest user base and the greatest testing volumes. This year it was realized that 40% of glucose meter results took longer than 5 minutes to appear in MiChart. Most of the very long delays were due to user manual entry of the MRN rather than CSN. In the 5-25 minute delay range, it was discovered that there were 3 primary peaks: two between 10 and 15 minutes, and one just over 20 minutes (see Figure 1). Nick Wesener designed a set of experiments revealing the source of these three peaks. He showed that when the meter is powered down after testing (but before the result is uploaded), delays of between 10-15 minutes occur. And, when the checkmark 'completion' button is not pressed, delays of 20 minutes occur. Training of test performers to reduce these two practices was initiated and data is again being collected to determine if delays have been reduced.

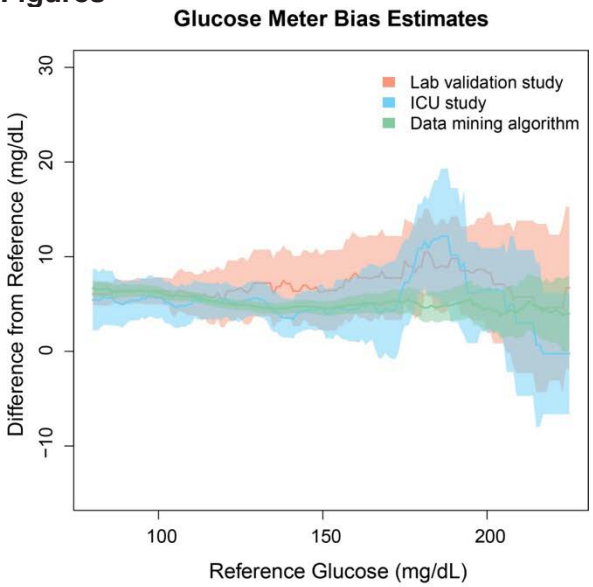
Figure 1. Collect time to MiChart Result, Oct. 2014

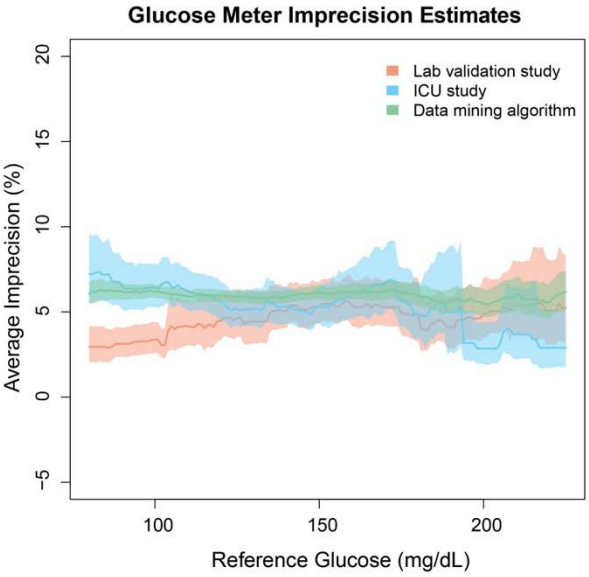


Although providers have clearly voted for expansion of Point of Care testing, feedback has been this is only where quality of results can be assured. Although initial validation of instruments will be performed using standard methods, this does not provide fine-grained ongoing surveillance of instrument performance, nor do these studies typically involve the volumes necessary for a deep understanding of performance characteristics (e.g., interference from medications, or user-dependent errors). To address the question of quality and accuracy in point of care testing, we have developed an automated method of performance surveillance through secondary use of the Electronic Medical Record. The approach involves identification of paired events, where a patient receives both point of care and central laboratory testing for the same analyte at the same time. These paired events can be used to characterize the point of care instrument performance. To validate this methodology, we obtained IRB waiver to implement a quality improvement project with ICU nursing in CVC ICU and 5D. The project involved nursing flagging optimal paired events through the comments feature of the glucose meter. These were the gold standard paired events, where the nurse confirmed that the same matrix was sampled and that no change in management took place in between point of care and central laboratory testing. A data

mining algorithm was then designed to produce equivalent bias and imprecision results as the gold standard ICU study. After filtering for similar collection time differences, ICU patients, patients with arterial lines in place, non-extreme laboratory processing delays, and lack of repeat testing in the next 30 minutes (that may indicate a failed test, e.g., iv contamination or hemolysis), a very similar characterization of the instrument was obtained through mining the EMR as was obtained in the ICU nursing study (see Figures 2 and 3 at the end of this document). The Point of Care section plans to implement this data mining method for glucose and to expand to other point of care testing devices over time to provide early detection of device failure using limited human and reagent resources.

Figures





In Satellite Support, we implemented a Blood Bank double check to reduce errors and cancellations as well as an action plan for the Briarwood-Chelsea group in response to multiple mislabels. An “Observation Checklist” was implemented for the supervisory group to review staff performance and interaction with patients. This platform sets clear performance expectations, reinforces appropriate behavior, and provides immediate feedback to staff.

Clinical Microbiology/Virology Laboratory

Dr. Duane Newton is the Director of the Clinical Microbiology/Virology Laboratory and Dr. Michael Bachman serves as the Associate Director.

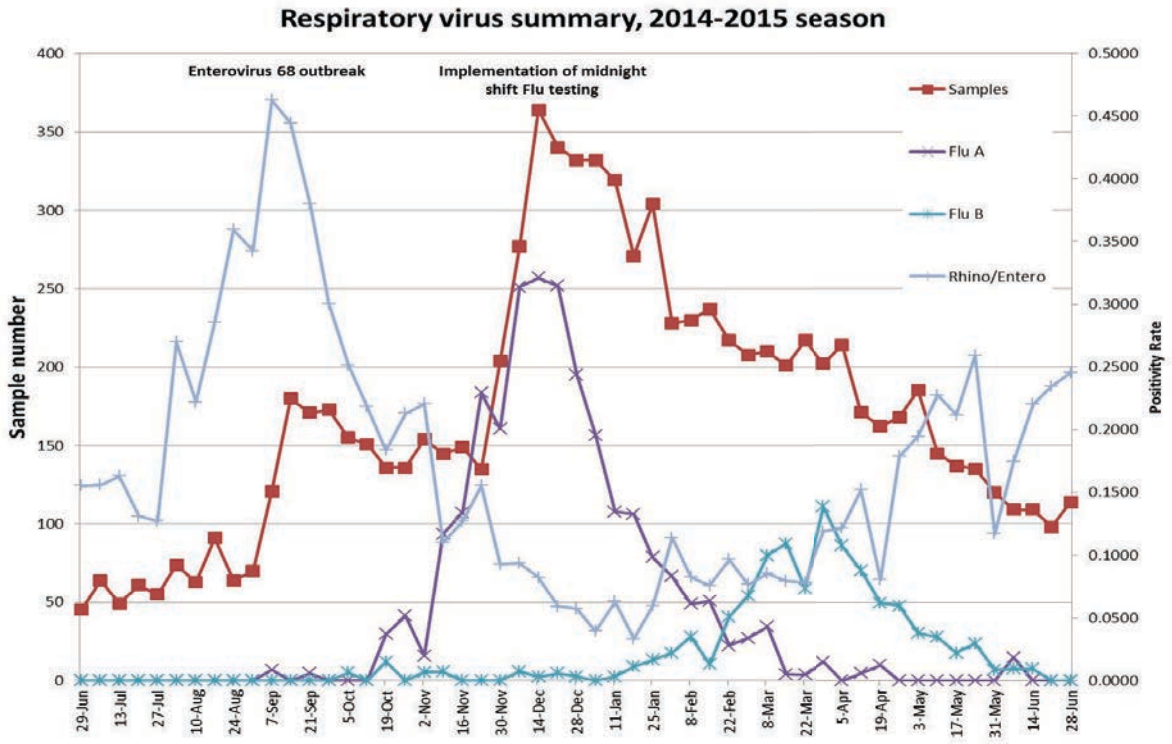
The activities with the greatest impact on the laboratory in the past year have revolved around reorganization of the administrative structure of the laboratory. One longtime supervisor retired (Rosemary Hankerd) and the other (Carol Young) took on a new role in the laboratory as a clinical research coordinator. Two new supervisors were promoted internally (Peggy Mahlmeister and Jill Russell), and a considerable amount of time has been spent redefining the supervisors' roles and responsibilities within the lab. This new structure and approach is being designed to remove silos of knowledge and responsibilities so that all technical areas and all shifts are more fully integrated.

Employee engagement and development activities:

The participation of the lab staff in the survey was the highest it has ever been (56/60 staff participated compared to 50% or less in previous years) and the scores were consistently higher than last year across almost every question and category. A variety of activities have been undertaken that have positively impacted engagement, and will continue to be addressed so that appropriate growth and development can occur, including but not limited to supervisors participating in HR training, daily huddles, flexible schedules for supervisors to improve communication with afternoon and midnight staff, and educational in-services for staff.

Major clinical activities over the last year:

- Ebola planning and preparedness
- Susceptibility testing system (TREK) implementation
- UMHS response to Enterovirus 68 outbreak, early fall 2014 (see graph below)
- Surveillance for cabapenemase-producing Enterobacteriaceae in endoscopes
- Pathology Relocation and Renovation project
- Rapid identification of blood cultures
- Rapid identification of gastrointestinal pathogens
- 24/7 testing for respiratory pathogens
- 24/7 testing for enterovirus
- Reduction in Send-out costs
- Quality Improvement by implementation of newly available testing methods



The common theme from each of the items describe above is that they are all high impact activities for our patients and the Health System. Planning for potential Ebola virus patients has shifted to developing a system whereby patients with any novel serious communicable disease could be managed safely and effectively, and the Clinical Microbiology Laboratories have played an integral role in this planning. Furthermore, the laboratory has continued to focus not only on providing results quickly, but has partnered with clinicians to develop mechanisms to enhance optimal utilization of results. These changes have improved the clinician's ability to rapidly make management decisions—therapeutic and infection control—which have the opportunity to improve efficiency within the health system.

In addition, 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, continues to meet 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 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. Ongoing research projects include: MRSA surveillance in radiology patients; Surveillance for multidrug-resistant organisms in nursing home patients; Enterovirus D68 in pediatric patients; Changing susceptibility to daptomycin in vancomycin-resistant enterococci; Clinical trial for MRSA Select II in surveillance specimens; Characterization of viral pathogens and subsequent immune response in children with clinical respiratory tract infections; H. influenzae genes associated with COPD; Cryptococcosis in patients with end-stage liver disease and liver transplants; Clinical features and outcomes in immunocompromised and non-immunocompromised adults with RSV; Effects of multiple cervical inoculations of *Chlamydia trachomatis* and the pelvic inflammatory disease in the Baboon; whole genome sequence analysis of hospital-acquired pathogens including *Citrobacter freundii, Serratia marsencens,* and *Enterobacter cloacae*. Dr. Bachman, with the help of laboratory staff, led a multi-disciplinary research team of infectious disease physicians, bioinformaticians, a biostatistician and a molecular epidemiologist in a MICHR-funded project to identify bacterial and patient factors associated with *Klebsiella pneumoniae* infections from a cohort of nearly 2000 patients.

All laboratory personnel continued to provide instruction to Pathology house officers and Infectious Disease fel-

lows and residents on diagnostic procedures used in the Clinical Microbiology Laboratories. We also provided several laboratory preceptorships for medical students, pharmacy students, and PharmD residents during the year. A Molecular Pathology fellow, Mark Kiel, completed a six-week rotation 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 multiple manuscripts have resulted from these efforts. In addition, the Laboratory subscribed to audio-conference programs which provided multiple conferences during the year that were available to all staff members and Pathology House Officers as part of our ongoing CME program. Pathology residents and faculty also provided in-service programs to the laboratory staff.

Blood Bank/Transfusion Medicine

Dr. Robertson Davenport continued to provide strong leadership for the Blood Bank and Transfusion Medicine section. Dr. Laura Cooling served as the Associate Medical Director and Director of the Cell Therapy Laboratory. Dr. Chisa Yamada served as the Assistant Medical Director and Co-Director of Plasmapheresis.

Total utilization of blood products decreased significantly. This is attributable to efforts of the clinical services to implement more conservative transfusion triggers.

Main Laboratory	FY 2014	FY 2015	Percent change
Total Blood Products	100887	90471	-10.3

Activity in the Cellular Therapies laboratory showed an overall decrease. This reflects a shift in activity within the Blood and Marrow Transplantation program.

Cellular Therapy Lab	FY 2014	FY 2015	Percent change
Collections processed	538	473	-12.1
Bags frozen	785	614	-21.8
Transplants, autologous	161	137	-14.9
Transplants, allogeneic	37	45	21.6
Transplants, unrelated	77	69	-10.4
Transplants, total	275	251	-8.7

Overall activity in the Reference laboratory decreased. While the largest category, antibody identifications, increased slightly, there was an accompanying decrease in the most complex tests, adsorptions and eluates.

Reference Laboratory	FY 2014	FY 2015	Percent change
Antibody identifications	1084	1107	2.1
ABO resolution	146	150	2.7
M-Labs/referrals	27	18	-33.3
BMT	425	322	-24.2
Eulates	188	184	-34.0
Adsorptions	365	241	-31.5
Titers	213	259	21.6
Total activity[1]	2938	2763	-6.0

[1] Includes procedures not listed above

Overall activity in the Apheresis Procedure Unit decreased slightly. A decline in LDL apheresis and HPC collections was offset by an increase in therapeutic plasmapheresis. LDL apheresis activity has been impacted by recently approved cholesterol lowering drugs. A notable increase in red cell exchange procedures reflects an increase in the activity of hemoglobinopathy clinics in adult and pediatric hematology.

Apheresis Procedure Unit	FY	FY 2015	Percent change
Therapeutic plasmapheresis		1313	9.3
HPC collections	418	386	-7.7
Donor pre evaluations	250	258	3.2
Therapeutic phlebotomy	158	163	0.7
LDL apheresis	228	212	-7.0
RBC exchange	53	96	81.1
Total Procedures		2218	-3.9

Professional billing activity decreased slightly in gross charges and charge units.

Prof. Billing	FY 2014	FY 2015	Percent change
Gross charges	$775,794		-3.5
Charge units	2,473	2,461	-0.9

A significant transfer in leadership occurred with Suzanne Butch stepping down as Administrative Manager after 44 years in the Blood Bank. Her leadership has been a major contributing factor to the national prominence in blood banking that the University of Michigan enjoys. The position of Administrative Manager was filled by Theresa Downs, who transitioned smoothly into the role. Another significant retirement was that of Louann Drake, the Immunohematology Reference laboratory Supervisor who also participated in at the national level. This position was filled by Sheri Hugan. Two successful recruitments were those of John Ko as day shift supervisor and Holly Wilson as afternoon shift supervisor.

A number of technologists were active in professional associations at the national and regional level. Susanne Butch and Terry Downs gave presentations at the AABB national meeting. Sheri Hugan gave a presentation at the International Conference on Investigative Immunohematology. Sheri Hugan, Michelle Herrst, Kelly Anderson, and Terry Downs gave presentations at the American Society of Clinical Laboratory Scientists – Michigan meeting. Louann Dake received the Founder's Award from the Michigan Association of Blood Banks.
Notable operational improvement implemented with the year included storage of O negative emergency red cells at East Ann Arbor Health Center, initiation of a new test code to prioritize outpatient type and screen testing, a new computer option to communicate back to caregivers when a cord sample is received in a condition that in not appropriate for testing, and a significant reduction in solid waste through creative reuse of foam packing materials.

Research activities that the Blood Bank had significant involvement with included clinical evaluation of a new automated blood typing instrument, the Age of Blood in Children (ABC) randomized clinical trial, the Safety and Efficacy of Investigational Anti-Influenza Immune Plasma in Treating Influenza clinical trial, and the Study of Efficacy and Safety of CTL019 in Pediatric ALL Patients clinical trial.

In support of the educational mission, the fellowship in Blood Banking/Transfusion Medicine was filled by Shih-Hon (Sean) Li, MD. The faculty participated in a clinical elective for M2 students that is intended to provide them with an in-depth clinical experience. The primary goal for the Department of Pathology is to expose the

students early to the practice of Pathology as a recruiting tool for potential residents. The elective was offered in October for three hour sessions open to 2 to 4 students. Topics covered include 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.

Histocompatibility and Immunogenetics Laboratory

Dr. Daniel Ramon is the Director of the Histocompatibility Laboratory. This year has been a busy and a productive year. The changes in the leadership and the tools acquired in previous years have begun to produce their advantages.

Service Improvements

One of the great achievements of this year was the opening of the cell culture and storage cell laboratory. With the introduction of the Cell Culture laboratory, they have the ability to perform crossmatches immediately using frozen donor cells. In using frozen cells, the time delay waiting for fresh samples will be eliminated and there will be enough frozen cells to perform multiple crossmatches over a long period of time. For all of the Paired Donor Programs, this is a monumental improvement. They will no longer need to contact each donor for every potential paired donor recipient since we will have stored cells on-hand for crossmatches, (which will also eliminate donor fatigue). In these cases, crossmatches may be performed instantly and compatibility reviews will be much faster. In addition to the Paired Donor Programs, They will have stored cells for all of our living and deceased donors as well. Therefore, post-transplant crossmatches can be performed to aid the clinicians in diagnosis and treatment. This service will help our programs tremendously.

The team completed the entire Freezer Patient Serum Reorganization Project. This massive project took 2 years to complete. The new serum storage system is organized by our LIMS Histotrack and allows them rapid storage and retrieval of the serum samples to perform antibody screening and crossmatch reactions. The efficiency of this system is translated in less time for the team to store and to locate a sample, less freezer maintenance and easy and secure freezer monitoring.

The team completed validation of the new instrument Luminex FLEXMAP 3D instrument used for antibody screening and high resolution SSO typing. This new generation of the Luminex instrument is capable of analyzing 500 beads vs. the 100 beads by the previous Luminex model.

The high resolution HLA typing for the Hematopoietic Cell Transplant (HCT) recipient and donor demand multiple reactions to achieve an unambiguous result, the lab has validated a new version of reagents known as high definition LABType kits. So far, only A, B and DR locus has been completed, but as a result, they will have to perform less SSP testing for ambiguous typings for HCT patients. In addition, solid organ patients will benefit by the high definition testing when there are subtype antibodies present. This will represent a significant improvement to our typing workflow.

To improve lab safety for the technologists, they have removed the teratogenic agent Ethidium Bromide used for the DNA fragment gel visualization and replaced it with a nontoxic agent GelRed. This change providing a safer work place for the team and less hazardous waste for the environment.

The team finished the validation of the JANUS Automated Workstation to aliquot the large number of serum samples from our solid organ transplant patients. Every sample is aliquotted in multiple tubes for future use in our laboratory and to send to the Organ Procurement Organization Laboratory Gift of Life Michigan. This instrument will release the pressure to our support team while they can focus on urgent sample aliquoting for immediate testing.

In preparation to laboratory relocation in the NCRC we are transforming all our patients' paper files into a PDF file. The goal is to have all files digitized before the move to NCRC. This is a big task that will last for couple of years at least.

Personal Reorganization

They have created the critical position of Bioinformatics Specialist and promoted Lena Kleyman to this position. In this position Lena and hopefully other members in the future are going to be in charge of implementation of new informatics tools to process the large amount of information generated by our current assays. In addition to the maintenance and constant updating of the critical database Lena has been developing many tools for data mining which significantly optimize our data analysis, workflow and reports. She is developing new tools to process massive amounts of data from our patients undergoing desensitization, and they have defined the need of many other tools to help our DSA and routine antibody reporting. Lena's position is shared with the Molecular Diagnostics Pathology Laboratory.

Staff development and engagement activities

- Presentation by Yusuf made at the Clinical Pathology Quarterly All Staff Meeting: *Freezer Storage Reorganization Plan: Time, Space, Maintenance*
- Sent a total of 8 staff to national and regional meetings.
- Presented 2 posters at the annual ASHI conference in October 2014:

  LIS Implementation and Integration: Achieving a Fully Functional System
  High Nonspecific AT1R Reaction in a Non-Sensitized Kidney Recipient
- Oral presentation at the annual ASHI conference in October 2014: *Crossmatch Options: Can a Captured Image of Cells be Worth a Thousand Flow Events?*
- Presentation made by Lena to the OTIS Staff titled : *Pair Kidney Exchange (PKE) HistoTrac® Module (Tool for Transplant Coordinators)*

Molecular Diagnostics Laboratory

There was a transition this year from Dr. Kojo S. J. Elenitoba-Johnson to Dr. Noah Brown (serving as on-site Medical Director in FY2015). Both Dr. Brown and Dr. Thomas Wilson served as Associate Medical Directors. The laboratory's Technical Director is Dr. Bryan Betz. The technical Supervisor/Laboratory Manager is Jennifer Bergendahl. Laboratory Supervisor is Nancy Lefebvre. Research and Development Supervisor is Helmut Weigelin and Jennifer Bergendahl is the Laboratory Manager.

Educational and Operational Activities

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 also conducts regular monthly Administrative Project Meetings, which include the directors, technical director, attendings, supervisors, R&D technologists and fellows/residents associated with the laboratory. These meetings aid in organizing ongoing projects and provide information on new and updated tests and assay problems/issues.

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

Bimonthly operation meetings are now conducted with the director, on-site director, associate director, technical director, lab manager and supervisor. Discussions focus on operations of the laboratory.

Monthly Manager/Supervisor meetings are now conducted with the lab manager, molecular supervisor, FISH supervisor, and research and development supervisor. These meetings discuss the various operational issues, assay workflow concerns, progress in assay validation, employee concerns, and any matters arising from each of our core areas.

Huddles are now 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 and cannot wait until the staff meeting.

New Tests

10/15/2014	NRAS Mutation
12/17/2014	RET (10q11) Rearrangement by FISH
2/18/2015	KIT Mutation for AML
6/16/2015	1p/19q Deletion by FISH
6/16/2015	CIC (19q13) Rearrangement by FISH

Specimen Volume

Specimen Volume 1/1/2014 – 12/31/2014: 18840 (This is a 6.5% increase from 2013). A shift to more solid tumor samples being received by the laboratory resulted in a 44% increase in solid tumor testing (3783 in 2013; 5434 in 2014).

Educational Improvements

We created a more rigorous Resident Training program. Our onsite Medical Director, Dr. Noah Brown, wanted to have a training program where the residents are more involved in learning our procedures. Dr. Brown developed, and with the help of our Supervisors and technologists implemented a new in-lab procedure-based training program in October. All first year residents go through the program and current residents that have not gone through the new training get re-trained. Additional daily didactic sessions are also performed by Drs. Noah Brown and Bryan Betz when residents are on service. A problem-based teaching portfolio is currently being created.

Operational Improvements

Additional Staff (1FTE)

We had one addition to our FTE's. We hired a Research and Development medical technologist to assist with our Research and Development team.

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 joined as Associate Director July 2014.

Additional Instrumentation

The laboratory received 3 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.

Clinical Testing Improvements

Two FTE positions were repurposed to support increased demand for FISH testing and our Next Gen Sequencing startup. With this repurposing, the molecular rotation schedule is constantly being evaluated to see what changes or issues need to be addressed. This is now performed on a weekly and daily basis.
Saturday technologist rotation schedule was changed so that all technologists now rotate Saturdays. They had two dedicated technologists who worked Tuesday – Saturday, but with the constant turnover of staff on this work schedule we now rotate amongst all technologists in all sections (Molecular, FISH and Next Gen).

Staff work shifts were assessed and adjusted to improve test workflow and staff coverage. This has resulted in earlier staff coverage which allows technologists to better advance work in progress.

They created a cancel test report within SOFT for their QNS solid tumor testing to cross over to MiChart. They also worked with U of M oncologists to better communicate our workflow and for them to have a better understanding of MiChart capabilities. These discussions resulted in a process improvement for both the physicians and our lab.

Tissue review is now performed exclusively by board-certified attending pathologists. In addition, we implemented a QC review of tissue following nucleic acid extraction to ensure the accuracy of this process. Re-extractions are then performed if necessary. Any discrepancies are also now discussed with the technologist performing the micro dissection for continuous training purposes. A dissecting microscope is also being used by technologists to improve the accuracy of micro dissection. Together, these changes have resulted in a 55% decrease in cancelled tests due to insufficient material and a 90% reduction in low-level positive results.
Billing for tissue micro dissection service was implemented which will capture additional revenue for solid tumor testing.

As a result of the Lean and spaghetti diagram activities, they re-configured existing lab space to better accommodate workflow for the Histology, Tissue extraction, and Tumor review areas. As a result, they were able to bring the disparate FISH areas together instead of on opposite sides of the lab. The re-configuration also helped reduce traffic in the high traffic areas due to moving equipment closer to the benches that the technologists utilize.

They had an in-service with Pathology Administrative Assistants, to lend a better understanding of what our laboratory does and the impact of not filling out the requisitions appropriately for testing. This has led to an increase in the amount of requisitions that they receive that are filled out correctly.

Storage of archived test worksheets and data. In the shared storage room, shared with Immunology and HLA, they were running out of space due to our storage of the entire assay worksheets since the Molecular Lab opened. The Medical Director approved the scanning and digitization of the old assay worksheets by Automatic Imaging. This provided additional storage space for supplies and reagents. Moving forward they implemented digital scanning of these media in SoftMedia.
Ordering change. For the 3730 Genetic Analyzer, they previously ordered polymer by single vials. The cost was $1,204.00 for one vial. They would purchase 2 vials, at a time, for a total cost of $2,408.00. They change out the polymer every 14 days with a new vial of polymer. The vendor now offers a discount for ordering a package of 5 vials of this polymer. The total cost for 5 vials is $3,505.00. They order the package of 5 vials now, with a yearly projected saving of $13,779. They also order our AmpliTaq Gold 360 mastermix from Life Technologies in a similar way. The previous cost use to be $2650 for 10 vials and now it is $1708. They are currently saving $5652 per year for this reagent.

Accountability for patient reports. They implemented procedures to reduce the percentage of amended reports due to reporting. Investigation of amended reports revealed that most were due to errors initiated by external clients or due to bugs in the laboratory information software. The lab manager and supervisors are now more diligent in previewing reports, and when errors are found, the error source is identified and resolved by working with the client and pathology informatics. The lab staff are also informed. With the new system of checks, most errors are being caught before the cases reach the Manager or Supervisor for final review and

reporting.
They established a new workflow for our reflex testing for both molecular and FISH tests. They created an orderable test code to better track this testing so that second-order tests would not be run or missed before the original test was completed.

Traverwood II labs were cited by the MDEQ in regards to the hazardous waste storage. They worked with OSHA and U of M chemical safety to establish a better storage area and instituted a new workflow within our lab for the hazardous waste stream.

Cytogenetics

The laboratory Director is Lina Shao, M.D., Ph.D. and Director Emeritus Diane Roulston, Ph.D.. Thomas Glover, Ph.D. (Professor, Department of Human Genetics, Department of Pathology) continued to provide invaluable expertise and sign-out coverage, primarily for constitutional genetics cases. Beth Cox serves as the Laboratory Manager.
Over the past fiscal year, the Cytogenetics Laboratory made several important changes and additions to the clinical service. Dr. Lina Shao was appointed Director and Dr. Diane Roulston as Education Director. Turquessa Brown was appointed Laboratory Supervisor, Teri Scott Senior Technologist for Blood/Bone Marrow section, and Hong Xiao Senior Technologist for FISH section. GSL scanner was introduced to the laboratory and validated in scanning malignant cases. In addition to hematological malignancies, the Affymetrix Cytoscan HD microarray platform was validated in pediatric solid tumors and put into clinical use, making significant improvement in the diagnosis and clinical management of malignancies.

Clinical Services

n FY2015, the Cytogenetics Laboratory had slight increase in overall sample volume compared to FY2014. A total of 3,846 tests were performed, representing an increase of 2.9% (+108 cases). The main increase came from cancer cytogenomic microarray (+398%, +199 cases), however, single FISH probe tests kept declining (-20.5%, -167 cases). (Table 1).

The volumes for karyotype had an increase of 3% (+78 cases) compared to FY2014 with moderate increase in tumor (11.4%, +33 cases), constitutional blood samples (13.6%, +43 cases), and product of conception (8.1%, +8 cases). Prenatal sample volumes (amniocentesis and chorionic villus) continued the decline (-5.5%, -7 cases). The volume for bone marrow/leukemic blood stayed the same (+1 case).

FISH tests were lower than the previous year in every category except FFPE FISH with a total 16.7% decrease (-176 cases). The decline was mainly due to continued significant decrease in single FISH probes (-20.5%, -167 cases) which started in FY2013. 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. The request for FISH panels stayed about the same (-1.5%, -2 cases). Constitutional FISH requests including CMA confirmation and FISH tests for constitutional disorders also had significant decline (-29.5%, -28 cases). We had significant increase in FFPE FISH request (+123.5%, +21 cases). A new FFPE FISH test, ERG breakapart FISH for the *ERG* gene rearrangement, was validated and offered this year. This test along with pre-existing TFE3 and TFEB breakapart FISH tests was developed through collaboration with Rohit Mehra, M.D. and the Michigan Center for Translational Pathology (MCTP). A cytogenetic technologist (total 3) was trained to perform FFPE FISH. The section also consolidated bench work by one technologist handling all the bench work, the consolidation significantly decreased test failure rate and improved efficiency.

The Microarray Section of the laboratory began offering clinical testing for hematologic malignances last March and saw steady increase in the volume (+342%, +171 cases). Cancer Cytogenomic Array provides valuable diagnostic and prognostic information for patients with acute lymphoblastic leukemia/lymphoma (ALL), and becomes standard of care for ALL patients at diagnosis. The microarray test is gradually accepted by physicians to replace the MDS FISH panel (sendout test) and ~40% of the requests came from myeloid malignancies with a normal karyotype. The microarray test was also validated and started offering clinical tests for pediatric solid

Future Plans

The recently acquired scanner already proved that it improves efficiency and productivity in oncology samples. Validation of product of conception and constitutional blood samples using the scanner is planned. In order to fully utilize the scanner, we'll need to improve the quality and quantity of chromosome slides, and acquire more Cytovision analysis stations. We'll continue optimization of slides preparation in the Thermotron and use it for fast dropping with consistent quality. They will work with Tom Peterson to add more Cytovision analysis stations so technologists have easy access to the analysis software. They will renew effort to address areas identified by employee engagement survey and improve communication and patient care in the laboratory.

Table . Sample Volumes in Clinical Cytogenetics (FY2015)

Sample type	N	Change from FY2014
Bone marrows	1,786	+1 (+0%)
Tumor/Lymph node	322	+33 (+11.4%)
PB constitutional	359	+43 (+13.6%)
Prenatal		
Amnios	62	-5 (-7.5%)
CVS	59	-2 (-3.3%)
Tissues (POC)	107	+8 (+8.1%)
Total (chroms):	**2,695**	**+78 (+3.0%)**
Tissue culture only	8	+1 (+14.3%)
Add tissue culture for AM, CV or TI	18	+6 (+50 %)
Total	**26**	**+7 (36.9%)**
FISH		
Genetics	67	-28 (-29.5%)
Oncology	643	-167 (-20.5%)
Panels*	128	-2 (-1.5%)
FFPE	38	+21(+123.5%)
Total (FISH):	**876**	**-176 (-16.7%)**
Microarray		
Hem- onc	221	+171 (+342%)
Solid tumor	28	N.A
Total (microarray):	**249**	**+199 (+398%)**
Total tests:	**3,846**	**+108 (+2.9%)**

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

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

Division of Pathology Education

Barbara J. McKenna, M.D.
Godfrey D. Stobbe Professor in Pathology Education, Gastrointestinal and Hepatobiliary Pathology
Director, Division of Education Programs
Director, Residency Training Program

OVERVIEW

As with the University and the Medical School, education is a core mission of the Department of Pathology. For decades, the department has been a key provider of learning for medical students, graduate students, dental students, residents and fellows. Or faculty have been among those most revered and remembered by graduates of the medical school, and have garnered formal recognition in the form of teaching awards. 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 2014-15 academic year was marked by significant achievements, as outlined below The leadership and administrative team consists of the Program Director, Barbara J. McKenna, M.D., Associate Program Directors Scott Owens, M.D., Fellowship Coordinator Marie Goldner, Residency Program Coordinator Pamela Howard, and Medical Student Program Coordinator and Conference Coordinator Desire Baessler , The Residency Program GME Committee included Allecia Wilson, M.D., Scott Owens, M.D., Jonathan McHugh, M.D., David Keren, M.D., Nathaniel Bailey, M.D., David Lucas, M.D., and the Chief and Assistant Chief Residents and Theodore Brown, M.D and Reena Singh, M.D.

Recruitment: We continue to recruit high caliber residents from a wide geographic region. All incoming first year residents for 2014-15 were highly ranked by UM in the NRMP match. The group includes two students from the University of Michigan Medical School class of 2015 , and two graduating with MD, and PhD degrees. This group hails from Michigan, Ohio, Nevada, New York and Iowa.

Achievements: Our residents were very active academically, with a total of 19 publications during 2014-15, and 23 abstracts.

Our residents were also highly involved in Quality Improvement and Patient Safety projects, including efforts to create a new Cytogenetics protocol for products of conception specimens, improve fixation of highly fatty specimens to achieve better quality sections, improve turnaround time for frozen sections, improve communications for residents on call, optimize frozen section protocol to prevent

specimen mislabeling, clarify the wording in surgical pathology reports, decrease cold ischemia time for breast biopsy specimens, develop a customized report view for hemolysis laboratory parameters, assessment of the potential of in-house Fungitell testing in microbiology, improve processes related to charting of transfusion reaction evaluations, and improve the Laboratory Information System processes. For the coming year, a new Quality Improvement Curriculum for the residents will be piloted, led by Dr. Scott Owens, Director of the Division of Quality and Health Impovement (DQHI), Mr. Brian Tolle Manager, DQHI, and a workgroup of other faculty and resident representatives.

In the fall of 2014, the Pathology Resident Program at the University of Michigan was ranking #1 in the United States among large public hospitals, and #7 overall by Doximity, an online social networking service for U.S. physicians with over 400,000 verified physician members. In addition, a recent survey of gradates of our residency over the past 5 years indicates that 100% of respondents rate the training they received as “excellent.”

Board results: 100% of the graduating class of 2014 passed the American Board of Pathology certification examination on the first attempt.

Graduates: Eight residents completed training in 2015. All are proceeding to fellowships, 6 of them here at Michigan, one at the University of Iowa Hospitals and Clinics and one at Miami-Dade County Medical Examiners’ Office.

Graduate Medical Education--Fellowship Programs

The fellowship training opportunities continue to grow. With the approval of a new Bone and Soft Tissue Pathology Fellowship, there are now 9 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 outlines receive between 400 and 600 hits per month, generating traffic to our own department website, and reflecting the interest in our programs.

A Fellow Selection Committee 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.

Fellows completing training in 2015 moved on to jobs in academic institutions (7), jobs in private practice (4), a job in industry (1), or additional fellowships (7).

Medical Student Teaching

M1 and M2 Teaching

The Department has a long history of playing an integral role in pre-clinical medical student education. We have a unique presence in the M1 year, starting with the first sequence, titled Patients and Populations, introducing pathology concepts and terminology. This is reinforced by additional lectures and laboratory sessions in the winter and spring of the M1 year. 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 there are 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).

The Department of Pathology has several faculty members involved in the planning for implementation of the new Medical School curriculum that was approved by the faculty in June of 2015, including Drs. Scott Owens, Madelyn Lew, Nate Bailey, Lauren Smith, and Barbara McKenna.

M4 Pathology Elective Rotation

In recent years, the caliber of the M4 Pathology Elective experience under the direction of Dr. Jonathan McHugh has made this an increasing popular choice of Michigan Medical Students, Students electing this experience gain exposure to many areas of Anatomic and Clinical Pathology, with required tours and observation. They select cases for presentation at daily meetings, and must either make a formal case presentation to the department or write a paper of similar depth to successfully complete the elective. In the past academic year, 86 senior medical students (approximately 50% of the graduating class) rotated in Pathology, and 2 additional students from other institutions. 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.

There is a workgroup currently working to evolve the M4 elective rotation to optimize the experience for students from any of the several Branches that will constitute the 3rd and 4th years of the curriculum.

Molecular and Cellular Pathology (MCP) Graduate Program

The Molecular and Cellular Pathology (MCP) Graduate Program, under the direction of Zaneta Nikolovska-Coleska, Ph.D., has 26 students who are presently in Pathology Department laboratories performing their Ph.D. thesis research.

Statistics of our current students

Candidacy exam:
In this year, four students (3 PhD. And 1 MD) wrote, defended and successfully completed their preliminary exams that allowed them to pass to candidacy during their 2nd year and focus on their research thesis work.

PIBS students graduated in 2014/2015:

- Garrett Gibbons (Nikolovska-Coleska)
- Bernadette Zwaans (Lombard)
- George Lund (Cierpicki)
- Sunita Shankar (Chinnaiyan)

MSTP students graduated in 2014-2015:

- Ania Owczarczyk (Lukacs)
- Anirban Sahu (Chinnaiyan)

Productivity of MCP students

Individual extramural and intramural fellowship (10)

- Sierrah Grigsby (NSF fellowship, Rackham Research Grant & TREC)
- Talha Anwar (F30)
- Ulas Ozkurede (Munger Housing Junior Fellow)
- David Rogawski (Rackham Research Grant, Alex's Lemonade Stand Foundation Pediatric Oncology Student Training Program)
- Hung-An Ting (Barbour Scholar, Rackham Graduate School; Best Poster Award from 2015 American Association of Immunologist annual meeting)
- Shayna Bradford (Beth Halloran Scholarship from CEW)

Travel awards (9)

- Ed Grimley (International Workshop on Developmental Nephrology Travel Grant)
- George Lund, Jon Pollock, David Rogawski, Ania Owczarczyk, Rebekah Martin, Talha Anwar, Allison Johnson, Ed Grimley (Rackham and MCP travel awards (8))

Training grants (4):

- Emmalee Adelman (Training in the Biomedical Research of Aging)
- Ed Grimley (PICTP)
- Amy Han (Training in the Biomedical Research of Aging)
- David Rogawski (CBI)

Published papers by our students as first authors: 2

- First author (2): Pollock and Rogawski

Papers published by our students as co-authors: 12

- Co-authors (12): Chung, Engelke, Lee x3, Morgan, Ozkurede, Pollock x3, Serio, and Ting

Recruitment activities

- New class 2015/2016

In April we finished the recruiting for the fall, 2015 class for the Program in Biological Sciences (PIBS) and successfully recruited 3 high quality students,

Following the progress of the current students and their satisfaction of the MCP Program

- Annual reports of our students (introduced from 2014)

Annual reports are by the end of the June 30th each year and students are meeting with the Director of MCP by the end of August and discuss their progress. If there is any concern or a need the Director will meet together with the student and the mentor

- Initiated annual meeting with MCP student council to hear students' opinion and suggestions (May 13 2015)

  - Research Seminars - feedback from our students about covering broader topics and having faculty who will provide them with the feedback after the seminar;

  - Students also asked for bigger involvement of the faculty members in the dissertation committees

Students' activities

- Academic activities, including mentoring of younger students and undergraduates.

- Perhaps the most impressive extramural accomplishment that the MCP students perform on an annual basis is the organization of the annual Department Research Symposium that is held in the fall each year for past 13 years. The MCP students invite an internationally known keynote speaker that gives a talk in a symposium that highlights short research talks from faculty, graduate students and post-docs. Last year (November 2014) keynote speaker was Jennifer Lippincott-Schwartz, Ph.D., Distinguished NIH Investigator, Chief, Section on Organelle Biology, Cell Biology and Metabolism Branch, National Institute of Child Health and Human Development, National Institutes of Health. During the symposium they also organize a poster session that this past year had more than 40 posters from laboratories in the Pathology Department. For the first time the career panel was organized and following participants were invited: Jennifer Lippincott-Schwartz, Ph.D., NIH; Neali Lucas, Ph.D., Food and Drug Administration (graduated from MCP program); Charlie Taylor, Ph.D (Pfizer); Ed Pagani, Ph.D. (U of M Office of Technology Transfer) and David Lombard, M.D., Ph.D. (Associate Professor, U of M Department of Pathology). Last year, new award was established with the support from the Department: Outstanding senior student with a cash award of $500. The first recipient was Anirban Sahu (Mentor Dr. Chinnaiyan). The Research Symposium has

become a true success and highlights the student's enthusiasm, collegiality, and passion for research.

Translational Pathology training grant

- The revised application will be resubmitted September 2015

- Translational Pathology pilot grant:

    - So far 3 students participated in this program (1 student dropped MCP program because of medical reasons). The students' clinical rotations and progress was discussed with their mentors and co-directors of the training program.

    - The committee meeting selected 2 new candidates for this training program for 2015/2016.

Social events supported by MCP Program 2014/2015

9/11/14 Annual MCP student/faculty picnic – Island Lake Park

11/6/14 Happy hour student/faculty mixer – Bar Louie

4/30/15 Happy hour student/faculty mixer – Bar Louie

6/6/15 Student camping trip – Pinckney Recreation Area

8/6/15 MCP Ice Cream Social - BSRB

Pathology Education Series

A vibrant and varied morning Pathology Educational Series takes place most mornings at 8 am, from September through mid-June. In 2014-15 there were 159 conferences, each offering CME credit. Five were presented by visiting faculty from other institutions, 40 by residents, 19 by fellows, and 2 by faculty from other clinical departments at UMHS. The remaining 93 were presented by departmental faculty 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 together residents, fellows, AP faculty and CP faculty.

Division of Experimental Pathology

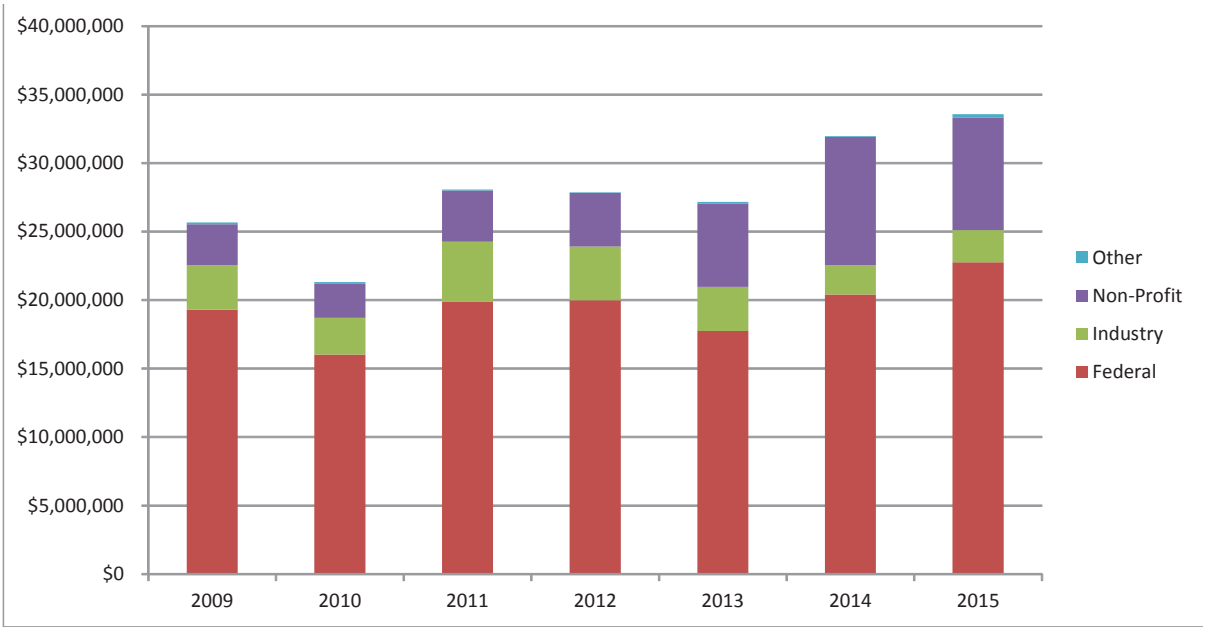
Asma Nusrat, MD
Aldred S. Warthin Professor, Mucosal Inflammation and Epithelial Pathobiology
Director, Experimental Pathology

The past year was another productive year for the division of Sponsored Programs, recently reorganized and named the division of Experimental Pathology. The division includes investigators from the basic and translational sciences whose studies are aimed at understanding the pathobiology of human disease and development of therapeutic strategies.

To thematically unify our diverse research portfolio, the various research programs have been consolidated into several sections, including Cancer Biology, Development, Neuroscience, Epigenetics, Aging, Epithelial and Mucosal biology, Immunology and Inflammation, and Experimental Therapeutics.

Our chair, Dr. Parkos generously provided stimulus funds for purchase of cutting-edge shared equipment that will further promote collaboration between Pathology research faculty members and enhance their ability to successfully compete for extramural grants.

The research funding trajectory continues to increase in Pathology. Committed grants in the department have increased to over $33 million in 2015 and the majority of this amount is from Federal sources (figure below). Additional sources of research funding include Non-profit organizations as well as Industry. This is indeed a remarkable achievement given the challenging funding environment. As a further evidence of our research productivity, the Indirect Cost (IDC)/sq. ft. of the greater than 67,000 sq. ft. of research space allocated to the department is presently at 115/sq. ft., which is above the University of Michigan Medical School benchmark of $110/sq. ft. We are currently ranked #7 nationally in NIH funding, further demonstrating the strength and sustainability of our research programs.



A few examples of special achievement by EP faculty members are worthy of special notice. Nick Lukacs continues to serves as the Scientific Director of the Mary H. Weiser Food Allergy Center. The philanthropic goal of the center is $42 million and thanks to the naming donation of $10 million from Ambassador Ron Weiser and

his wife Eileen, as well as the tireless advocacy of their daughter-in-law Mary Weiser, the Food Allergy Center is two-thirds to its goal in committed funds. He will continue to recruit top notch basic and clinical researchers to the University of Michigan to build an outstanding center to address food allergy. Dr. Lukacs also heads the Immunopathology of Lung Disease T32 training grant that supports training for basic and translational researchers across the medical campus. An equally important T32 training grant in Pathology was successfully renewed by Dr. Alexey Nesvizhskii. This is the Advanced Proteome Informatics of Cancer grant which is working to address the needs for trained scientists in the rapidly growing Proteome Informatics field. The Michigan Center for Translational Pathology (MCTP) directed by Arul Chinnaiyan, continues to successfully develop molecular tests and to identify new therapeutic targets in human cancer. The MCTP also continues its remarkable track record of success as evidenced by high profile publications and successful funding. In 2015 Dr. Chinnaiyan received the Prostate Cancer Foundation Challenger Award that funds transformational prostate cancer research.

There have been numerous faculty highlights during this past year. In 2015, Experimental Pathology faculty published over 220 manuscripts, including papers in high-impact journals such as *Cell*, *Immunity*, *Nature,* and *Science*. In addition to this, two of our senior EP faculty members have been recognized for their dedication to research by receiving prestigious awards. Peter Ward received the Honorary Lifetime Award for Excellence in Leukocyte Biology Research, celebrating a career of over 50 years investigating immunity and inflammation. Chuck Parkos was the recipient of the American Society for Investigative Pathology Rous-Whipple Award. This highly competitive award recognizes a senior scientist with a distinguished career in research that has advanced the understanding of disease. Ul Balis was inducted into the American Institute for Medical and Biological Engineering (AIMBE) in recognition of his outstanding contributions to the fields of laboratory instrumentation, pathology bioinformatics and computational imaging in histology image search/analysis. In addition to these prestigious external awards, Yali Dou earned the Dean's Basic Science Research Award, which recognizes scientists who have made outstanding contributions to the Medical School in basic biomedical science research.

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

Division of Pathology Informatics

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

The division of pathology informatics, situated as one of the 7 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 topics as well as digital imaging and systems 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.

As was the case with the prior 2013-2014 academic year, the Division has maintained its primary focus upon stabilization and optimization of the SCC Soft laboratory information system (SCC), which was activated on June 1st of 2013. Since the time of activation, and similarly, since the time of the prior annual report, the division has mitigated 2000 total and 1000 major software change requests, respectively, with the remainder of the most important functional enhancements to be delivered by Q1, 2016. As compared to the time period associated with the application's initial activation in June of 2013, the contemporary reality demonstrates a far more mature LIS solution, with the department now realizing many of the operational, safety and automation benefits. These enhancements were the very reason for which we originally selected the SCC platform. At the current pace of feature enhancement and system modification, the division is on track to complete the overall stabilization/optimization process by early-mid 2016, with the most important features featured in place by Q1 2016.

The Laboratory Information System – SCC Soft

Continuing on the extensive work of the 2013-2014 academic year, the Division expended significant effort on further enhancement and mitigation of the Soft application, with over 1000 corrections and/or enhancements going into the production environment, over the span of five separate major upgrade cycles. Each upgrade cycle benefited from the ongoing close partnership of pathology's 17 separate lab units, working shoulder to shoulder with staff of the Informatics Division, to realize the succession of seamless and minimally disruptive upgrade cycles needed to realize this brisk rate of application evolution.

Towards the goal of enhanced application development, this past year witnessed the deployment of a new Quality Assurance environment in the SCC application suite, with this allowing for expedited testing and validation of new candidate features, upon their delivery from SCC for our evaluation. With receipt of this new environment, our deployment productivity, in SCRs deployed per calendar month, nearly doubled. In tandem with this new environment, the division activated a new mirror image of our live environment, the "SIM-1 environment," as a means of pre-qualifying specific new modules, without encumbering the entire QA environment for such activities – again, with this extension allowing the division to move new solutions into the production environment more quickly.
Also, in late 2014, we substantially enhanced our computational infrastructure supporting Soft, with the pairwise upgrade of both of our prior IBM P6-based clusters to contemporary P7 servers. Following several cycles of hardware optimization, the new hardware allowed for substantial mitigation of perceived system slowness in

most workflow areas. Those remaining areas that intermittently exhibit sluggish response are the subject of ongoing evaluations, with the likely root cause being network topology issues. Already, a task force has been stood up to address that separate functional limitation, with a solution expected by Q1 2016.

Over the next academic year, the division looks forward to fully mitigating the remaining defects and at the same time, incorporating enhancements that have been under development for as long as three years (optimized frozen section workflow, managers' dashboards, real-time production kiosks, etc.). With the completion of these final anticipated application enhancements, the department will be in a position to fully leverage the significant informatics potential intrinsic to the SCC architecture, and in so doing, allow us to be ready for both the impending move to North Campus and in concert with that move, the pending tsunami of demand for IT support in the genomics and digital AP workflow spaces.

During the preceding year, the Division was successful in completing SoftReports training for a sizable cohort of laboratory staff, thus creating a valuable critical mass of expertise throughout the department with the capability of generating on-demand reports from any of the categories of data that is captured and housed in the SCC architecture. Already, there are a number of compelling examples where self-empowered laboratory staff have been able to extract the operational information that they were seeking, without the assistance of Informatics specialists.

PDF Delivery of LIS Reports via Atlas to MLabs Connect
Long recognized as a limitation of the prior text-only reporting model for the delivery of results to MLabs' many clients, the Informatics Division completed a multi-year project to convert the delivery of results into PFD format, thus preserving both content and layout, with client physicians now able to view MLabs reports as they are generated in the native SCC application. This enhancement has greatly improved MLabs' ability to showcase sophisticated reporting layout, where appropriate, in addition to simply conveying results themselves.

Upgrade of the Overall Cytogenetics Imaging System
This monumental effort essentially refreshed this entire laboratory's imaging technology solution, thus preparing it for the nextdecade of simplified electronic workflow, utilizing modern technology. The upgrade effort included replacement of essentially all core hardware components, including: the Cytovision dual servers, 14 analysis workstations, 7 camera capture stations, the metaphase robotic slide scanner, and finally, a new bidirectional electronic interface to SCC Soft.

Anatomic Pathology Image Capture Technology Refresh
As part of Informatics' continuing mission to identify and replace legacy hardware with more reliable and better performing contemporary solutions, the Division carried out a technology review of current gross image capture solutions, ultimately selecting the Spot Camera solution for five grossing stations that had substantially antiquated imagers. Additionally, the remaining MacroPath Grossing Imaging Workstations in active use were further stabilized with enhanced interfaces to the SCC Soft Media module, thus simplifying workflow for gross image capture and at the same time, reducing user frustration from unreliable hardware.

New Positions
Recognizing a critical need in the area of targeted management reports for anatomical pathology, the division hired John Hamilton as a senior level analyst, to rapidly develop and deploy solutions.

Routine Application and Hardware Upgrade Projects
As part of the Division's mission to carry out technology refreshes wherever appropriate, the prior year witnessed significant efforts in this category, with the following general projects being completed:

- Upgrades to the hardware infrastructure in the External Results Reporting workflow area at the NCAC complex, including ten imaging workstations interfaced to both MiChart and SCC Soft
- Upgrades to the External Results Reporting Interface Server (Windows 2008) with subsequent customer migration.
- Histotrac LIS for Transplant support, upgrading 25 workstations that are interfaced to MiChart

for PDF reports, and interfacing these units to SCC Soft for result reporting and incoming orders; finally, also interfacing these units to OTIS for report / KPE identification

- WinScribe support for digital dictation, with support of 50 faculty authors, 8 full time transcriptionists, 15 part-time transcriptionists, and support from home. Improvements were made to the Winscribe-SCC interface, via federated query of patient demographics, with upgrade of the federated query of patient demographics from WinScribe, via advanced Oracle/Microsoft inter-vendor orchestration technology.
- Supported Molecular Diagnostics imaging and analysis software, and additional support for special result reporting (e.g. BCR/ABL time series reporting) of images and archival of raw data.
- Continued support of document imaging for the department (and specifically HR), using the Freedom Imaging Image Archival Repository Solution, including support of four physical servers and many concurrent users.
- Upgraded the HLA lab's Fusion Analysis workflow for this class of molecular results, with this effort including support of four new instruments and interfaces to Histotrac.
- Supported the Statlia Analysis for Chemistry with new interfaces between these Instruments and SCC (for both orders and results reporting).
- Supported the deployment of a new HLA robotics system for both aliquoting and specimen preparation.
- Implemented high volume outpatient label generation in multiple locations
- Established UMHS network connectivity and workstation setup for the Wayne County Medical Examiners' primary facility, thus providing simplified access to SoftPathDx
- Integrated the Clinitek POC application suite to both the LIS and directly to MiChart
- Deployed new wireless printer solutions for multiple Blood Draw areas
- Upgraded several Cisco communication closets, in partnership with the MCIT Networking Team
- Supported the Northville Health Center Opening (MLabs, glucometers, workstations, printers, Sysmex, Cellavision, etc)
- Provided logistical support for the machine room's power substation upgrade
- Deployed a new bidirectional interface to the Cellavision instrument suite
- Upgrade performed on the Master Control application suite
- Developed and implemented a bidirectional interface for the recently deployed Rotem instruments
- Upgraded the RALS server, in support of portable POC glucometers
- Provided departmental coordination and orchestration of the enterprise workstation encryption initiative
- Initiated Airwatch support for PDAs
- Mobile device encryption was initiated, with integrated data recovery services made available for machines with lost decryption keys
- Provided IT and logistical support for the opening of the new Livonia Health Center
- Initiated a series of Blood Bank-to-Epic interface kick-off meetings
- Planned and execute a migration to new version of the Atlas LabConnect solution, utilizing the new Atlas Gateway
- Created a workflow in association with the American Society of Telepathology for dermatology cases
- Completed testing and validation for *MiChart version 2014,* which was upgraded in April 2015
- Updated the U-M logo to match the current approved UMHS logos, in all standard patient reports
- Implemented the test orderable mix and results/report formats for the new Dermatopathology Molecular Diagnostics Laboratory
- Implemented a new Faculty Absence Request Form for the Front Office
- Implemented new Aperio software and hardware within the photo lab (new servers, storage, and software version)

Complete Rewrite of the Department's Electronic Billing interfaces and Submission System
Continuing on the groundwork set in place during the 2013-2014 year, in the present cycle the Informatics Division completed development of the critically-needed replacement Billing Tracking System and Web-based logistics tracking interface. With this new infrastructure in place, the department is now much better positioned to scale to larger billing volumes without the need to add staffing or additional support resources. Additionally, the new tool suite affords a measure of real-time tracking to in-process billing that facilitates greater accuracy and accordingly, improved overall billing capture.
As part of this application development process, the existing Enterprise Master Patient Index (EMPI) in use by the division was further enhanced to support expanded billing patient search and match requirements, further elevating the first-time quality of billing ledgers.

Redesign of the New Academic HR (Faculty) Tool
Although the prior web-based HR application served the department well for seven years, its age and legacy-based application development stack were beginning to show their age, making a compelling reason for the ground-up design and implementation of a new suite of applications, intended to support the complex documentation needs surrounding the collective faculty recruitment, credentialing and promotion processes. In designing this replacement solution, the web development team utilized fully contemporary programming tools and approaches, allowing it to complete this project in a fraction of the effort associated with the original project.

Participation with the Bi-Annual CAP Inspection
Being an inspection year for CAP accreditation, the Division participated in the bi-annual on-site CAP inspection process and logged its eighth consecutive cycle, over a 16 year period, of turning in a deficiency-free record for the informatics section of the CAP checklist. This year was similarly noteworthy for the Division's exclusive use of the Master Control on-line policies and procedures resource for all aspects of the inspection process, with this tool now representing a mature construct upon which to base the documentation for support of laboratory and LIS workflow.

Successful Completion of Both Medical School and Main Campus IT Audits
As part of the U-M's routine rotating cycle of university-wide IT audits, Q4:2014 through Q1:2015 was the window in which Pathology Informatics was comprehensively audited. The outcome of this exercise was a laudatory review, with the audit supervisor, Eric Randle, adding that PI's CI/CD pipeline for patch management was a model system that he would like other departments to emulate. Similarly, UMHS conducted an audit of PI's entire clinical IT infrastructure, with the conclusion of that process granting us uniformly high marks and no deficiencies.

Great Lakes Information Exchange (GLIE) Readiness
With the pending UMHS commitment to provide identified laboratory results as a major component of the health information record data to be provided to this now-forming health information exchange, Pathology Informatics was charged with the task of establishing a live feed to MiChart that was suitable for external consumption by the inbound GLIE electronic interface. Working with MCIT, the division stood up the needed interface, well ahead of the deadline, such that the enterprise-at-large could quality for incentive payments, under the provisions of the MU2 guidelines.

Support of Intramural Departmental Conferences
Continuing the Division's tradition of providing both IT and presentation logistical support for the Pathology Department's internally-developed educational conferences, Informatics provided full support for both the *New Frontiers* and *Forensics* Conferences, including custom designed websites for each event, along with electronic registration and payment capability, as well as on-site support for presenters and attendees.

Pathology Website Underlying Services/Development Model Infrastructure Refresh
Given the rapid pace of software and interoperability developments underlying website stewardship, it was appropriate in the prior academic year to carry out an assessment of current practices, changing or amending them where indicated. As a result of that ensuing 360-review process, a number of areas were targeted for deployment of more contemporary solutions, with the most significant enumerated below:

- Elasticsearch / Logstash / Kibana: Infrastructure tools to simply searches on our intramural website
- Migration of projects to *source control*: a necessary step, given the depth and breadth of concurrent website-directed programming now taking place within the division. This critical process control prevents programmers from tripping over other people's concurrent work in the same code bases at the same time.
- Jenkins Continuous Integration Pipeline –deployed: This monumentally important new functional layer will afford the division a much greater degree of automation with generating new website content and carrying our large-scale stylist updates. This pipeline essentially condenses many manual steps, which are prone to errors in user execution, to a single seamless invocation command, thus greatly simplifying overall website stewardship.
- Migrated from Kubernetes to Apache Mesos: This change in our development stack recognizes the availability of a more advanced tool suite for sophisticated websites. Briefly, Apache Mesos abstracts CPU, memory, storage, and other compute resources away from machines (physical or virtual), enabling fault-tolerant and elastic distributed systems to easily be built and run effectively.
- Deployed Docker Trusted Registry: Similar to the rationale for deploying Mesos, use of Docker allows for greatly simplified stewardship of a large ecosystem of concurrently developed and deployed web applications. Given that the natural evolution of the department's website has been systematically evolving from mere content generation to now hosting a multitude of applications, it recently became necessary to orchestrate the over development lifecycle and support process with a centrally managed tool suite. Docker answers that need, with it being "… an open platform for building, shipping and running distributed applications. It gives programmers, development teams and operations engineers the common toolbox they need to take advantage of the distributed and networked nature of modern applications." With Docker now in place, the Division's Webteam has substantial plans for further website development in the upcoming 2015-2016 academic year.
- Upgraded to latest supported build of vCloud Director:
- Decommissioned the VMware 3.5 cluster and PATH Domain
- Planned the pending vSphere6 migration along with investigation of use of Hyper-V as an augmentative management tool

  These three preceding upgrades are in consonance with the division's long-term strategy of staying current on all aspects of virtualization tools as provided by vmWare.
- Deployed new Website metrics & Analytics Engine solutions using InfluxDB, Grafana and Reimann: These tools were deployed to address the aging Graphite application & standard, and their inherent limitations in providing accurate, real-time metrics of website usage and utilization.
  See: http://www.slideshare.net/nickchappell/pdx-devops-graphite-replacement
- Implemented automated database migration capability, with schema changes no longer performed by hand.
- Utilized Docker for local development, across all web team members and affiliates (John Hamilton, Josh Jacques)
- Implemented Gitlab within the webteam for change control, project management, issue tracking and documentation.
- Implemented a stand-alone intrusion detection system to detect and prevent web-based attacks

Collectively, the above solutions allow the relatively small webteam to effectively maintain and extend a larger portfolio of software solutions, than would be possible with more traditional manual means alone. The 2015-2016 academic year will be a significant alembic for whether or not such an approach can effectively scale to the department's ever-growing IT needs with preliminary indications being that the tools are indeed delivering upon the originally envisioned efficiencies.

Pathology Data Center Infrastructure Upgrades

As with prior years, the Informatics Division has remained very active in refreshing our infrastructure, with the preceding year witnessing a dramatic transformation of prior storage approaches to contemporary solutions, including the deployment of the much-awaited HP 3PAR solution. In tandem with this large effort, the division also redesigned significant aspects of our multi-site fiber-optic-based inter-site network fabric topology, shifting dependence from Radiation Oncology as our secondary site to use of the new state-of-the-art MCIT North Campus Data Center (NCDC). In so doing, the division has obtained access to a Tier IV class secondary data center, allowing for very robust data stewardship. In tandem with this large infrastructure project, a number of smaller, but equally important projects were completed, including the following:

- Completed the long-term file services replacement project (Isilon hardware installed, validated, configured, and segments of Research storage fully migrated)
- Completed Backup Express enterprise backup version upgrade (with now over 8PB of archives in the master backup catalog)
- Completed VMware training and preparation for vSphere 6.0
- Executed cleanup of outstanding security tickets to none over 90 days, as a component of the overall UMHS IT audit process
- Upgraded UPS batteries in the primary datacenter

Petascale Deployment of the HP 3PAR Enterprise Storage Solution, as a Partnered Exercise with MCIT

Representing the culmination of a five year capital cycle request process for seeking a petascale replacement to the division's aging Enterprise Virtual Array storage solution (HP EVA 8000), in Q2 2015, Pathology Informatics began the complex process of replacing its core storage solution, with completion of this project estimated to be no later than Q1, 2016. This state-of-the-art storage solution has the ability to grow with the needs of the department, from its initial "starter" configuration of 2 PB to greater than 100 PB, as departmental needs expand. The selection and acquisition of this hardware should be viewed as a "model approach" from an enterprise perspective, as both aspects of this process were carried out in partnership with MCIT, ultimately leading to shared request being forwarded to the Information Technology Strategic Advisory Committee (ITSAC) – a first of its kind for the UMHS enterprise, and one that leveraged shared expertise and scalable needs of the enterprise (essentially future-proofing the selected solution). In tandem with this request, a jointly maintained oversight model was proposed, again reinforcing opportunities for economies in scale for both infrastructure and staffing. The net effect of this joint proposal is that both the Pathology Department and MCIT will be well served by a contemporary and a scalable, high performance storage solution.

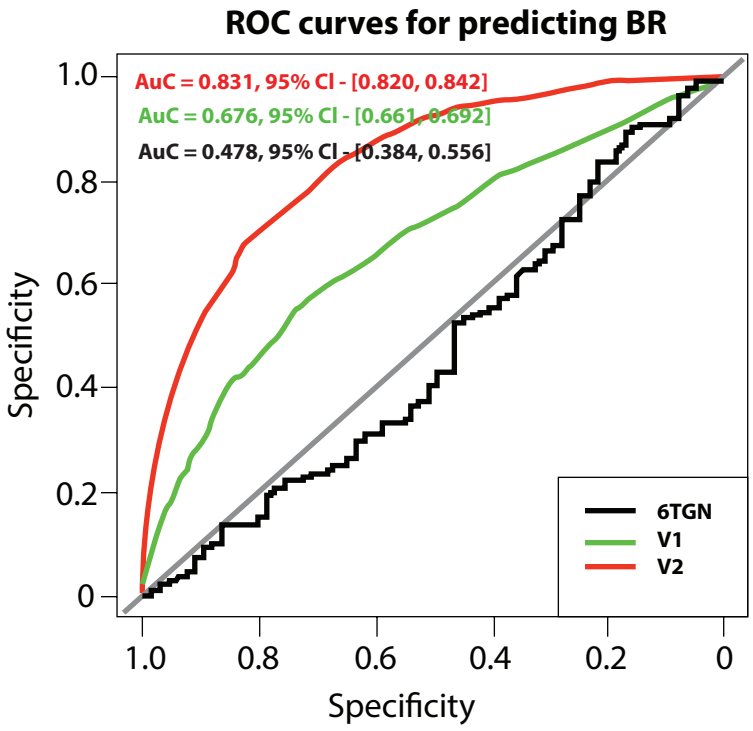
For Pathology, this specific solution is particularly compelling, as it possesses three levels or tiered performance storage, allowing the Division to apportion storage volumes based on computational need. The fastest tier, SSD –based storage (SSD=Solid-State Drives) allows for extremely fast information retrieval, as compared to conventional spinning disc technology, with this solution being suitable for applications where rapid file retrieval an load times is essential (e.g. NGS computational pipelines ad whole slide image retrieval). The intermediate tier of storage is based upon fast spinning drives (10K or 15K rpm fiber-attached discs), with this category of storage suitable for supporting enterprise-class applications (e.g. the department's Laboratory Information System: SCC Soft). The third tier of storage, based on the use of Serial ATA drives (SATA), utilized the currently most cost effective form of long-term storage, suitable for low concurrency file storage (e.g. personal drive storage and the department's all-important "W" drive). However, it should be noted that all three tiers of storage carry with them the same level of redundancy and fault tolerance. Redundancy, in this case is quadruple-redundant as the system possesses the following major duplication:

- Raid 5 or higher for each physical location
- Complete and independent copy of the same data in two locations
- Daily LTO-based Tape Backup of ALL enterprise data housed in the 3Par solution
- Off-site journaling of at least one backup copy of the local LTO tape journal

Taken together, the above plurality of solutions represents an extremely robust approach to data curation, with concurrent failures of all three of the above mentioned layers at the same time being exceedingly unlikely.

With the significant operational load sustained by Pathology Informatics to carry out continued stabilization/optimization of SCC-Soft, and in tandem, this prior year being a non-active year for the Pathology Informatics Fellowship, overall research activity was decreased (but not absent). Primary thrust was maintained in the R01 funded machine learning project, with the division being able to publically demonstrate the clinical superiority of computationally-derived Thiopurine testing (part of the emerging class of MAAAs – Multi-analyte Assay with Algorithmic Analyses), over the commercially-available Prometheus Labs' bench-based molecular test, with a tertiary external study confirming the superiority of such computational testing (via ROC analysis). The pilot results of this study allowed the division to secure an intramurally-funded FFMI M-TRAC award, which in turn, allowed for a split study with the Henry Ford Health System. As a result of the confirmatory data obtained from the split study, FFMI is now in negotiations with a third party to license this technology for national and international clinical distribution, via a new CLIA-certified entity that is being purpose-built for the offering of such computational clinical assays. The results of these studies have been showcased in no less than eight keynote presentations by the two PIs (Balis and Higgins) in seven countries (US, England, Sweden, Australia, Israel, Germany and Hungary. Commercialization in anticipated by no later than Q3, 2016.

Comparing Machine Learning Algorithms to 6-TGN



MLabs Outreach Program

Jeffrey L. Myers, M.D.
A. James French Professor, Pulmonary Pathology
Vice Chair of Clinical Affairs and Quality
Director, Divisions of Anatomic Pathology and MLabs
Director, Pulmonary Pathology Fellowship

MLabs offers access to the expertise of the faculty and staff and the sophisticated testing in the laboratories of the Department of Pathology for those outside of the University of Michigan Health System. As we celebrate our 30th anniversary in the reference laboratory business with another successful year of growth and client retention, we thank our clients for the opportunity to provide them with the highest quality reference laboratory services necessary to meet the needs of the patients we serve together. Our continued growth and ability to establish long term relationships with our clients is built on the promise of *expertise delivered personally* with a passionate commitment to service excellence. As a reference laboratory embedded within one of the largest academic medical centers in the country, MLabs is here for the long haul with patients at the center of everything we do.

WORKFORCE

The Department of Pathology has a large and diverse faculty and staff with 150 faculty members representing all disciplines of Pathology and 800 professional laboratorians and administrative staff. We are focused on excellence in service, education and research. All employees of the Department of Pathology share in the support of MLabs and our Clients.

The MLabs Division has a manager and sixteen individuals in key administrative, operations, informatics, sales and client services roles. MLabs informatics staff work closely with counterparts in the Pathology Informatics unit who are also dedicated to meeting the demands for IT support in the reference laboratory business. MLabs Client Services is consistently applauded by our clients as one of the most helpful and friendly in the reference laboratory industry. MLabs Client Services does not utilize a phone tree menu approach to call triage: each call is answered personally. Our trained client service representatives are available to answer questions related to specimen procurement and handling, look up testing status and serve as facilitators for client interactions with technical laboratory staff and pathologists. The MLabs Client Services hours are Monday through Friday from 7:00 a.m. to 9:00 p.m. and Saturday 8:00 a.m. to 4:00 p.m. Telephone calls received after-hours, weekends and holidays are handled by our MLabs Specimen Processing Customer Service staff providing 24 hour attention to client needs. In addition to MLabs Client Services, our MLabs homepage and on-line Handbook are user friendly references www.mlabs.umich.edu.

Licensure and Accreditation

The University of Michigan Health System's Department of Pathology Laboratories (MLabs) located in Ann Arbor, Michigan maintains Clinical Laboratory Improvement Amendments (CLIA) Accreditation, College of American Pathology (CAP) Accreditation, The Joint Commission Accreditation, American Association of Blood Banks, American Society for Histocompatibility and Immunogenetics (ASHI), State of California Licensure and State of Florida Licensure. State of New York Licensure is pending.

MLABS DIVERSIFIED CLIENT PORTFOLIO AND SERVICE LINE

MLabs client portfolio includes over 700 accounts. We provide reference laboratory services to hospitals throughout the State of Michigan and primary laboratory services to physician offices and nursing homes of strategic interest to UMHS. MLabs extends molecular diagnostic testing, specialized anatomic and hematopathology services and consultations to a national market including other reference laboratories and academic medical centers.

The following is an overview of each market/service line.

Physician Office
MLabs provides laboratory testing to 339 physician offices (all subspecialties) within geographic catchment of University of Michigan Health System (UMHS). Some patient specimens are collected at the physician offices (pap smears, urines, cultures) and MLabs provides routine daily courier service to those physician offices for those specimens. However, the physician offices do not provide their own phlebotomy service. Our clients' patients are referred to UMHS Patient Service Centers where their blood is drawn and specimen(s) are couriered to MLabs for testing. Testing preformed is primarily clinical pathology; automated chemistries, hematology and microbiology, although certain subspecialties also draw heavily on our esoteric test menu. We are the exclusive provider of BRCA testing for a large commercial payer (Blue Care Network) with statewide membership contracted through Joint Venture Hospital Laboratories. We have extended dermatopathology service to select dermatology practices throughout the State. MLabs is interfaced with several common EMRs for electronic result reporting. At this time, one-third of our physician office clients receive results electronically and the large group practices are interfaced for both orders and results. We are working on multiple interface projects so that we can provide electronic result reporting to all interested parties.

Hospital (HL) and Hospital/Pathology Groups (HPG)
MLabs classifies its Hospital market into two groups reflecting the primary referral pattern of the hospital. Support of each is unique to the reference laboratory services provided. MLabs (HL) hospitals include those to whom we provide primary reference laboratory and full esoteric testing. Also included in this group are hospitals requesting our specialty services, e.g., renal, muscle, nerve biopsies, flow cytometry, histocompatibility and molecular diagnostic testing. Currently, this group includes 79 hospitals throughout the state and the country.

The (HPG) hospital group reflects 180 clients primarily requesting surgical pathology, hematopathology and dermatopathology consultations (OC Cases) and associated IHC special stains and molecular diagnostic testing. This group is significantly larger reflecting the strength of our diagnostic pathologists and the personal manner in which they deliver their expert consultations. Most diagnoses are rendered within 24-48 hours of receipt and results are reported by facsimile or electronically via MiShare, a secure email delivery.

Reference Lab/Commercial Accounts
The University of Michigan Health System and MLabs combine clinical, education and research missions to deliver unique value to our clients and patients as a recognized leader in the field of molecular diagnostics and precision medicine. MLabs extensive test menu and personal approach to the unique needs of each client, has allowed us to be the provider of choice to many hospitals, commercial laboratories and academic medical centers throughout the country. MLabs Molecular Diagnostic Laboratory, with a triaged approach to test ordering, offers 45 qualitative and quantitative single mutation assays, to assist with the diagnosis of hematologic and solid tumor malignancies. Michigan Molecular Genetics Laboratory has an extensive menu of 50 + assays which test for rare genetic disorders and the Michigan Center for Translational Pathology's Mi-Prostate Score, (MiPS) an early detection test for prostate cancer is a recent example of how research translates to clinical application. The MiPS assay is available exclusively through MLabs. Through Paradigm, our joint venture partner, we also provide the most sophisticated and comprehensive next-generation sequencing cancer diagnostic test, PCDx.

Nursing Home/Acute Care Facilities
Laboratory testing and phlebotomy services are provided to regional nursing home and acute care facilities of strategic interest to UMHS. MLabs provides qualified phlebotomists specially trained in geriatric draws, accessing lines and port collections to successfully perform this service for our nursing home/acute care patients. Our nursing home clients are completely interfaced with MLabs for both orders and results via a secure, internet-based application*, MLabs Connect*. All laboratory results on patients from these accounts are also populated into UMHS' clinical data repository (MiChart) if that patient is known to UMHS. This allows both hospital and nursing home labs to be in the same computer system; improving quality and continuity of care should that patient receive additional care at UMHS.

FINANCIAL METRICS – TOTAL BUSINESS

FY15 Total Gross Charges increased 5 million dollars over FY14 allowing MLabs to make significant contribution to the margin that supports all of the missions of UMHS and the Department. This increase reflects organic growth from 701 current MLabs Clients as well as new client acquisition.

Figure : MLabs Total Gross Charges (Professional and Technical) Trend FY06 - FY15 with PB (professional) and HB (facility) detail.

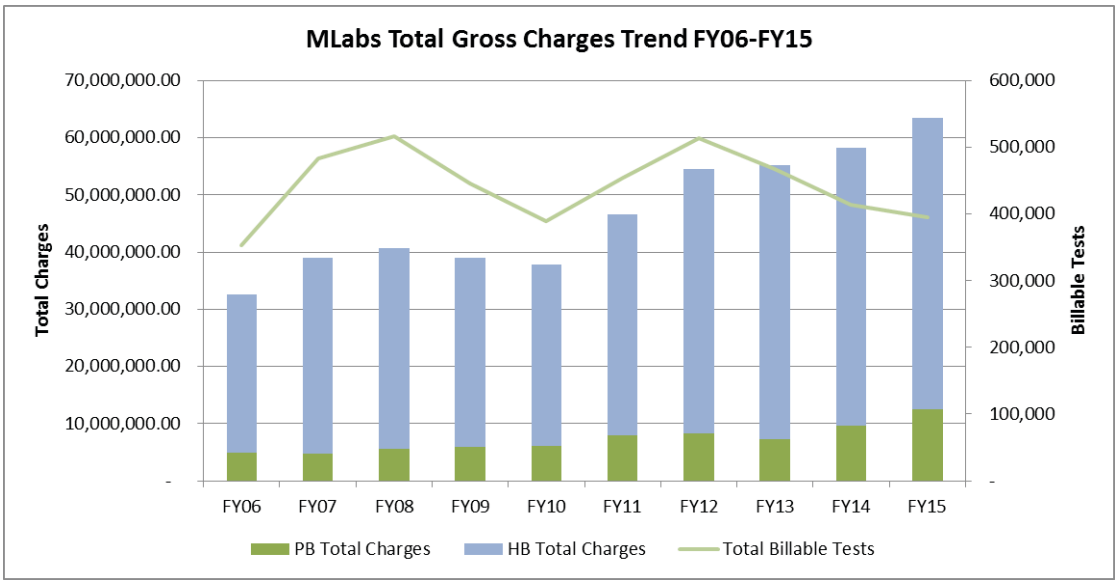


Figure : Percentage of Total Gross Charges by Individual Market/Service Line

Total # Clients: 701

Physician Offices: 339

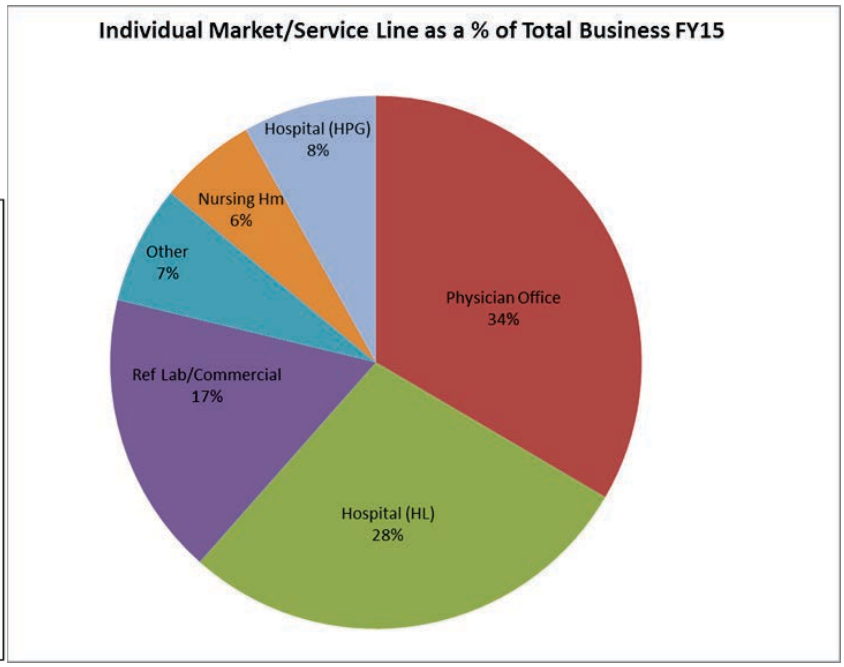
Hospital (HL): 79

Ref Lab/Commercial: 72

Other: 21

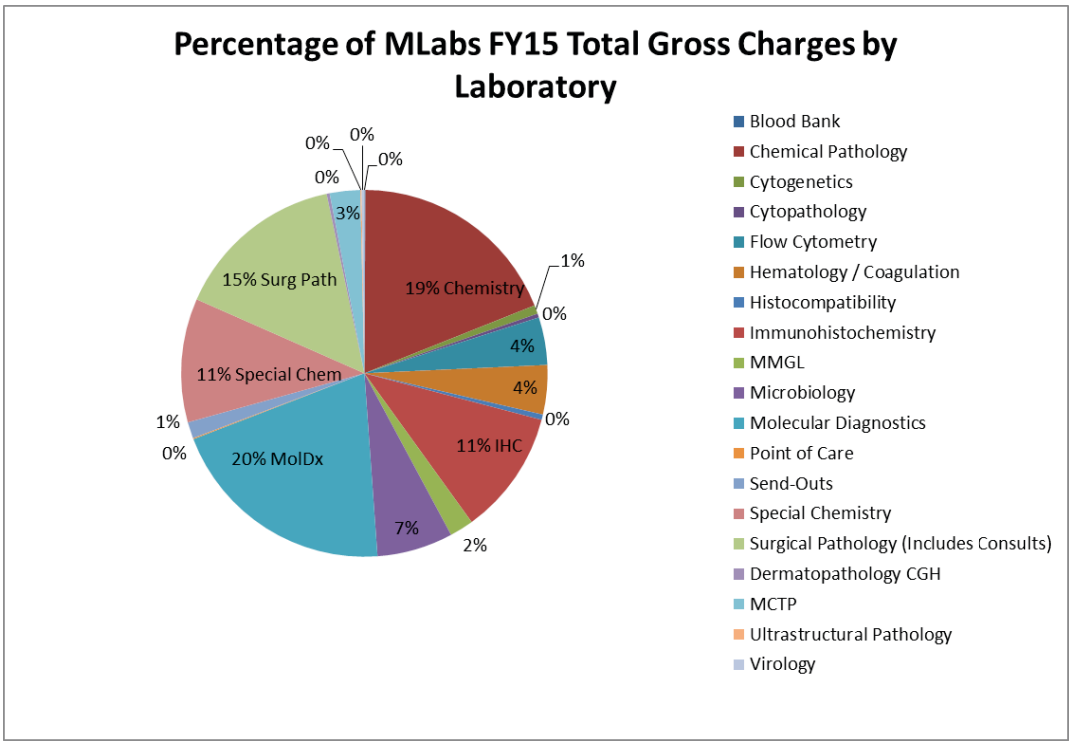
Nursing Home: 6

Hospital (HPG): 187



-

Figure : Percentage of Total Gross Charges by Laboratory



FY15 KEY ACCOMPLISHMENTS

- Continued Expansion of MolDx Test Menu

  CIC (19q13) Rearrangement by FISH
  1p/19q Deletion by FISH
  RET (10q11) Rearrangement by FISH
  NRAS Mutation
  CALR Mutation
  TFEB Rearrangements by FISH
  TFE3 Rearrangements by FISH
  Biliary Tract Malignancy by FISH
  MiPS (Mi-Prostate Score)

- Increased market share in Molecular Diagnostics, Surgical Pathology Consultations, Dermatopathology.
- Maintained market share in Hospital market.
- Awarded first exclusive provider contract; BCRA testing for Blue Care Network (BCN) members throughout State of Michigan.
- Successful recruitment of 2 client service representatives and IT support specialist.

SALES AND MARKETING

MLabs primary sales and marketing effort remains focused on making certain that pathologists, hospitals, and reference laboratories everywhere recognize The University of Michigan MLabs as the center of excellence for specialized laboratory testing, especially molecular diagnostics, subspecialty services and pathology consultative services. Exhibiting at regional and national meetings affords us an opportunity to be visible and

recognized as a national reference laboratory provider. During FY15, MLabs exhibited at four national meetings (USCAP, CAP, AMP, and ASCP) and five pathology meetings across the country. We have established a notable presence at these meetings. Our partnership with Paradigm has allowed for collaborate sales and marketing initiatives with prospective clients as well as planned joint exhibit at national meetings. While our focused sales and marketing effort has been the Molecular Diagnostic Laboratory, we continued our efforts to market the services of various sub-specialties within Pathology.

MLabs Statewide Laboratory Network Participation – JVHL and GLN

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. UMHS (MLabs) became an equity member of JVHL in 1997 and serves on its Executive, Quality Assurance and Operations Committees.
Great Lakes Laboratory Network (GLN) a network of hospital laboratories located primarily on the western side of the state. MLabs became a member of GLN in 1996 and plays an advisory role through representation on the Steering Committee.

MLabs helps facilitate Departmental issues pertaining to contractual obligations as a member of Joint Venture Hospital Laboratories and Great Lakes Laboratory Network. MLabs serves as a resource for UMHS Managed Care Operations Office with lab related issues.

ACKNOWLEDGEMENT
The MLabs Division continues to experience solid growth and remains successful in retaining existing clients in a very competitive market. Its success reflects the efforts of each and every individual within the Department of Pathology, their commitment to service and their ability to push forward with innovative solutions to meet the sophisticated needs of our Clients.

Michigan Center for Translational Pathology

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

OVERVIEW

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) to establish the University of Michigan as the international leader in discovery and characterization of disease biomarkers and therapeutic targets using an integrated multi-disciplinary, systems biology approach 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 UM Health System, MCTP also has four core components to the mission: research, education, patient care and service. Our specific goals are to:

- Discover new disease biomarkers and candidate therapeutic targets using genomic, proteomic, and bioinformatics approaches.
- Employ a systems biology perspective in characterizing the molecular alterations in human disease.
- Translate and commercialize molecular discoveries for clinical utility.
- Train 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.

The Center 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. The Center has established strong partnerships with industries such as Agilent Technologies, Ventana, and GenProbe to translate basic research discoveries into clinical applications.

Earlier we reported the development and release of a new 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, 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. A recent study evaluated pre-trained multivariate regression models combining urine T2:ERG and/or PCA3 scores with serum PSA in a large independent validation cohort to develop methods for individualized PCa risk estimates (Eur Urol. 2015 May 15. pii: S0302-2838(15)00397-8). T2:ERG and PCA3 scores were generated using clinical-grade transcription-mediated amplification assays. Pre-trained MiPS models were applied to a validation cohort of whole urine samples prospectively collected after digital rectal examination from 1244 men presenting for biopsy. Incorporating urine T2:ERG and PCA3 scores improved the performance of serum PSA (or PCPTrc) for predicting PCa and high-grade PCa on biopsy.

Our clinical sequencing study, Michigan Oncology Sequencing Center (MI-ONCOSEQ), continues to experience tremendous rate of growth since its inception in 2011; nearly 1000 adult and pediatric (under PEDS-ONCOSEQ study) patients have undergone clinical sequence analysis thus far, for many of whom actionable mutations were identified and suggested therapies that would otherwise not be considered. Overall, the average turnaround time from sample collection/receipt to return of results to physicians is 62 days. Clinically relevant results were identified in approximately 60% of patients and clinically significant germline aberrations were identified in 26 adults and 10 pediatric patients.

Recently, we developed a targeted panel called Onco1500 that utilizes in solution hybrid-capture methods focusing "sequencing bandwidth" on the protein coding exons in a 1500 target gene set. The Onco1500 gene set is designed to efficiently identify genetic aberrations in both highly recurrent cancer genes as well as a larger additional panel of candidate genes with suggestive links to cancer. This approach enables a faster turn-around time that is more feasible for routine clinical use.

In collaboration with investigators across all Prostate Cancer Foundation-Stand Up 2 Cancer (PCF-SU2C) Dream Team sites, we led a study to develop a precision medicine framework for metastatic, castration-resistant prostate cancer (mCRPC) by obtaining a comprehensive landscape of cancer-related mutations in order to potentially incorporate this information for therapeutic strategies and/or enrolling subjects into appropriate clinical trials (Cell. 2015 May 21;161(5):1215-28). The patient enrollment and biopsies took place across 8 clinical sites (including UMHS) and the clinical sequencing took place across two sites (Univ. of Michigan and Broad Institute). A total of 150 patient biospecimen that passed all requisite quality control measures were subject to clinical sequence analysis (whole-exome and transcriptome). Our results showed that 89% of affected individuals harbored a clinically actionable aberration, including 62.7% with aberrations in AR and 65% in other cancer-related genes. Non-AR related, clinically actionable alterations included aberrations in the PI3K pathway (49%), DNA repair pathway (19%), RAF kinases (3%), CDK inhibitors (7%), and the WNT pathway (5%). In addition to somatic alterations, clinically actionable pathogenic germline variants were seen in 8% of mCRPC affected individuals, potentially emphasizing the need for genetic counseling in affected individuals with prostate cancer. Overall, our efforts demonstrate the feasibility of comprehensive and integrative genomics on prospective biopsies from individual mCRPC affected individuals to enable precision cancer medicine activities in this large affected individual population.

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 AR-MLL complex interaction as a potential therapeutic target in advanced prostate cancer (Nat Med. 2015 Apr;21(4):344-52); 2) the global landscape of long non-coding RNAs (lncRNAs) in the human transcriptome (Nat Genet. 2015 Mar;47(3):199-208) and; 3) the prostate cancer-specific lncRNA, PCAT-1 promotes prostate cancer cell proliferation through the cMyc oncogene (Neoplasia. 2014 Nov 20;16(11):900-8). Overall, we published 37 papers in FY 2015, several in high-impact journals (Nature, Nature Medicine, Nature Genetics, Cell, Sci Transl Med).

MCTP researchers continue to engage in both national and international collaborations with other research groups and industry partners. The Center 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 (CRPC). Recently, the SU2C-PCF International Dream Team hosted a scientific review as it enters the final stages of the proposal. Plans are underway to leverage the current patient cohort and samples to molecularly track the various courses of disease progression by re-biopsy, and characterize novel aberrations we identified- AR splice variants, DNA repair genes and germline variants. We also have plans to study "exceptional responders" from the associated clinical studies. Further, the data generated here was deposited into a web-based portal (http://www.cbioportal.org) along with associated clinical data and made available to the research community to enable novel discoveries and associations in prostate cancer progression. 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 Chicago Tribune, Detroit Free Press, BBC News, among others.

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, Howard Hughes Medical Institute and an American Cancer Society Research Professor, was the recipient of the McNair Scholar Award from Baylor College of Medicine.

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

- Drs. Arul Chinnaiyan and Shaomeng Wang were named 2014 National Academy of Inventors (NAI) Fellows.
- Dr. Irfan Asangani received the highly competitive and prestigious NCI Pathway to Independence Award (K99/R00).
- Graduate student Brendan Veeneman received a Rackham Travel Award to attend the 23rd Annual International Conference on Intelligent Systems for Molecular Biology in Dublin, Ireland.
- Dr. Rohit Malik and graduate student Yashar Niknafs both received Keystone Symposia travel awards.

Students, postdoctoral and clinical fellows that trained at MCTP have successfully obtained positions as independent faculty or in industry. Former junior faculty member Dr. Nallasivam Palanisamy joined the Henry Ford Health System as an Associate Scientists and Dr. Sooryanaryana Varambally joined the faculty at the University of Alabama-Birmingham as an Associate Professor. Dr. Irfan Asangani, a former postdoctoral fellow, took a tenure-track Assistant Professor position in the Department of Cancer Biology at University of Pennsylvania. Ming Wu, a former post-doctoral fellow, was recruited by Illumina as a Field Application Scientist.

MCTP funding continues to be strong despite the challenging funding climate. This past fiscal year, the Center obtained $10,754,484 in committed awards. In addition, MCTP discoveries generated $3,621,007 of royalties to UM in FY 2015.

MCTP continues to be successful on all fronts and make progress towards our goal of translating basic laboratory discoveries into clinical applications. We strive to remain at the forefront of and 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.

Division of Molecular and Genomic Pathology

Thomas J. Giordano, M.D., Ph.D.
Henry Clay Bryant Professor, Endocrine Pathology
Director, Tissue and Molecular Pathology Core
Director, GI Spore Biosample Core
Director, Molecular Pathology
Compliance Officer

Starting in July 2015, the Department of Pathology created the Division of Molecular and Genomic Pathology (MGP). Thomas Giordano, M.D., Ph.D., serves as Division Director. The overarching mission of this new division is to coordinate the various molecular diagnostic laboratories within the Department of Pathology, including the Molecular Oncology / Genetics Diagnostics Laboratory (MOLDX), the Cytogenetics Laboratory, and the Molecular Testing Laboratory (MTL) of the Michigan Center for Translational Pathology (MCTP). Higher levels of coordination with a global institutional strategy will be necessary as the Department of Pathology anticipates the move to shared molecular diagnostic laboratories within the NCRC in the coming years and to fulfill our common goal of precision medicine and oncology.

The MGP Division will also work closely with the MCTP for further implementation of the *MiOncoSeq* genomic cancer assay for patients with advanced cancers to fully realize precision oncology at UMHS. In addition, the MGP will explore development of the Oncomine Comprehensive Panel (OCP) and other molecular profiling assays as needed for broad clinical testing of UMHS patients.

Finally, the MGP Division will also explore ways to further leverage the substantial genomic data generated by these and other molecular profiling assays for research opportunities.

Division of Quality and Health Improvement

Scott R. Owens, M.D.
Associate Professor, Gastrointestinal Pathology
Medical Director, Professional Practice Evaluation
Director, Division of Quality and Health Improvement

The Division of Quality and Health Improvement (DQHI) spent its first six months assembling an excellent and increasingly complementary team of like-minded individuals to tackle both quality improvement projects focused on daily processes and broad, value-creation projects that are envisioned to span the interests of the entire Health System and beyond.

WORKFORCE

- Manager: Brian Tolle
- Administrative Assistant: Lisa Brown
- QA Managers: Kellen Kangas (accreditation); Suzanne Butch (CP); John Perrin (AP)
- Project Managers: Amy Mapili (UMHS/FGP/MQS/OCS); Jeff Lott (Pathology)
- Business Systems Analyst Senior (Liaison from PI): Marianne Mara

ACCOMPLISHMENTS AND MILESTONES

- Hiring of DQHI Manager and assembly of team complete (PM positions started early September 2015)
- Team assembled with only two incremental hires (DQHI was approved for all positions to be incremental); other positions filled from within Pathology
- DQHI space (3244/3244A MSI) renovated and occupied, providing cohesive team operation and an “experimental” space piloting design and workflow principles for Pathology Relocation and Renovation (PRR) project
- Creation of a comprehensive Departmental Quality Plan
- Prioritization of initial projects (see below)
- Development of a Division-level “vision” document that unifies individual projects, the concept of a high-reliability organization and the attendant quality system endorsed by DQHI, and the over-arching role of Pathology at UMHS in transforming the patient experience
- Initial meetings with stakeholders both inside (lab Directors, Managers, Supervisors) and out-side Pathology to establish relationships and develop a list of potential projects and collaborative goals
- Development of a formal quality-centered educational program for Pathology residents to satisfy ACGME requirements and bolster quality activities in the Department (to begin early calendar 2016)
- Incorporation of many pilot projects from the Michigan Innovative Personalized Patient-centered Pathology (MiP3) project as DQHI priorities

Specific Projects
Tier 1 Priorities

	Project	Risk Level to PS/ Quality	DQHI Member(s)	DOP Member(s)	UMHS Member(s)
Quality	QI Monitoring & Report System (CP) (including metrics)	High	Suzanne Butch Marianne Mara Project Manager	Kristina Martin Lab managers	N/A
	Incorporate Lean in Daily Work framework in lab operations	Medium	Suzanne Butch Lisa Brown Project Manager	Kristina Martin Lab managers	MQS Lean coaches(?)
	QI Monitoring and Report System (AP) (including metrics)	High	John Perrin Marianne Mara Project Manager	Christine Rigney Lab managers	N/A
	Incorporate Lean in Daily Work framework in lab operations	Medium	John Perrin Lisa Brown Project Manager	Christine Rigney Lab managers	MQS Lean Coaches (?)
	Specimen Tracking System. Includes: • SOFT tracking • RMPro monitoring • SWAT team	High	John Perrin Suzanne Butch Lisa Brown Marianne Mara Project Manager	Path Informatics Kristina Martin Harry Neusius Bonnie Grayson Lab Managers	

	Project	Pathology Value Proposition	DQHI Member(s)	DOP Member(s)	UMHS Member(s)
Health Improvement (Value)	Inpatient Blood Draws Optimization Includes: • test ordering • phlebotomy efficiencies • hospital-acquired anemia reduction • expedited discharge	Positioning blood draws in a value-based model	Suzanne Butch Project Manager	Kristina Martin Harry Neusius	Robert Chang, MD Jeff Rohde, MD
	NICU Pathology Patient Care (autopsy report)	Direct interaction between pathologist and patient (family of deceased baby)	John Perrin Project Manager	Raja Rabah, MD	Bob Schumacher, MD

Tier 2 Priorities

	Project	Risk Level to PS/ Quality	DQHI Member(s)	DOP Member(s)	UMHS Member(s)
Quality	Updating CLIA lab certificate medical director information, including lab director training	Medium	Kellen Kangas	Lab managers	N/A
	AP Reading Room culture (diminishing status-based communication)	High	Project Manager Scott Owens, MD	Jeff Myers, MD (AP Director)	N/A
	Residency QI Education	Medium	Project Manager	Barbara McKenna, MD Lisa Wilson, MD Desire' Baessler	Cindy Priddy (QMS)
	Increase Employee Engagement Scores (Readiness measure) for low performing labs	Medium	Project Manager	Dave Keren, MD	Customer Performance Metrics & Improvement
	Operationalization of Quality System Essentials	Medium	Suzanne Butch	Lab managers	N/A

	Project	Pathology Value Proposition	DQHI Member(s)	DOP Member(s)	UMHS Member(s)
Health Improvement (Value)	Wayne County Medical Examiner Office (WCMEO) and School of Social Work	Partnering with UMHS resource to deliver greater customer value	Project Manager	Jeff Jentzen, MD Francisco Diaz, MD	TBD
	SICU Death Paperwork	Positioning Pathology as valued partner with provider stakeholders	Project Manager	Jeff Jentzen, MD Diana French Christine Rigney	SICU
	Breast Care Center & Patient Friendly Path Reports	Direct contact with patients re: diagnosis and clearer path results description	Project Manager John Perrin	Julie Jorns, MD Shirley Andrews	Breast Care Center
	Test Utilization (Troponin)	Positioning Chemistry Lab in a value-based model	Project Manager	Don Giacherio, PhD Lee Schroeder, MD	Cardiology ED Internal Medicine

SWOT Analysis:

Strengths

- Broad and established departmental and institutional support for quality improvement activities
- Michigan Quality System and Michigan Pathology Quality System established and commodities for utilization by DQHI
- Excellent, diverse, knowledgeable, respectful, and rapidly cohesive team members
- Team incorporates extensive experience with and knowledge of UMHS "culture" and practices, while also including members with fresh perspectives
- Collective team desire to avoid maintaining "status quo"
- DQHI Manager has extensive experience in organizational structure and change management
- Project Manager positions will provide a unique skillset and additional bandwidth in value-oriented work
- "Liaison" position from Pathology Informatics provides significant skill in data mining and management

Weaknesses

- Obtaining data from LIS remains challenging, both from the standpoint of competing interests given stability issues related to clinical operations and due to lack of existing data infrastructure
- New departmental organizational structure remains in evolution, leading to some uncertainty as to lines of accountability
- Vice-chair for Clinical Affairs and Quality has thus far had difficulty becoming as involved in DQHI as desired due to continuing responsibilities as Director, Anatomic Pathology
- Delay in obtaining unified senior leadership ("Clinical Executive Team") endorsement of priorities and Departmental vision for quality and value creation activities has resulted in some team anxiety about DQHI's future success
- Latent reliance on "customers" and end-users as primary identifiers of quality improvement opportunities rather than systematic and purposeful internal audits and validations

Opportunities

- Continued engagement of stakeholders from within Pathology and in broader Health System likely to yield abundance of potential projects ("no shortage of work")
- Collaboration with Department of Learning Health Sciences may provide opportunities for system-wide value creation and a path to external funding
- Initial meeting with personnel from Center for Healthcare Engineering and Patient Safety scheduled for 9/4/15 should provide additional collaborative opportunities and connections with potential "customers"
- Michigan Quality System resources largely untapped by DQHI as of yet

Threats

- Resistance to culture change/institutional comfort with status quo
- Perception among laboratory personnel that DQHI will request more work without attendant tangible benefits
- Broader institutional expectations for what constitutes "quality improvement work" (largely operations-focused) may be difficult to manage vis-à-vis DQHI's desire to have a significant component of value creation/health improvement
- Potential overutilization of single data/informatics-oriented team member may result in overwhelming workload and/or being pulled into other (non-DQHI-centered) informatics work

The Division of Quality and Health Improvement is poised to make what the DQHI team firmly believes will be meaningful and valuable contributions not only to the Department of Pathology and the University of Michigan Health System, but to the broader practice of medicine.

VA Ann Arbor Healthcare System

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

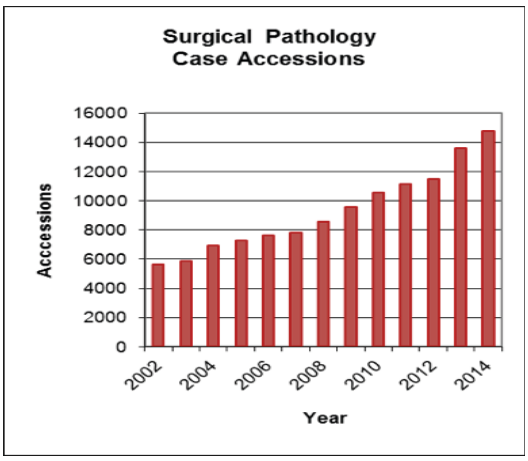
The VA Ann Arbor Healthcare System (VAAAHS) is a University of Michigan affiliated tertiary health care provider for veterans. It is one of three tertiary medical centers in the Veterans Integrated Service Network (VISN) #11 serving the veteran population of Michigan, and portions of Ohio, Indiana and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

In addition to the Toledo Outpatient clinic there are additional community based outpatient clinics (CBOCs) in Flint and Jackson, Michigan. The 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

Background: 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 and Grand Rapids. The Ann Arbor PALMS also performs all gynecologic cytopathology for Saginaw, Battle Creek, Detroit, Toledo, and affiliated CBOCs. Beginning FY14, the department began providing Telepathology services to the VA Northern Indiana Healthcare System. This program continues with significant success improving efficiency and diagnostic quality for smaller VA facilities.



Case Load

14,731 surgical cases were accessioned and reported during this reporting period, this represents a 5.0% increase over last year. This continues the trend of steadily increasing workload.

Quality Assurance

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

Surgical pathology diagnosis under 48 hr:	98.2%
Average surgical pathology report turn-around-time:	1.4 days
Case concordance (10% case second reviews):	97.6%
Average frozen section turn-around-time:	8.9 min
Frozen section to permanent section concordance:	98.8%

Informatics, Infrastructure, and Automation

As noted above, in FY14 the VAAAHS PALMS instituted a digital telepathology program using whole slide imaging. 230 telepathology consultations were completed in the current reporting period.

Autopsy Pathology

Background: The Department of Veterans Affairs maintains a policy to recognize the value of the autopsy and to encourage increased utilization. Currently, VHA policy does not establish a target autopsy rate but rather encourages performing a maximum number sufficient to examine a variety of diseases and clinical circumstances. The VHA requires all autopsy reports to be finalized in under 30d. Autopsies performed at the 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 to clinical findings. Each autopsy is also evaluated as to correlation of clinical and anatomic pathologic findings by review of the pathologist. Monthly reports are submitted to the VHA central office.

Autopsy completion turn-around-time average:	11 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.

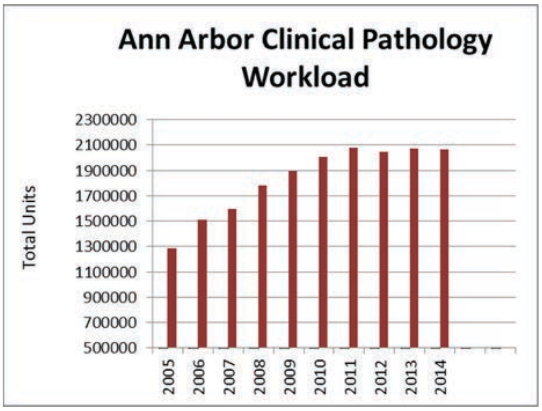
Case Load

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 hr:	96.2%
Average non-gyn and gyn turn-around-time:	4.7 days
Cytology PAP diagnostic concordance:	100%

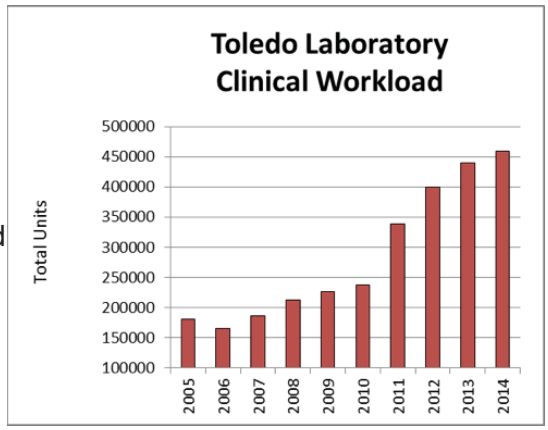
CLINICAL PATHOLOGY



During the period of this report 1,970,518 clinical pathology tests were performed in the Ann Arbor laboratory with the following breakdowns:

Chemistry	1,701,620
Hematology/Coagulation/Urinalysis	179,699
Microbiology	65,920
Blood Bank	23,279

A total of 126,261 phlebotomies were performed. Our affiliated community-based outpatient clinic laboratory in Toledo performed 458,802 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 available interesting and pertinent clinical laboratory information available to residents as desired. Clinical Pathology and medical historical data is available to pathology residents via CPRS for their information in surgical pathology, autopsy pathology, and elective rotations.

Quality Assurance

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

Informatics, Infrastructure, and Automation

The VAAAHS clinical laboratories have continued to incorporate as much automation as possible employing state-of-the-art analyzers.

EDUCATION AND TEACHING

In surgical pathology the staff pathologists provide one-to-one mentoring during the surgical case sign out. The resident assigned to surgical pathology, usually a first year resident in training, has the opportunity to examine all of the specimens grossly and microscopically under close one-to-one mentoring by the staff pathologists. The resident interacts with the clinical teams. Weekly Urology Case Review Conference is held by Dr. Murphy. The residents 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.

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 pathologist 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/UoM Affiliation Council as well as local and national VA oversight committees. Staff pathologists at the VA Ann Arbor Healthcare System serve in various capacities involving administrative tasks for the University of Michigan, such as the University Affiliation Council, Resident Selection Committee, the Medical Student Admissions Committee, Graduate student preliminary exam and thesis committees, teaching faculty for post graduate courses in the medical school. At the VAAAHS, the pathology staff members serve on all major committees involved with institutional policies and procedures.

SUMMARY

The VAAAHS Pathology and Laboratory Medicine Service is the major provider of Anatomic Pathology services for the northern tier of VISN 11 (to become VISN 10 by FY16). The primary goal of the department is to provide high quality diagnostic services and appropriate care to the veteran patients. This is evidenced by continuing accreditation by external review agencies such as the College of American Pathologists (CAP), the Joint Commission (JC) for hospital accreditation and the Food and Drug Administration (FDA). There is close supervision of resident activities as they are involved with patient care. All staff members are privileged and evaluated in accordance with their training, experience, continuing education and participation in quality improvement activities. Within the service there is an extensive quality improvement program that integrates with that of the hospital as a whole. The affiliation with the University of Michigan serves to strengthen and improve the quality of patient care to our veterans. The teaching effort involving both residents and medical students is of benefit to the two institutions. The VAAAHS PALMS is positioned to continue delivery of high quality service to Veteran patients as demand for medical care continues to mount in the next decades.

Division of Finance and Administration

Martin Lawlor
Director, Division of Finance and Administration

The Division of Finance and Administration, which is under the auspices of the Office of the Chair and directed by Mr. Martin A. Lawlor, Department Administrator, is responsible for the business, operational, and fiscal affairs of the Department of Pathology as mandated by the policies of the Chair, University of Michigan Health System (Medical School and Hospitals), and the University. In addition to directing this Division, Mr. Lawlor serves on various departmental, Health System and University committees including the Financial Advisory Committee, and the Cancer Center Ambulatory Care Coordinating Group. Mr. Lawlor serves as a Team Executive for the VMI IT and a member of the VMI Research Services Team. Mr. Lawlor serves as Chair of the Executive Committee for the Joint Venture Hospital Laboratories. He has also been elected Chair (two-year term) for the APC PDAS Committee starting July 2015.

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

- Renegotiating the Wayne County Medical Examiner's Office contract to add three years (2015 – 2018) and increase staff, and the Washtenaw County Medical Examiner's Office contract, which has allowed us to add 8 new faculty positions and 2 new fellowships and negotiating a new contract through 2017 that will integrate all Wayne County Medical Examiner activities with UMHS.
- Continue to support the nonprofit joint venture with Paradigm for personalized medicine and incorporating it into our workflow.
- Assisting Dr. Parkos in obtaining Regents' approval for the next phase of the PRR project.
- Planning space solutions for NCRC Buildings 30, 35, 36 and 60.
- Assisted the Department with the transition and integration of the new Chair.
- Created the new Warthin Endowed Chair of Experimental Pathology that allowed Pathology to recruit a new tenured Professor and Division Director for Experimental Pathology.
- Received institutional approval for a new Quality Division for Pathology, and obtaining approval for the incremental FTE's and finding space for the new Division.

We saw our professional revenues increase once again this year. Pathology began professional component billing for Clinical Pathology outpatient services in 4th quarter of 2010, and FY15 revenue for component billing was $974,879. UMHS Department of Pathology is the first group to institute professional component billing in the state of Michigan. We reorganized the next four years and should achieve $5,000,000 in savings.

ADMINISTRATIVE SUPPORT CENTER
Administrative Support Center/Pathology Laboratories

The Administrative Support Center for Pathology Laboratories is responsible for the preparation and monitoring of all Hospital laboratories' revenue, expense and capital budgets, and personnel and payroll systems. During this period, total laboratory expenditures were $113.1K. Pathology is responsible for 10.3% of total Hospital Gross Revenue and 4.3% of total expense. As detailed below, Mr. Thomas Morrow is responsible for administration of the Clinical Pathology Laboratories, Ms. Christine Rigney for the administration of the Anatomic Pathology Laboratories, and Ms. Suzanne Butch for maintaining licensure and accreditation for our laboratories.

Mr. Thomas Morrow oversaw the Clinical Pathology Laboratories. Clinical Pathology laboratory activity was above last fiscal year's levels, as was Clinical Pathology revenue Mr. Morrow was instrumental in putting together submissions and ROIs to get our capital needs met, as well as leading LEAN workflow improvements. Several long-term contracts with major vendors like Mayo Medical Laboratories, Ventana and Atlas Medical Systems were re-negotiated under Mr. Morrow's supervision this year.

Ms. Kristina Martin, Clinical Pathology Operations Manager, oversees our blood donations which have allowed us to improve our partnership with the American Red Cross and set better contract terms. Kristina has assisted with promoting LEAN concepts by teaching quarterly basic LEAN classes and focused sessions. She has also assisted in the planning for the Pathology Relocation and Renovation project. Kristina is responsible for the Clinical Pathology Operations meetings and coordination of subsequent projects resultant from these discussions. Kristina also serves as the department liaison with nursing.

Ms. Christine Rigney, Anatomic Pathology Operations Administrator, oversees the Anatomic Pathology Laboratories. These labs include Surgical Pathology, Cytology, Electron Microscopy, Immunoperoxidase, Autopsy and Forensic Services, Transcription Services, Central Accessioning, the Administrative Assistant Team supporting AP Faculty and AP Customer Service Desk. Services are provided in University Hospital, Cardiovascular Center, Children's and Women's Hospital and East Ann Arbor Ambulatory Surgery Center. Ms. Rigney is the department lead for many building and renovation projects which include future laboratory space planning. Included in these projects are the relocation of AP laboratories to NCRC scheduled for 2018 and the anticipated Brighton 23 hour stay surgical center building project. Ms. Rigney was also involved in the development of the new Laboratory Information System and serves as the AP liaison responsible for setting priorities for open tasks and enhancements. Additionally, she continues to participate and represent Anatomic Pathology in many LEAN projects or process improvement initiatives with the Cancer Center, Operating Rooms, procedure units, Office of Clinical Safety and Biomedical Engineering. All of which transform our patients' experience by promoting value to our customers.

Ms. Suzanne Butch, transitioned her role of Compliance Manager to Kellen Kangas who 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. This role was integrated into the Quality Division this year.

Office of Academic and Business Affairs–Medical School

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

Mr. Golden managed the UMHS and All Funds expenditures and forecast processes. Total Medical School All Funds expenditures for FY 2015 (Pathology and MCTP) were $64,745,284 and Hospital expenditures were $113.1K. He also developed the 2016 forecast for the Hospital, Pathology and the MCTP. Mr. Golden managed the pre- and post-award research enterprise for both Pathology and the MCTP. There were 179 research proposals submitted to external sponsors this year. 60 of these proposals were submitted to the NIH. Committed awards for FY 2015 were $32,379,503. An increase of 4% over FY 2014 committed awards. Actual sponsored research revenue was $32,071,997. A 1% increase over FY 2014 actual research revenue. Overall, the academic side of the Department saw a 4.1% increase ($2,314,653) in the following revenue components: net patient care, federal and non-federal research and other revenue (Washtenaw and Wayne County contracts, Royalties, rebill activities, operating transfers) from FY 2014 to FY 2015. Overall gross charges for Pathology's group practice were up 3.2% ($2.02M). Mr. Golden and his billing team played a pivotal role in the launch of the new LIS (Soft). They successfully transitioned all of professional and technical billing to the new LIS with minimal impacts to revenue capture. He continues to manage and mentor Cindy Benedict, Karen Giles, Mary

Green, John Harris, Laura Labut, Michael McVicker, Nancy Parker, Thad Schork and Christine Shaneyfelt in their analytic and managerial roles.

Ms. Nancy Parker is responsible for all front-end (charge capture) billing operations. Hospital technical gross revenue for FY2015 was $640.2M, compared to $601.7M in FY2014, an increase of 6.4%. Professional fee gross charges were $63,164,514. Ms. Parker is responsible for send-out billing, component billing, MLabs client statements, ensuring the accuracy of the daily billing files, correction of all errors with the appropriate Hospital department and responding to all questions regarding interdepartmental, MLabs or Hospital patient billings. Soft implementation this year had a profound effect on front-end billing with the addition of many new tasks and a complete overhaul of professional and technical billing charge capture functions. This implementation resulted in a new internal Oracle billing system as well as significant changes to workflow processes within the team.

Mr. John Harris is responsible for oversight of the accounting and financial staff supporting our research programs and the daily management of post award process. Extramural sponsored expenditures for FY2015 amounted to $32,071,997. Mr. Harris manages a staff of two accountants and two procurement specialists. This year, Mr. Harris and his team began managing all faculty and staff effort and funding changes. He also provides many *ad hoc* financial reports related to Medical School and clinical operations.

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

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

Human Resources, Faculty Affairs and Education

The non-instructional human resource function in the Department of Pathology is part of a larger Human Resource Team entitled Diagnostic Services, which includes Radiology and Pathology. The team lead for this area is Ms. Katie Adams with support from Ms. Karyn Procter-Wicks and Ms. Audrey Morton-Dziekan. Our Staff Human Resources Team provides support for Pathology's hospital laboratories (approximately 690 FTEs) and Medical School support staff, including our research programs (approximately 240 FTEs).

Faculty Affairs is the responsibility of Ms. Sarah Dudley-Short, who coordinates appointments, reappointments and promotions for our 151 faculty. Ms. Marie Goldner is responsible for the Education Office activities including the Residency and Fellowship Training Programs (28 residents and 23 fellows in 8 ACGME and 6 non-ACGME programs) and the Medical Student Education Teaching Programs for the M1 and M2 laboratories and the M4 Clerkship Program.

Ms. Laura Labut is responsible for administration of the Molecular and Cellular Pathology PhD program with 25 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. Ms. Labut is the administrator for the department's two NIH training grants (PIs Steven Kunkel, Ph.D. and Nicholas Lukacs, Ph.D.) which support 4 pre- and 8 post-doctoral trainees. Ms. Labut performs the human resource functions for the department's graduate students (35 including 10 non-MCP students with Pathology mentors) and training grant trainees (6).

Office of the Chair

Ms. Angela Suliman provides support to the Administrator, Mr. Martin Lawlor, including scheduling, travel arrangements, data collection, and event planning in addition to supervising and managing activities in the Chair's office. 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. She has been the facilitator for the Cancer Center Ambulatory Care Coordinating Group and has also served as the conference coordinator for the Advances in Forensic Medicine & Pathology Conference, which was held for its sixth year.

Ms. Vashni Santee is the Executive Assistant to Dr. Parkos, the Chair of Pathology. She is new to the Department, having been in her current position since February, 2015. She provides complex administrative support for the office, managing Dr. Parkos' calendar, scheduling meetings, gathering and creating meeting materials, making travel arrangements, and organizing special events for the Chair's Office. She brings over 25 years of administrative and executive-level support to the position. Vashni has been employed with the University of Michigan since 2001, having worked for the Director of the Life Sciences Institute and for the Associate Vice President and Associate Dean in UMHS' Office for Health Equity and Inclusion. Prior to joining the U-M, she worked for over 10 years at Parke-Davis Pharmaceutical Research and Pfizer.

Ms. Elizabeth 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. Ms. VanderElzen 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 Ms. Santee and Ms. Suliman.

Pathology Professional Fee Billing Office

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