

Annual Report

2020

Department of Pathology



MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN





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Message From the Chair

Fiscal Year 2020 (FY20) clearly demonstrated the outstanding work and commitment of our faculty, staff, and trainees in the face of challenges none of us have previously experienced. These challenges enabled us to identify opportunities to make changes that will result in lasting improvements to Pathology as a whole.

The first half of FY20 began strong. Clinical cases and billed revenues were on pace to grow at least 5% over FY19. Dr. Carol Farver joined us as our new Director of Pathology Education Programs to lead an excellent class of residents, clinical fellows, graduate students, and postdoctoral fellows. Several new faculty were recruited to our Department, along with a number of our graduating fellows. Experimental Pathology reported many new grants awarded and an impressive number of high-impact publications.

We began to examine ways in which Michigan Medicine Laboratories (MLabs), the Department's outreach laboratory service, could better serve patients nationally. The MSTAR project, including 40 faculty and staff from across the department, was launched to create a proposal for designing and implementing breakthrough improvements in MLabs' ability to deliver high quality reference laboratory/pathology services. The aim of this project was to not only serve Michigan Medicine patients and providers in support of our health system's goals and aspirations, but to also serve as a leader in value-based laboratory services that advance health in the region, the nation, and the world.

In addition, our Pathology Relocation and Renovation Team continued to move forward with the University Hospital multi-phase core laboratories renovation project, which you can learn more about in the PRR section of this report. These renovations will

be completed over the next 3 years as individual laboratories are sequentially relocated, renovated, and moved into the new space within UH.

In March, a pandemic caused by the novel SARS-CoV-2 virus arrived in Michigan. Within one week of the first known case being diagnosed, our microbiology laboratory had developed, tested, and received approval for our first PCR-based diagnostic test. Our microbiology and molecular diagnostic teams proceeded to validate additional test platforms, expanding our capacity and fully utilizing the equipment located in our laboratories. By the end of the fiscal year, our labs had performed over 40,000 COVID-19 diagnostic tests.

As COVID-19 cases spiked in the spring of 2020, our faculty and trainees volunteered to care for COVID patients if the need arose, and engaged in clinical and bench research to better understand the new virus and how to combat it. Staff volunteered to provide support for drive-through testing sites, cross-cover in the laboratories hardest hit by increased demands, and organize blood drives for much-needed blood products. Our research laboratories experienced major reductions in on site personnel due to mandated COVID restrictions as well as long delays in many important experiments. Despite these challenges, our teams worked diligently, responsibly and remained productive. Our Path Informatics team stepped up to the plate and ensured our faculty and staff had the necessary equipment and configurations to work remotely. Our DQHI division helped create new COVID dashboards to report demand for testing and our ability to meet those demands. It was an "all hands on deck" response across the board.

Closure of many primary and specialty care clinics to limit COVID spread resulted in a sharp decline in pathology case volumes with

the exception of COVID-related care. This decline was partially offset by a 22.7% increase in microbiology's revenues generated by COVID testing. Due to a strong first half of the year, FY20 ended with only a 3.31% decline.

The department experienced many changes this year that made us better for the future. We expanded our use of enhanced digital pathology tools, such as whole slide imaging for remote diagnostics, that are creating efficiencies and opportunities to care for patients anytime, anywhere. Lessons learned in rapid test development in response to the pandemic will enable us to meet changing demands. We have been stretched and will be forever changed by the pandemic. I am confident this will position us to lead the field in the future. As you read through this report, I trust that you will be just as proud as I am at all we accomplished this year.



Charles A. Parkos, MD, PhD

Carl V. Weller Professor and Chair



Development

The Department of Pathology at the University of Michigan is most grateful to our alumni, faculty and staff, and friends who have made a gift to the programs in education, research, and patient care. In FY20, the Department of Pathology received over \$2.4 million in donations from foundations, trusts, former faculty and trainees, and others. If you would like to be a part of our future and wish to talk more about making a gift or including the department in your estate planning, please contact:

Jason Keech

Assistant Director of Development

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734-763-0866

179
Faculty

39 / Instructional
82 / Clinical
35 / Research
23 / Supplemental
52 / Student Temps



PEOPLE

1,050
Staff

8 Direct Reports
CDA

18 Dotted Line Reports

COVID-19

First Three Months

9 Diagnostic Tests Developed & Validated → 41,824 Tests Performed

4 Serology Test Developed & Validated → 1,770 Tests Performed

OTHER

Partnerships

M-Labs – Primary Reference Lab, Mid-Michigan Metro Health and national presence in molecular/genetic testing, totaling 77.7 million in gross charges

MISSIONS / RESEARCH & CLINICAL

\$77.9M
MS Annual Expense Budget

\$145M
UMHS Annual Expense Budget

Ranked #9 In Funding Received by NIH in 2020

Received 56 Awards from NIH in 2020

\$32.5M
Sponsored Spending in 2020

5.7% ↑
Growth in Billable Tests

Research Space Occupies **61,293 SQFT**
\$322 DC/SF
\$131 IDC/SF

15 / PhDs
21 / Fellows
68 / Post Doc Fellows
26 / Residents



Clinical
Outpatient Phlebotomy in all Health Centers

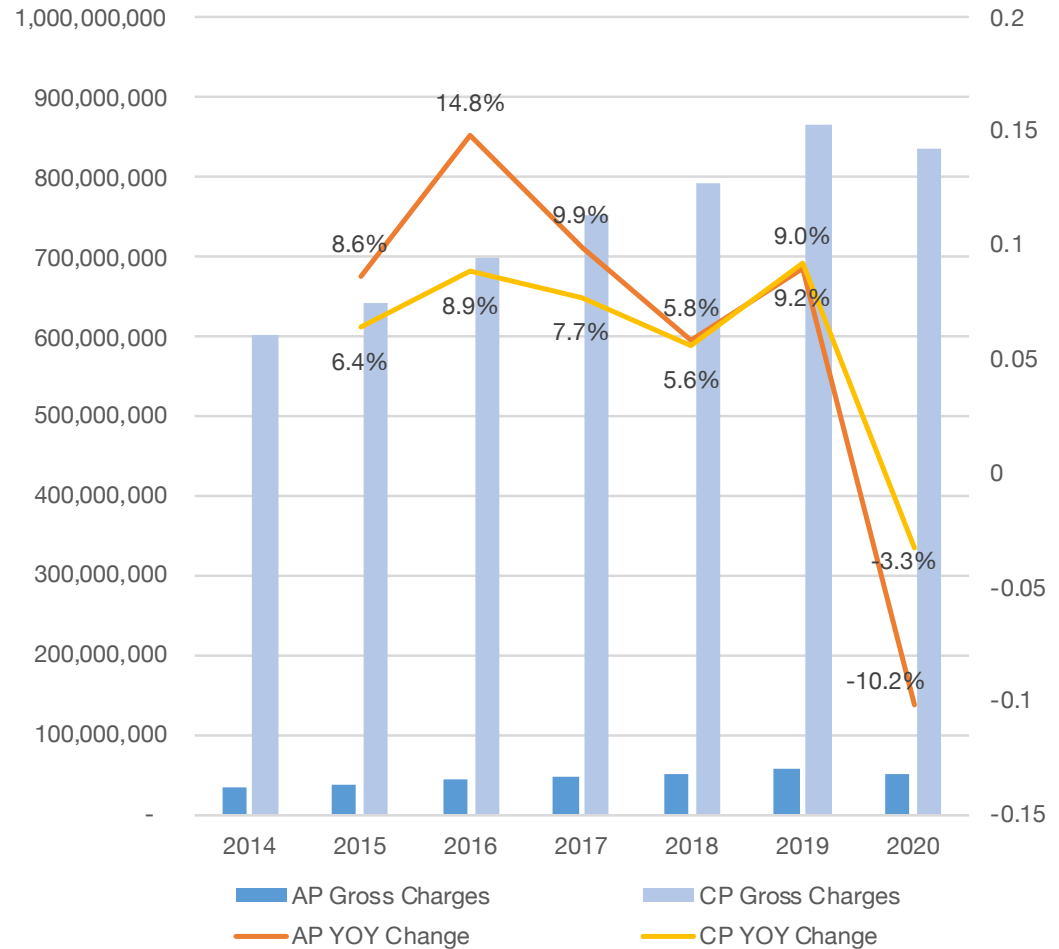
Clinical Mission

The mission of the Department of Pathology is, “to create the future of our discipline by educating and nurturing the leaders and health providers who will care for us, unifying our common commitment to excellence across traditional barriers to collaboration and creativity, building solutions that leverage the power of data to solve real problems and create unique value, and leading the way for application of the right diagnostic tools, for the right patient, at the right time.”

To accomplish this mission, our department has three primary foci: Clinical Care, Research, and Education. The clinical mission is committed to providing the best patient care, taking advantage of the strengths of our research and education expertise. To enhance our ability to provide optimal patient care, we built state-of-the-art clinical laboratories at the North Campus Research Complex and are currently renovating space at the University Hospital (UH) for modern core laboratories with automation lines and STAT services.

The clinical laboratory services are divided into four primary divisions: Anatomic Pathology, Clinical Pathology, Molecular Pathology, and Michigan Medicine Laboratories (MLabs). The following pages describe the activities of these four divisions.

Anatomic and Clinical Pathology Gross Revenues



Anatomic Pathology

Anatomic Pathology (AP) deals with testing of tissues, solid tumors, and cells as well as autopsies and forensics. AP experienced a slight decrease in volume (-13.7%) from a total of 119,598 from FY19 to 103,167 cases for FY20. The decrease in specimens was attributed to the general reduction in non-COVID related clinical services in response to the global pandemic. The AP clinical service is comprised of several sections including Surgical Pathology, Cytopathology, Dermatopathology, Ophthalmic Pathology, Renal Pathology, Neuropathology, Autopsy and Forensic Pathology, and Pediatric/Perinatal Pathology, each with its own Section Head. Surgical pathology includes multiple subspecialty services each with a designated Service Chief(s). Most of these services support weekly multidisciplinary tumor boards. Dr. Liron Pantanowitz was appointed as the new Director of Anatomic Pathology in July 2020.

Clinical Activities

RVU Trends in Anatomic Pathology

Total RVU's generated by AP in FY20 expressed as a 12-month rolling average were 20,123 RVU's/month. This represents a 9.4% decrease over FY19 and reflects the decreased workload in response to the COVID-19 crisis. RVU stands for relative value unit and is an incomplete payer-imposed measure of professional work that has become an industry standard for monitoring clinical productivity.

FTE Trends in Anatomic Pathology

Total clinical FTEs for AP faculty was 40.85 in FY20 compared to 41.31 in FY19, representing 1.2% year-over-year decrease. Over a five-year time period, AP staffing has similarly decreased by 1.2% from 42.19 FTEs to 40.85 FTEs, largely through reallocation of effort to other missions.

RVU and FTE Trends in Anatomic Pathology

Total work RVUs/FTE in FY20 showed a 23.61% decrease. On average, each clinical FTE in AP generated 709 RVUs/month in FY20 compared to 928 in FY19.

Surgical Pathology

The Surgical Pathology section encompasses a general sign-out service and multiple subspecialty services, each with its own service chief. The clinical service provided by surgical pathology faculty includes frozen section coverage at University Hospital (UH), adult surgeries at C.S. Mott Children's and Von Voigtlander Women's Hospital, Frankel Cardiovascular Center, East Ann Arbor Medical Center, and Brighton Center for Subspecialty Care. Telepathology was leveraged to support our frozen section service. General Surgical Pathology (also known as "Room 1") service handles biopsies and surgical resection specimens not covered by other subspecialty areas. In FY20, 12,581 general specimens were processed, which represents



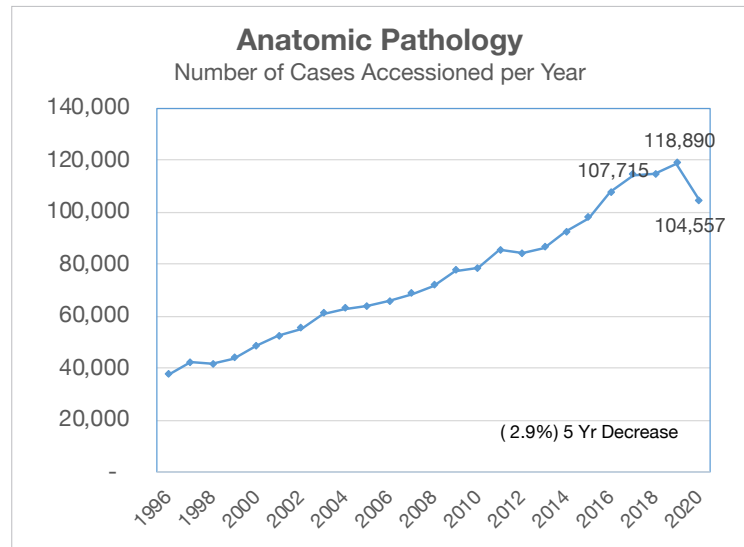
Liron Pantanowitz, MD, MHA
Director, Anatomic Pathology



Lakshmi Priya Kunju, MD
Director, Surgical Pathology
Director, Genitourinary Pathology
Director, General Surgical Pathology



David Lucas, MD
Director, Bone and Soft Tissue Pathology



a decrease of 11% over the prior year due to the impact of COVID-19. This service has experienced a 2% overall growth when compared to specimen volumes from five years ago.

Bone and Soft Tissue Pathology

Bone and Soft Tissue Pathology is focused on the diagnosis and study of diseases of the bone and surrounding soft tissues. Bone & Soft Tissue consult cases, which include very challenging, unique, and rare lesions, decreased by 9% with 1,481 cases received in FY20. This consult service has shown an overall 17% increase compared to specimen volumes from five years ago.

Breast Pathology

Breast Pathology is a subspecialty of surgical pathology with expertise in the interpretation of breast lesions from various specimen types including needle core biopsy, lumpectomy, and mastectomy specimens. Our Breast Pathology service includes a unique, dedicated frozen section laboratory for margin assessment and intraoperative consultation. The Breast Pathology division features a consultation service that assists with diagnostically challenging cases from the US and abroad. This division also conducts cutting-edge clinical and basic science research. In FY20, despite the COVID-19 pandemic, which led to 12% reduction in breast procedures, the Breast Pathology service processed 2,578 cases.

Cardiovascular Pathology

Cardiovascular Pathology examines the heart and major blood vessels to determine the diseases of these organs, whether congenital or acquired in life. Cases include surgical specimens from living patients or autopsy specimens from deceased patients. Case numbers are reflected in the aforementioned annual Surgical Pathology volumes and RVUs.

Endocrine Pathology

Endocrine Pathology is the study of diseases of the endocrine system including the thyroid, parathyroid, pituitary gland, endocrine pancreas, and adrenal glands. This service completed 551 challenging consult cases in FY20, which represents a 10% decrease from FY19 and 0.2% decrease compared to specimen volumes from five years ago.

Gastrointestinal/Hepatobiliary Pathology

Gastrointestinal Pathology (GI) is a subspecialty of surgical pathology that deals with the diagnosis and characterization of neoplastic and non-neoplastic diseases of the digestive tract and accessory organs such as the pancreas, gallbladder, and liver. Despite the COVID-19 pandemic, the Gastrointestinal/Hepatobiliary Service completed 19,639 cases, which is a 17% decrease compared to FY19 and 14% decrease compared to five years ago. Our GI Pathology group helped many referring pathologists resolve challenging consult cases.

Genitourinary Pathology

Genitourinary Pathology (GU) is a subspecialty of surgical pathology that deals with the diagnosis and characterization of neoplastic and non-neoplastic diseases of the urinary tract, excluding medical disorders of the kidneys, which fall under renal pathology. This includes diseases of the male genital tract and testes. The GU service provided continuity of care during the COVID-19 lockdown and processed 3,545 cases in FY20, which was down 11% from the prior year. Overall, GU specimen volumes are up 22% compared to specimen volumes from five years ago.

Gynecologic Pathology

Gynecologic Pathology (GYN) is the subspecialty that deals with the study and diagnosis of disease involving the female genital tract. The GYN service processed 6,611 cases in FY20, which is a 15% decrease over the prior year. This represents a 2% decrease compared to specimen volumes from five years ago.

Head and Neck Pathology/Oral-Maxillofacial Pathology

Head and Neck Pathology covers neoplastic diseases of the thyroid gland, salivary glands, and head and neck. Oral-Maxillofacial Pathology is concerned with the diagnosis and study of diseases affecting the oral and maxillofacial region and is sometimes considered to be a specialty of dentistry and pathology. Internally generated head and neck cases were included in the general Surgical Pathology service described above. Consult cases are handled by our head and neck service and amounted to 1,255 cases in FY20, which was an 8% decrease over FY19 but represents a 5% increase compared to specimen volumes from five years ago.



Celina Kleer, MD
Co-Director, Breast Pathology



Andrew Sciallis, MD
Co-Director, Breast Pathology



David Gordon, MD
Director, Cardiac Pathology



Douglas Fullen, MD
Director, Dermatopathology



Thomas Giordano, MD, PhD
Director, Endocrine Pathology



Laura Lamps, MD
Director, Gastrointestinal Pathology

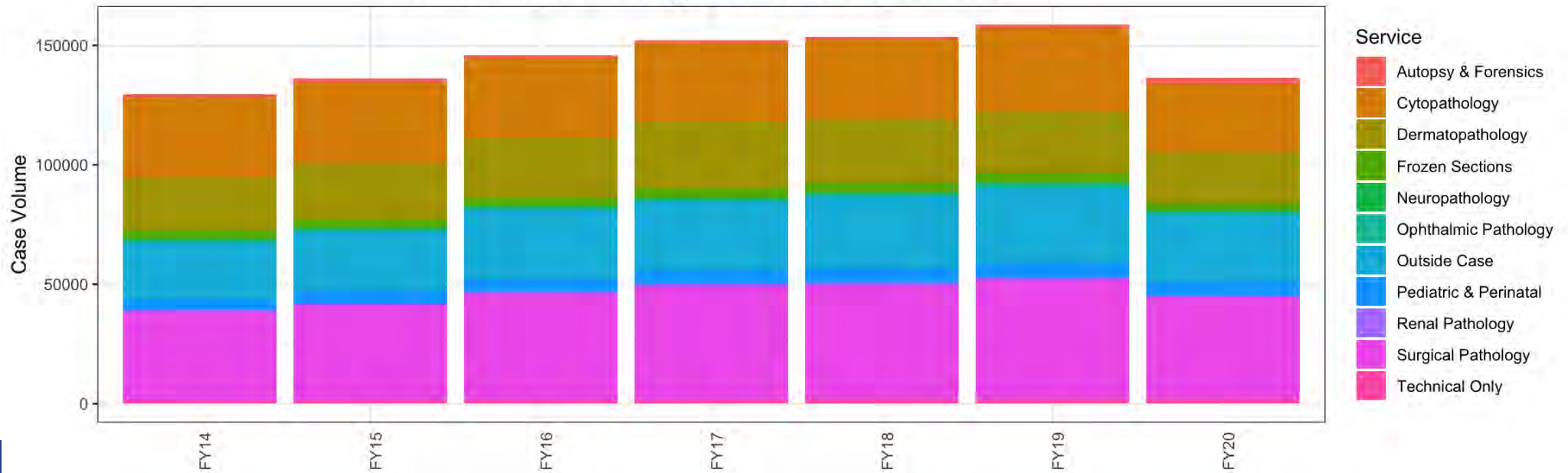


Kathleen Cho, MD
Director, Gynecologic Pathology



Jonathan McHugh, MD
Director, Head and Neck / Oral-Maxillofacial Pathology

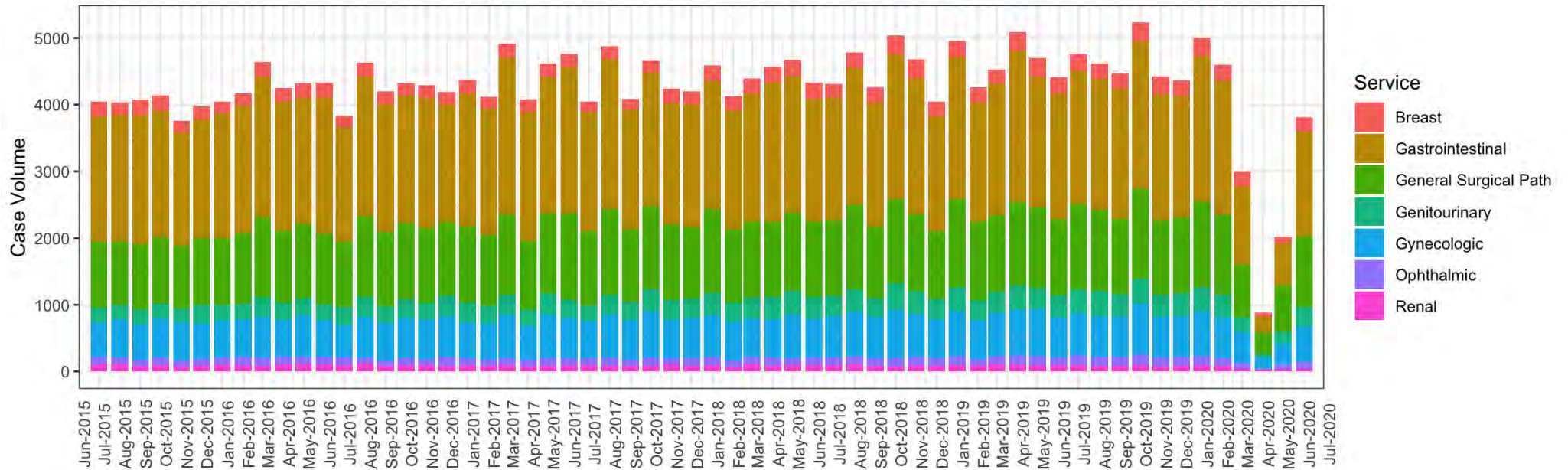
Anatomic Pathology Annual Case Volume



10

| AP Service | FY14 | FY15 | FY16 | FY17 | FY18 | FY19 | FY20 | 1-YR | 5-YR |
|-----------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|---------------|
| Autopsy & Forensics | 1,452 | 1,913 | 1,031 | 1,024 | 1,202 | 1,722 | 2,472 | 43.55% | 139.77% |
| Cytopathology | 33,351 | 33,553 | 33,650 | 32,954 | 33,347 | 34,835 | 28,737 | -17.51% | -14.60% |
| Dermatopathology | 22,086 | 23,403 | 24,601 | 28,001 | 26,715 | 25,720 | 21,017 | -18.29% | -14.57% |
| Frozen Sections | 3,442 | 3,431 | 3,596 | 3,567 | 3,719 | 3,620 | 3,162 | -12.65% | -12.07% |
| Neuropathology | 817 | 803 | 759 | 825 | 782 | 789 | 682 | -13.56% | -10.14% |
| Ophthalmic Pathology | 1,090 | 1,255 | 1,252 | 1,220 | 1,289 | 1,424 | 1,353 | -4.99% | 8.07% |
| Outside Case | 23,590 | 24,535 | 28,695 | 29,022 | 30,298 | 31,472 | 28,341 | -9.95% | -1.23% |
| Pediatric & Perinatal | 4,509 | 5,193 | 5,141 | 5,407 | 5,723 | 5,973 | 5,297 | -11.32% | 3.03% |
| Renal Pathology | 1,204 | 1,130 | 1,180 | 1,099 | 1,294 | 1,413 | 943 | -33.26% | -20.08% |
| Surgical Pathology | 36,697 | 39,502 | 44,314 | 46,989 | 47,191 | 49,460 | 42,297 | -14.48% | -4.55% |
| Technical Only | 1,288 | 1,500 | 1,616 | 1,933 | 2,072 | 2,167 | 2,133 | -1.57% | 31.99% |
| Total | 129,526 | 136,218 | 145,835 | 152,041 | 153,632 | 158,595 | 136,434 | -13.97% | -6.45% |

Surgical Pathology In-House Volume



| AP Service | FY16 | FY17 | FY18 | FY19 | FY20 | 1-YR | 5-YR |
|-----------------------|---------------|---------------|---------------|---------------|---------------|----------------|---------------|
| Breast | 2,484 | 2,319 | 2,479 | 2,927 | 2,578 | -11.92% | 3.78% |
| Gastrointestinal | 22,808 | 23,787 | 23,114 | 23,709 | 19,639 | -17.17% | -13.89% |
| General Surgical Path | 12,371 | 13,560 | 13,842 | 14,134 | 12,581 | -10.99% | 1.70% |
| Genitourinary | 2,910 | 3,365 | 3,734 | 3,974 | 3,545 | -10.80% | 21.82% |
| Gynecologic | 6,760 | 6,966 | 7,212 | 7,739 | 6,611 | -14.58% | -2.20% |
| Ophthalmic | 1,276 | 1,248 | 1,311 | 1,455 | 1,367 | -6.05% | 7.13% |
| Renal | 1,172 | 1,090 | 1,084 | 1,123 | 846 | -24.67% | -27.82% |
| Total | 49,781 | 52,335 | 52,776 | 55,061 | 47,167 | -14.34% | -5.25% |



Jeffrey Myers, MD
Director, Pulmonary/Thoracic Pathology

Pulmonary/Thoracic Pathology

Pulmonary Pathology is a subspecialty of surgical pathology that deals with the diagnosis and characterization of neoplastic and non-neoplastic diseases of the lungs, pleura, and mediastinum. In-house cases are not tracked separately from other Surgical Pathology cases. However, Pulmonary Pathology evaluated 2,712 complex consultation cases, which represents a 15% decrease from FY19 and a 1% increase compared to specimen volumes from five years ago.

Case Volume

Case volume for all Surgical Pathology services in FY20 includes all in-house specimens and extramural consultations (transfer and private consults). This case volume for Surgical Pathology was 146,527, which represents a varied year-over-year decrease for different subspecialties. The decrease in volume from the previous fiscal year was largely due to the impact of the COVID-19 pandemic. (See chart on pg. 11)

Frozen Sections

Despite COVID-19 related constraints on performing surgery, the frozen section case volume for FY20 was 3,162, representing a decrease of 13% compared to FY19.

Turnaround Time

Turnaround time, defined from when a specimen is received in pathology until the case is signed out, overall decreased an average of 32% compared to 1 year ago.

Pediatric and Perinatal Pathology

This medical subspecialty is focused on childhood diseases as well as perinatal conditions affecting the placenta and fetus. The work includes pediatric surgical pathology cases as well as autopsies and placental examinations.

Case Volume

Pediatric surgical pathology case volume of 3,307 reflects a 12% decrease compared to FY19 and a 1% increase compared to specimen volumes from five years ago. Placental exams decreased by 12% to 1,894 cases in FY20, but experienced a five-year increase of 3%. Pediatric fetal exams were down 7% and pediatric autopsies decreased by 11%. Overall, Pediatric and Perinatal Pathology has

experienced an increase of 4% compared to specimen volumes from five years ago. (See Appendix pg. 66)

Turnaround Time

Average turnaround time for pediatric surgical pathology cases averaged 2.2 days in FY20, which decreased by 11% in the last year. These turnaround times demonstrate that cases were signed out 8% quicker compared to five years ago.

Dermatopathology

Dermatopathology focuses on the study of cutaneous diseases at a microscopic and molecular level. Dr. Rajiv Patel was appointed as the new leader of this section in 2020.

Case Volume

The Dermatopathology service experienced an overall 17% decrease in FY20 with the arrival of COVID-19 and handled a total of 27,536 cases. This included a 16% drop in specimens from Michigan Medicine patients (“in house” cases) which accounted for 49% of the cases seen. Cases from patients outside of Michigan Medicine (“MLabs cases”) were also down 23% in FY20. (See Appendix pg. 66)

Turnaround Time

Overall turnaround time for Dermatopathology cases averaged 3.46 days, showing improvements over FY20 with a 14% decrease on average and a 24% decrease in time for In-house cases.

Neuropathology

Neuropathology is that branch of pathology that focuses on the diagnosis of diseases of the central and peripheral nervous systems and incorporates non-neoplastic conditions targeting skeletal muscle.

Case Volume

For FY20 there were a total of 1,634 cases signed out compared to 1,710 cases in FY19, representing a slight 4% decrease. Over a five-year period this service has witnessed a 9% increase in neuropathology cases. Outside cases (transfers and consults) increased by 14% in FY20 and demonstrated a 57% increase over 5 years. (See Appendix pg. 66)



Raja Rabah, MD
Director, Pediatric Pathology



Raiv Patel, MD
Director, Dermatopathology



Andrew Lieberman, MD, PhD
Director, Neuropathology

Turnaround Time

Turnaround time for neuropathology cases increased on average by 5.66 days, showing a 9% increase from FY20 and a 9% increase compared to 5 years ago. This change is attributed to the increasing dependency of incorporating molecular findings of brain tumors at the time cases are signed out.

Ophthalmic Pathology

Ophthalmic Pathology focuses on diseases of the eye and unique periorbital structures. These cases are predominantly signed out at the W.K. Kellogg Eye Center in Ann Arbor.

Case Volume

This service accounted for 1,440 cases in FY20, representing a 4% decrease from the prior year but an 8% increase from the past five years. (See Appendix pg. 66)

Turnaround Time

Ophthalmic Pathology turnaround time averaged 4.85 days showing a decrease of 50% in FY20 and a 22% decrease over 5 years.

Renal Pathology

The Renal Pathology service focuses on the diagnosis and characterization of medical diseases (non-tumor) of the kidneys. Dr. Evan Farkash was appointed as the new leader of this section, taking over from Dr. Paul Killen who successfully directed the Renal Pathology section for three decades.

Case Volume

The medical renal biopsy case volume decreased to 979 in FY20, representing 32% and 20% change in 1- and 5- year-over-year decline, respectively. (See Appendix pg. 67)

Turnaround Time

For medical renal biopsies the overall turnaround time was 15 days in FY20, representing a 43% and 5% decrease in 1- and 5- year-over-year times, respectively.

Cytopathology

Cytopathology is a branch of pathology that performs diagnostic

testing on samples consisting of mostly individual cells, such as Pap tests, body fluids, brushings, and fine needle aspirations (FNA). Our cytopathologists perform rapid on-site evaluations (ROSE) at multiple clinics and procedure rooms throughout Michigan Medicine. Telecytology is sometimes employed to support this service. ROSE enables rapid specimen triage and diagnostics for patients while they are still at the medical center, eliminating the need for some follow-up visits due to inadequate sampling. Our cytopathologist team are also skilled at performing palpation-guided and ultrasound-guided FNA themselves.

Case Volume

Our cytopathology service processed 28,737 cases in FY20, which was down 18% in FY20 and down 15% compared to FY16. Gynecologic Pap tests represent the bulk of these cytopathology cases. There were 10,058 non-gynecologic cytopathology cases in FY20 including 3,057 FNAs which included percutaneous and endoscopic aspirations. (See Appendix pg. 66)

Turnaround Time

Turnaround times have improved markedly over the past five years, secondary to the adoption of effective lean management practices in Cytology.

Autopsy and Forensic Pathology

Hospital and forensic autopsies and examinations represent major activities within Anatomic Pathology. Our fellowship-trained forensic pathologists handle forensic cases from Wayne, Monroe, Washtenaw, and Livingston Counties. All Michigan Medicine adult and pediatric autopsies as well as all forensic cases from Washtenaw and Livingston Counties are performed in the University Hospital (UH) morgue. Wayne and Monroe County forensic cases are performed at the Wayne County Medical Examiner's Office (WCMEO) in Detroit. Dr. Allecia Wilson was appointed as the new Section Head of this service in 2020. In response to the COVID-19 pandemic, our autopsy service boldly stepped up to perform autopsies on SARS-CoV-2 infected cases to learn more about this novel disease and tracked infected cases to help support public health surveillance in our region.



Victor Elner, MD, PhD
Professor, Ophthalmology



Evan Farkash, MD, PhD
Director, Renal Pathology Service



Judy Pang, MD
Director, Cytopathology



Allecia Wilson, MD
Director, Autopsy & Forensic Pathology

| Case Volume / UH, Washtenaw, and Livingston Counties | | | | | | | |
|------------------------------------------------------|------------|------------|------------|------------|------------|--------------|---------------|
| | FY16 | FY17 | FY18 | FY19 | FY20 | 1-Yr | 5-Yr |
| Brain Cases | 66 | 76 | 52 | 70 | 52 | -25.71% | -21.21% |
| Livingston Autopsies | | | 80 | 99 | 123 | 24.24% | |
| Livingston Exams | | | 3 | 9 | 26 | 188.89% | |
| UH (Adult) Autopsies | 159 | 148 | 152 | 167 | 164 | -1.80% | 3.14% |
| UH (Peds) Autopsies | 30 | 33 | 37 | 27 | 24 | -11.11% | -20.00% |
| Washtenaw Autopsies | 364 | 408 | 330 | 351 | 344 | -1.99% | -5.49% |
| Washtenaw Exams | 28 | 51 | 70 | 62 | 67 | 8.06% | 139.29% |
| Total | 647 | 716 | 724 | 785 | 800 | 1.91% | 23.65% |

Table: Autopsy and Forensics Total Examinations at UH, Washtenaw and Livingston Counties.

| Wayne County ME Office Case Volume | | | | | | | |
|------------------------------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|
| | FY16 | FY17 | FY18 | FY19 | FY20 | 1-Yr | 5-Yr |
| Full Autopsies | 2,053 | 2,359 | 2,417 | 2,318 | 2,116 | -8.71% | 3.07% |
| Externals | 769 | 867 | 855 | 865 | 891 | 3.01% | 15.86% |
| Total | 2,822 | 3,226 | 3,272 | 3,183 | 3,007 | -5.53% | 6.56% |

Table: Wayne County ME Office Case Volumes.

Case Volume

Case volumes of autopsies performed in the UH morgue was the same as last year but showed a 20% decrease over the past 5 years. Case volumes of autopsies performed at the Wayne County Medical Examiner's Office was relatively the same as last year but showed a 7% increase over the past 5 years.

Turnaround Time

Autopsy and Forensic turnaround times showed continuous improvement with adult and pediatric hospital autopsies.

Consultation Service

Our extramural consultation practice is an important component of our practice. The rare and difficult cases encountered with this service challenge our faculty to continue to deepen their expertise and expose our trainees to cases otherwise rarely seen. This practice strengthens our brand at regional and national levels, leads to research opportunities in rare diseases, is fundamental to the success of subspecialty fellowships, drives revenue, and enhances patient recruitment to Michigan Medicine.

Case Volume

In FY20 the extramural AP consultation practice total case volume was 27,695, which represents a slight 10% decrease from FY19. The decrease is due solely to lower surgical pathology volumes at referring institutions during the early months of the COVID-19 pandemic. (See Appendix pg. 66)

Turnaround Time

Our consultation service has showed continuous improvement with turnaround time, remaining excellent at 3.07 days.

Technical-Only Histological Service

Our histology laboratory offers outside laboratories access to our test menu including immunohistochemical stains and processing handled by our highly skilled technologists. For a limited menu, we perform both the technical stain and pathologist interpretation.

Case Volume

Technical-only cases were up by 4% compared to 5 years ago and

External Case Volumes

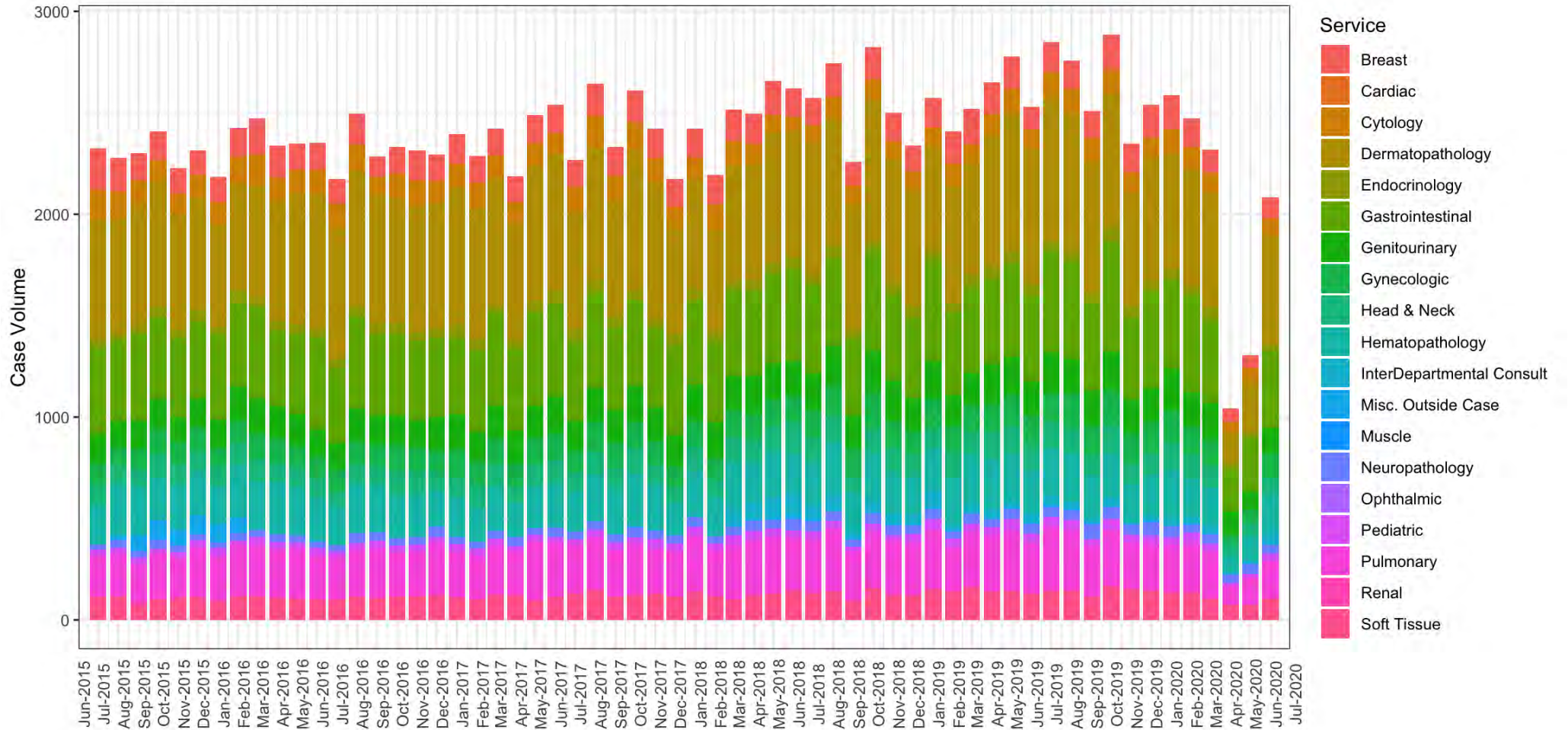


Chart: External Case Volumes. For figures table, see Appendix pg. 66.



those technical cases with interpretation for FY20 increased by 188% from the prior year. (See Appendix pg. 67)

Turnaround Time

The turnaround time for technical-only cases improved markedly, showing a 44% improvement from last year and a tremendous 91% improvement compared to 5 years ago.

Personnel

In Anatomic Pathology there are 47 faculty members, including many world-renowned pathologists. The service also involves 8 fellows. Newly recruited faculty include Steven Hrycaj, PhD, as the Technical Director of the Immunohistochemistry (IHC) Laboratory.

Academic Activities

AP faculty excelled at fulfilling our research mission. AP pathologists collectively published 346 peer-reviewed articles in prestigious journals and participated in 96 extra-mural grant-funded research projects. Our faculty collectively delivered close to 110 talks at regional, national and international meetings and other institutions. In response to the COVID-19 pandemic our faculty stepped up and contributed to offering many virtual online courses for national annual scientific meetings and delivered webinars to a global audience.

Education

Medical School Teaching Graduate School Teaching

Under the organizational leadership of Dr. Lew, over 20 AP faculty participated in medical school teaching (M1-M4 students) including lectures, labs, and experiential learning, and several faculty members also participated in organizational roles. Several AP faculty members also participated in teaching of our graduate students.

Residency Program/Fellowship Program

AP faculty across disciplines dedicated many hours to teaching our residents and fellows. Residents in AP were exposed to excellent learning opportunities in surgical pathology, cytopathology, and autopsy/forensic pathology. AP fellows were exposed to challenging cases from our extensive consultation practice and participated in many multidisciplinary conferences and tumor boards, including award-winning research projects.

Clinical Pathology

The Clinical Pathology Division encompasses a large number of the clinical laboratories within the Department of Pathology. These CLIA-certified and CAP-accredited laboratories support the diagnosis and management of human disease through automated and/or manual testing of blood, urine, body fluids, bone marrow, and even fresh or fixed tissue specimens.

The lab disciplines and support services comprising the CP Division include: Clinical Chemistry, Toxicology, Drug Analysis, Hematology, Coagulation (Clinical Core Laboratory Service); Blood Bank, Apheresis, Cell Therapy (Transfusion Medicine Service); Special Chemistry, Clinical Immunology; Clinical Microbiology; Bone Marrow, and Flow Cytometry (Hematopathology Service); Clinical Cytogenetics; Molecular Diagnostics; Histocompatibility; Point-of-Care Testing; Phlebotomy; Specimen Processing. The Michigan Medicine Genetics Laboratories and Dermatopathology Molecular Diagnostic Laboratory share resources with CP.

In FY20, Clinical Pathology (CP) achieved 6,109,122 billed tests and \$766,452,170 gross revenue, representing 5.0% and 2.9% year-over-year decrease, respectively. As compared to FY15, the CP Division

experienced a 18.2% growth in billed tests and a 30.2% growth in gross revenue. Our clinical pathologists average 305 RVUs per month, with staffing levels essentially unchanged from FY19 to FY20 (12.64 FTE). (See Chart in Appendix on pg. 68)

A list of the COVID-19 serologic tests validated by Clinical Chemistry in conjunction with the Clinical Immunology and Special Chemistry Laboratories is shown below:

- Krammer Protocol SARS-CoV-2 ELISA Assay
- Euroimmun IgG SARS-CoV-2 Immunoassay
- Diasorin Liaison XL IgG SARS-CoV-2 Immunoassay
- Siemens Total Ig SARS-CoV-2 Immunoassay
- Roche Anti-SARS-CoV-2 Immunoassay
- Multiple SARS-CoV-2 Serology Lateral Flow Assay

The team's work on these clinical assays yielded several funded research collaborations with the Michigan Medicine Division of Infection Prevention and Epidemiology, Division of Allergy, and the University of Michigan School of Public Health.

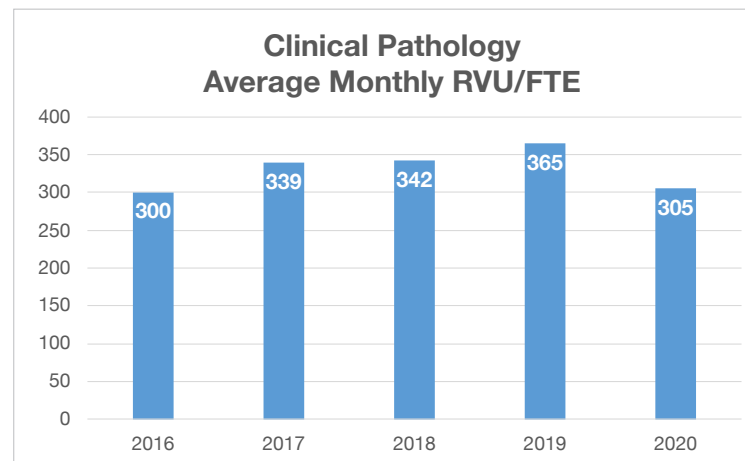
Clinical Core Laboratory Hematology and Coagulation

The Hematology and Coagulation laboratories perform testing on blood and urine specimens to measure the various blood components (e.g. red blood cells, white blood cells, and platelets), assess clotting factor levels, determine the impact of medications on blood clotting processes, and help diagnose diseases of kidneys and urinary tract. The hematology lab also remains involved in the bone marrow biopsy process, still providing lab techs to attend and assist these bedside clinical procedures. These lab areas have experienced steady growth over the past five years, with a 7.1% five-year increase in spite of a

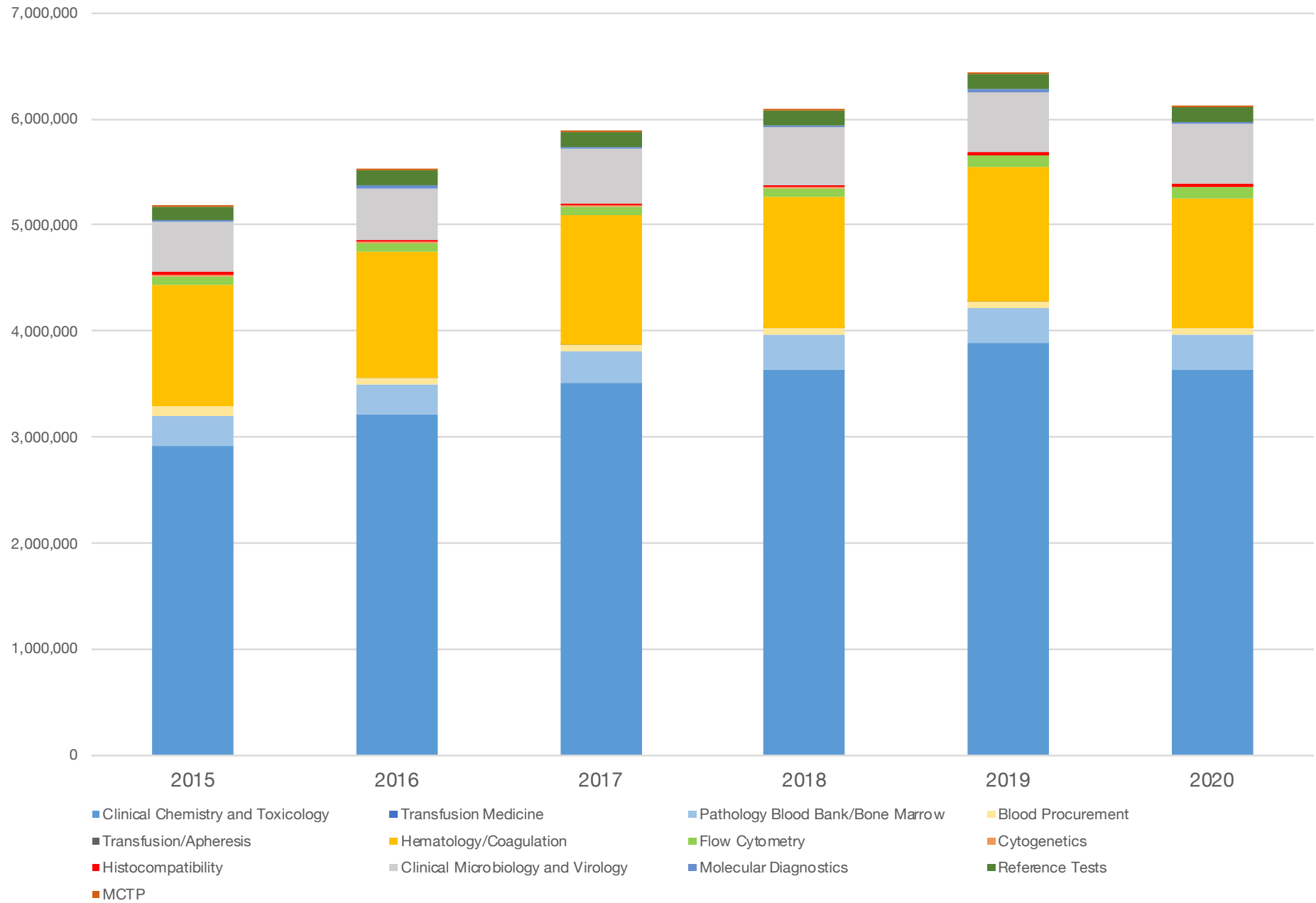


Riccardo Valdez, MD

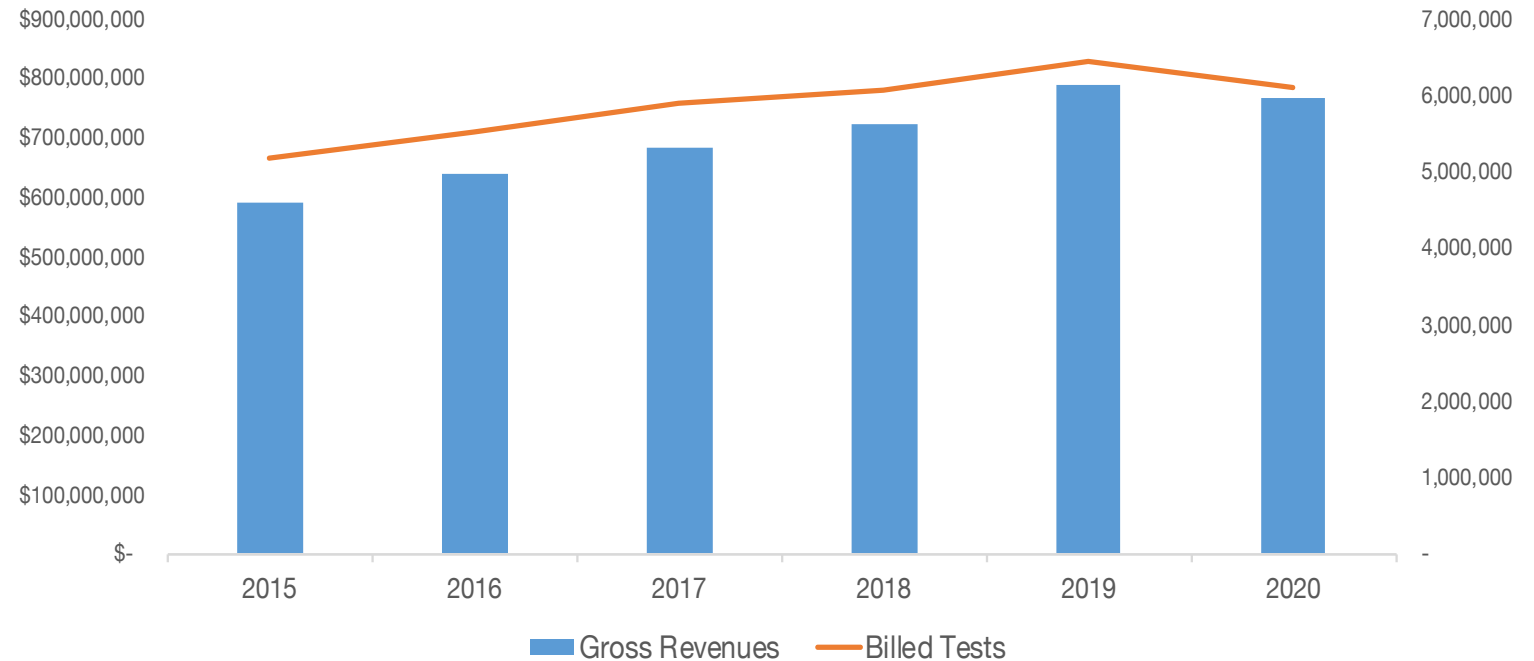
Director, Clinical Pathology



Clinical Pathology Billable Tests



Annual Gross Clinical Revenues and Billed Tests



3.2% decrease in FY20. In FY20, the hematology and coagulation labs performed 1,277,916 billed tests.

The hematology lab invested considerable effort toward updating the electronic rules and triggers programmed into middleware that supports the automated hematology analyzers. Optimizing these rules toward current clinical practice and new instrument capabilities yielded substantial improvement in the hematology lab workflow and throughput. A significant and sustained improvement in the turnaround time for completing Absolute Neutrophil Counts in less than 60 minutes from the Cancer Center is one measure of this success, with the target of 95% met every month and an average of 97.7% of cases resulted in <60 minutes in FY20.

The COVID-19 pandemic did not have a major impact on the hematology and coagulation laboratories, although there was a short-lived increased in requests for G6PD testing when

hydroxychloroquine was being used to help treat COVID-19. Similar to the other sections of the CCL, the hematology and coagulation lab sections were actively engaged in the renovation planning, with special emphasis on refining the parameters of the new automation line, selection of new automated coagulation instruments, and preliminary evaluation of a new platform for urinalysis testing. These two clinical lab areas will be the first to occupy new space in the Fall of 2020.

Clinical Immunology & Special Chemistry

The Clinical Immunology and Special Chemistry labs perform testing to assess immune responses in patients with rheumatoid arthritis, lupus, scleroderma, and other similar conditions; testing for patients with protein disorders such as those seen in multiple myeloma and related disorders; and hemoglobin evaluations in patients with suspected red blood cell disorders. These lab areas experienced a



Jeffrey Warren, MD
Director, Clinical Immunology

9.1% year-over-year decrease and a 5.5% five-year increase in billed tests, completing 649,436 tests in FY20.

In conjunction with Clinical Chemistry, these two lab areas were instrumental in developing serologic assays to detect and measure the immune response to SARS-CoV-2. An ELISA test using a protocol developed by Florian Krammer (Icahn School of Medicine at Mt. Sinai) was developed and validated by this lab section.

A significant highlight for the Clinical Immunology and Special Chemistry lab section in FY20 was the hiring of Dr. David Manthei, who is well known to our department as an outstanding AP/CP resident trainee, Molecular and Genetic Pathology Fellow, and Chemical Pathology Fellow. Dr. Manthei will serve as the Associate Director for both of these labs, under the technical direction of Dr. Jeffrey S. Warren.

Transfusion Medicine

Blood Bank, Immunohematology Reference Lab, Apheresis Procedure Unit, Cellular Therapy

Overall blood component utilization decreased in FY20, which was primarily driven by COVID-19-related clinical activity adjustments. Platelet utilization was impacted by the discontinuation of random donor platelets with transition to all apheresis platelets. However, overall platelet utilization increased compared to FY19, which was driven by increased complexity of surgical cases, and critical care patients. Overall activity in the Immunohematology Reference Laboratory increased, reflecting increased complexity of the inpatient population. Overall activity in the Cellular Therapies Laboratory decreased, which reflected a COVID-19-related pause in transplants and CAR-T therapies. Overall activity in the Apheresis Procedure Unit increased, which reflects continued outpatient activity despite COVID-19-related inpatient activity adjustments.

Transfusion Medicine was integral to the COVID response in provision of convalescent plasma therapy. The Transfusion Medicine faculty acted as site PI for the national expanded access program for the treatment use of COVID-19 convalescent plasma, screening and consenting patients, managing the inventory, and managing data reporting. When FDA issued Emergency Use Authorization for

COVID-19 convalescent plasma, the Blood Bank continued to provide access to the important therapy for Michigan Medicine patients. Transfusion Medicine also participated in the design and initiation of a multisite randomized clinical trial of COVID-19 convalescent plasma in outpatients (C3PO), as well as local performance site support. This NHLBI-supported clinical trial is the largest trial of its kind to address the critical question of the efficacy of convalescent plasma in prevention of disease progress in patients with early COVID-19 who have risk factors for severe disease.

Other notable initiatives in FY20 included implementation of VISION MAX immunohematology analyzers in the Blood Bank, which will increase testing capacity and decrease turnaround time for blood types and antibody screens. The Cellular Therapies Laboratory supported the opening of several clinical trials, including CAR-BCMA T cells (CT053) in patients with relapsed and/or refractory multiple myeloma, NY-ESO-1-specific (c259) T cells, alone or in combination with other agents, in HLA-A2+ participants with NY-ESO-1 and/or LAGE-1a positive solid tumors, JCAR017 in subjects with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma, and bb2121 versus standard triplet regimens in subjects with relapsed and refractory multiple myeloma. Transfusion Medicine faculty served as PI in a randomized, double-blinded, controlled, parallel group, non-inferiority, phase III study to evaluate the efficacy and safety of the intercept blood system for red blood cells in patients undergoing complex cardiac surgery procedures (the ReCePI study).

Hematopathology

Bone Marrow & Flow Cytometry

The Hematopathology service is focused on the evaluation and diagnosis of blood, bone marrow, and lymph nodes disorders, both reactive and neoplastic, using a variety of techniques including routine microscopy and flow cytometry.

In FY20, 1,897 bone marrow and tissue biopsies taken from Michigan Medicine patients were signed out by the hematopathology faculty, representing a 3.8% decrease as compared to FY19. The diagnostic service also handled 1,105 cases associated with patients transferred to Michigan Medicine from external healthcare systems (21.5%



Robertson Davenport, MD
Director, Blood Bank and Transfusion Service



Chisa Yamada, MD
Director, Apheresis Services



Laura Cooling, MD
Director, Cellular Therapy Laboratory



Lauren Smith, MD
Service Director, Hematopathology



Daniel Boyer, MD, PhD
Director, Clinical Flow Cytometry Laboratory



Duane Newton, PhD, D (ABMM), FIDSA
Service Director, Clinical Microbiology Laboratory



Michael Bachman, MD, PhD
Associate Director, Clinical Microbiology Laboratory



Paul Lephart, PhD
Associate Director, Clinical Microbiology Laboratory

decrease), as well as 1,370 cases referred for expert consultation by external providers (3.7% decrease). These decreases reflect lower volumes due to clinic closures during the last quarter of FY20. The diagnostic consult service has grown by 74.3% over the past five years.

The flow cytometry performed 99,902 billed tests in FY20, a 5.4% decrease as compared to FY19, which includes 5,539 leukemia and lymphoma immunophenotyping panels signed out by the hematopathologists. Over the past five years, flow cytometry lab test volume has increased by 26.3%. This growth was primarily due to the increased number of charged antigens tested per case, which also promoted a 39.6% increase in revenues.

Notable FY20 achievements in the flow cytometry laboratory include: completion of a project to improve the quality of the flow cytometry reports, training of medical technologists to help prepare flow cytometry for hematopathologist signout, cross-training of histocompatibility medical technologists and other lab staff to support flow cytometry testing, and completion of a Request for Proposal (RFP) for new flow cytometry instruments. The Becton Dickinson FACSLytic platform was selected to replace the aging Beckman Coulter flow cytometers. Instrument and clinical test validations will be completed in Q2 of FY21.

Clinical Microbiology and Virology

The Clinical Microbiology Laboratory consists of multiple subspecialty areas including: bacteriology, mycology, parasitology, susceptibility testing, molecular microbiology, and virology. These lab areas focus on identifying bacterial, fungal, and viral pathogens to aid in the diagnosis and treatment of patients. In FY20, the Clinical Microbiology Laboratory processed 540,725 tests, a 2.3% increase over FY19 and a 29.7% growth over the past five years. The virology laboratory processed 26,163 tests, a decrease of 39.4% as compared to FY19 and an 18.4% decrease over the past five years.

More than any other clinical laboratory section, the Clinical Microbiology Laboratory was most significantly impacted by the COVID-19 pandemic. It was quickly recognized that diagnostic testing was going to be a critical tool in fighting the Novel

Coronavirus. Within weeks of development of a COVID-19 diagnostic test at the Centers for Disease Control (CDC), the microbiology laboratory directors, development technologist, and other laboratory staff validated and implemented a clinical test for SARS-CoV-2 infection to be used for Michigan Medicine patients. Shortly on the heels of go-live with the initial CDC assay, a second assay with higher throughput was developed and validated. The Abbott m2000 SARS-CoV-2 assay supplanted the CDC assay as soon as sufficient test reagents and supplies were obtained.

Supply chains for critical test materials were quickly overwhelmed as the need for testing sharply increased across the nation and world. Recognizing this as a critical obstacle for meeting the COVID-19 testing needs for Michigan Medicine and our local community, the microbiology laboratory developed a strategy to expand testing including validating the Diasorin Simplexa COVID-19 assay, partnering with the Molecular Diagnostics Laboratory (MDL) to develop a back-up assay using the Thermo Fisher TaqPath protocol, and assisting in the evaluation of point-of-care options. The Diasorin assay not only expanded the number of COVID-19 tests that could be performed, but it also provided a rapid test for use by our Emergency Departments, enabling them to improve their ability to acutely manage patients. The MDL TaqPath assay eventually helped expand the COVID-19 diagnostic testing capacity and decompress the Clinical Microbiology Laboratory, especially as other microbiology lab testing volumes started to come back to normal following the first wave of the pandemic.

In addition to playing a central role in diagnostic COVID-19 testing, the Clinical Microbiology Laboratory leaders played an important part in defining the overall testing strategy for Michigan Medicine by serving on several organizational response teams, helped problem solve and mitigate the many supply chain shortages including the collection kit and viral transport media problems, contributed content expertise at the regional and national level, and contributed to the emerging literature on the clinical sensitivity of the various COVID-19 analytic tests.

Alongside the intense work related to COVID-19 diagnostic testing, the Clinical Microbiology Laboratory prepared for the 2020-2021 influenza season by developing a testing strategy in conjunction with

the Division of Infection Prevention and Epidemiology and securing sufficient test kits and supplies, and they advanced their work on the Kiestra automation system.

Molecular & Genomic Pathology

Molecular diagnostics is the science of analyzing biological markers in the genome and proteome, an individual's genetic code, and how cells express their genes as proteins. These techniques are employed to diagnose and monitor disease, determine response to therapy and risk of relapse, and decide which therapies will work best for individual patients. Year over year, the Division of Molecular and Genomic Pathology has made significant progress toward realizing its overarching goals of facilitating a coordinated strategy for the various clinical laboratories performing molecular tests within the Department of Pathology, and interfacing with Michigan Molecular Genetics Laboratory (MMGL) administered by the Department of Pediatrics.

A significant and landmark achievement in FY20 was the agreement between the Departments of Pathology and Pediatrics to jointly search for and hire a faculty member with appointments in both departments and clinical duties in the MMGL and Clinical Cytogenetics Laboratory.

Molecular Diagnostics Laboratory

In FY20, the Molecular Diagnostics Laboratory (MDL) processed 17,860 billed tests as compared to 20,106 in FY19, an 11.2% decrease. This is a rapidly developing field, both in single gene testing and next generation sequencing panel testing (NGS panels).

In the past year, the Molecular Diagnostics Laboratory added several new tests including an NGS panel for myeloid disorders in partnership with Sophia Genetics, and an assay for the molecular diagnosis of SARS-CoV-2 infection (Thermo Fisher TaqPath Combo Kit).

The laboratory undertook the following quality improvement projects over the course of the year:

- Optimization of RNA extraction and NGS testing procedures:

reduced repeated testing resulting from RNA failures from 11.9% to 5.2% resulting in a savings of \$60,348 per year in consumable and reagent costs.

- Transitioning to a higher capacity NGS testing platform (from the Ion PGM/OneTouch to the S5/Chef): more patients per run (max of 6 on the PGM 318 chip vs max of 24 on the S5 530 chip) resulting in savings of \$48,672 per year in consumable and reagent costs.
- Development of an automated bone marrow transplant engraftment analysis application and database: reduction in the potential for error as well as saving 243 hours of technologist time per year corresponding to an annual savings of \$7,296 per year.

Clinical Cytogenetics

Cytogenetics involves testing samples of tissue, blood, or bone marrow to look for changes in chromosomes, including rearranged, missing, or extra chromosomes. Changes in certain chromosomes may be a sign of a genetic disease or condition, or some types of cancer.

In FY20, our Cytogenetics Laboratory processed 11,709 tests as compared to 12,313 in FY19, a 4.9% decrease. This decrease was primarily due to the impact of the SARS-CoV-2 virus on clinical practices.

Cytogenetics undertook the following process improvement efforts in FY20:

- Direct harvest of FISH-only cases, which results in one-day reduced turnaround time for most FISH-only cases.
- Set up 48-hour cultures for newly diagnosed B-ALL which improved quality of metaphase cells and reduced tech's analysis time on each case.
- Streamlined the slide filing process so there is no need to file/organize slides in the analysis area then bring them back to the wet lab to be cleaned.



Thomas Giordano, MD, PhD
Director, Molecular and Genomic Pathology



Noah Brown, MD
Director, Molecular Diagnostics Laboratory



Lina Shao, PhD
Director, Cytogenetics



Matthew Cusick, PhD
Service Director,
Histocompatibility Laboratory

Histocompatibility Laboratory

The Histocompatibility (HLA) Laboratory performs an array of clinical tests used to help determine compatibility between donors and recipients and to assess immunologic risks associated with solid organ and stem cell transplantation. In addition to CAP accreditation, the HLA laboratory also maintains accreditation by the American Society for Histocompatibility and Immunogenetics (ASHI).

The most notable change for the HLA laboratory in FY20 was the hiring and onboarding of a new laboratory section director, Dr. Matthew Cusick, who joined the Department and CP Division in November 2019. Dr. Cusick brings a wealth of knowledge to the laboratory and has scholarly interests aligned with our clinical transplant teams. The HLA laboratory was pleased to onboard Dr. Kristina Davis as the Associate Director of the HLA laboratory. Dr. Davis is well known to the Department of Pathology having completed her residency in AP/CP in our program. Given her additional certification in Blood Banking, she also has shared duties in Transfusion Medicine under the direction of Dr. Robertson Davenport.

In FY20, the HLA laboratory built on process and technical improvement efforts started in the previous year. Changes in the antibody screening test yielded improved use of medical technologist and reagent resources while also improving patient care. The deceased donor evaluation process continued to improve as the on-call procedures were further refined and the staff gained more experience. Several low volume tests and tests with limited clinical utility for our patient population were removed from the active test menu, but with options for send-out if clinical need arises.

In conjunction with the flow cytometry lab in the Hematopathology service (which shares space, instruments, and personnel resources), the HLA laboratory participated in the RFP for new flow cytometers. New BD FACSLyric instruments were selected to replace the current CytoFlex instruments. These instruments will be used for the flow cytometric crossmatches used to support the living donor kidney transplant program. The HLA lab anticipates validating a new test method for the crossmatch using the new instruments. A significant part of the last year was spent evaluating options for

changing the current multi-step HLA typing test methods to a novel next generation sequencing platform, which is expected to reduce technologist effort and cost while increasing the amount of typing data provided to the clinical teams with an improved turnaround time over current methods.

The Histocompatibility Laboratory processed 19,098 billable tests in FY20, down 17.2% from FY19 when they completed 23,063 billable tests. In FY20, 1,469 high resolution typing were completed, as compared to 1,793 in FY19, an 18% decrease. In FY20, 3,690 low resolution typing were completed, as compared to 4,824 in FY19, a 23.5% decrease. Antibody specificity testing decreased 14.5% from 11,459 tests in FY19 to 9,801 in FY20. Antibody screening testing decreased 8.8% from 3,967 tests in FY19 to 3,618 in FY20. Flow crossmatches decreased 48.2% from 1,007 to 521 in FY19 and FY20, respectively.



Michigan Center for Translational Pathology



26

Arul M. Chinnaiyan, MD, PhD
Director, Michigan Center for
Translational Pathology

The research in MCTP is focused on functional genomic, proteomic, and bioinformatic approaches to study cancer for the purposes of understanding cancer biology as well as to discover clinical biomarkers; we've made progress and major discoveries on many of these fronts over the past year. Summaries from a few of the major studies are provided below.

We recently completed an extension of the earlier MET500 study, MET1000, that integrated the clinical outcomes of patients that had undergone clinical sequencing through the MI-ONCOSEQ program. In over 1,000 patients who underwent integrative genomic profiling, we identified a high rate of pathogenic germline variants and a subset of patients who derive substantial clinical benefit from sequencing information. The manuscript reporting on these results is in press at *JAMA Oncology*.

In collaboration with MCTP member, Dr. Shaomeng Wang, we developed AR degraders using PROteolysis TArgeting Chimeric (PROTAC) technology in order to determine whether depletion of AR protein can overcome mechanisms of resistance commonly associated with current AR-targeting therapies. Our study provided compelling evidence that AR remains a prominent oncogenic driver of prostate cancers which have developed resistance to AR antagonists and highlight the clinical potential of AR degraders for treatment of CRPC. (*Neoplasia*. 2020 Feb;22(2):111-119). Other degrader compounds targeting STAT3 and SMARCA are also under development and investigation.

The MCTP KRAS group identified a protein — Argonaute 2 — that appears to be critical for the progression of benign precursor lesions into pancreatic cancer. Both KRAS and EGFR are essential mediators

of pancreatic cancer development and interact with Argonaute 2 (AGO2) to perturb its function. Using *in vitro* and *in vivo* models, the results support a biphasic model of pancreatic cancer development: an AGO2-independent early phase reliant on EGFR-RAS signaling, and an AGO2-dependent phase wherein the mutant KRAS-AGO2 interaction is critical for progression. (*Nat Commun*. 2020 Jun 4;11(1):2817).

Investigators from MCTP and UM collaborators, along with other participants of the Clinical Proteomic Tumor Analysis Consortium (CPTAC) published on two major studies. The most comprehensive multi-omics dataset to date for clear cell renal cell carcinoma (ccRCC), the most commonly diagnosed kidney cancer subtype, were generated (*Cell*. 2019 Oct 31;179(4):964-983.e31). Additionally, a comprehensive proteogenomic characterization of lung cancer from 110 lung adenocarcinomas and 101 matched normal adjacent tissues incorporating genomics, epigenomics, deep-scale proteomics, phosphoproteomics, and acetylproteomics was carried out. Multi-omics clustering revealed four subgroups defined by key driver mutations, country, and gender. Proteomic and phosphoproteomic data illuminated biology downstream of copy number aberrations, somatic mutations, and fusions and identified therapeutic vulnerabilities associated with driver events involving KRAS, EGFR, and ALK. (*Cell*. 2020 Jul 9;182(1):200-225.e35).

COVID Impact

During the height of COVID-19 related restrictions, like all research labs at Michigan Medicine and UM, normal research activities were paused due to the COVID-19 pandemic for all but research deemed

“essential” on March 20, 2020. Clinical studies as well as all regular wet laboratory experiments were halted. Despite the ramp-down of laboratory and clinical research, we were able to direct some of our efforts during this pause to focus on COVID-related research/therapeutics whose results appear to be promising. Additionally, our group was recently awarded a NIH P30 supplemental award, “Targeting TMRSS2 expression as a therapy for coronavirus infection and replication.” This timely project leverages our vast history and expertise in prostate cancer research to determine whether FDA-approved drugs that markedly inhibit TMRSS2 expression, like enzalutamide, may be effective in inhibiting coronavirus replication and possibly infection.

Furthermore, MCTP was involved in prototyping direct saliva-based QPCR detection of SARS-CoV-2. We demonstrated the merits of saliva-based testing of asymptomatic individuals. An IRB protocol was submitted to receive saliva samples from COVID-19 patients. A variation of this direct QPCR saliva assay was further developed by LynxDx Inc. (of which Dr. Chinnaiyan is co-Founder) which entered into an agreement with University Health Service to provide COVID-19 diagnostic surveillance testing services on the Ann Arbor campus. The agreement allows the university to ramp-up its testing capacity to up to 6,000 individuals per week through the U-M COVID-19 Community Sampling and Tracking Program, a free, opt-in, voluntary surveillance testing program open to students living on or off campus, as well as faculty and staff who work in-person on the Ann Arbor campus.

Going forward, we will follow all the research reactivation guidelines and protocols at our respective institutions to quickly deploy personnel at allowed capacity to bring all research activities online.

Clinical Activities

To exploit the rapid advances in high-throughput DNA sequencing technologies to realize the goals of “precision cancer medicine,” we established the Michigan Oncology Sequencing Center (MI-ONCOSEQ) in 2011 (Roychowdhury et al, 2012). An “integrative sequencing approach” carried out in a CLIA-certified laboratory (#23D0366712) is utilized to provide a comprehensive landscape

of the genetic alterations in individual tumor specimens for the purpose of identifying informative and/or actionable mutations. This approach enables the detection of point mutations, insertions/deletions, gene fusions and rearrangements, amplifications/deletions, and outlier expressed genes. Furthermore, we can identify certain germline alterations that may also be relevant. We applied this to over 3700 adult and pediatric patients thus far; a breakdown of the major cohorts for whom results are returned in the form of a

| Cohort | Total Patients Enrolled | Patients Enrolled FY20 |
|---------------------------|-------------------------|------------------------|
| MO- (MiOncoseq) | 1616 | 171 |
| TP- (Tumor Profiling) | 854 | 114 |
| PO- (Peds Oncoseq) | 645 | 117 |
| MMRF- Molecular Profiling | 715 | - |
| MMRF- MyDrug | 93 | 60 |
| GL- (Germline for MMGL) | 313 | 17 |
| Total | 4236 | 479 |

molecular report is listed in the table below.

Additionally, our sequencing facility supports a number of specialized programs and clinical studies. We have continued our contract with the Multiple Myeloma Research Foundation into the next phase, MyDrug, that selects patients for therapies/trials based on their sequencing results. Internally, we provide back-up support for Michigan Medical Genetics Laboratories (MMGL), a comprehensive CAP/CLIA certified clinical genetics testing laboratories housed in the Department of Pediatrics. (See Appendix pg. 68)

As our clinical sequencing program experienced increased demand and with concurrent growth in outside entities offering clinical cancer sequencing services (such as Tempus), MI-ONCOSEQ has turned its focus to metastatic prostate and breast cancers, cancers of unknown primary, and challenging cases with unusual or rare disease presentation. MI-ONCOSEQ will also serve clients with whom we have contractual agreements and those that are requested through MLabs. We are also developing novel approaches for clinical sequencing as costs continue to decrease, and broadening

| Program | FY19 Revenue | FY20 Revenue | FY21 Projected Revenue |
|---------|--------------|--------------|------------------------|
| MMRF | \$513,308 | \$258,781 | \$500,000 |
| MMGL | \$281,697 | \$32,111 | \$4,379 |

the application of sequence data towards predicting response to immunotherapy and determination of epigenetic status.

MI-ONCOSEQ has been supporting several ongoing clinical trials/studies. (See Appendix on pg. 74) (charges based on select cases chosen for sequencing).

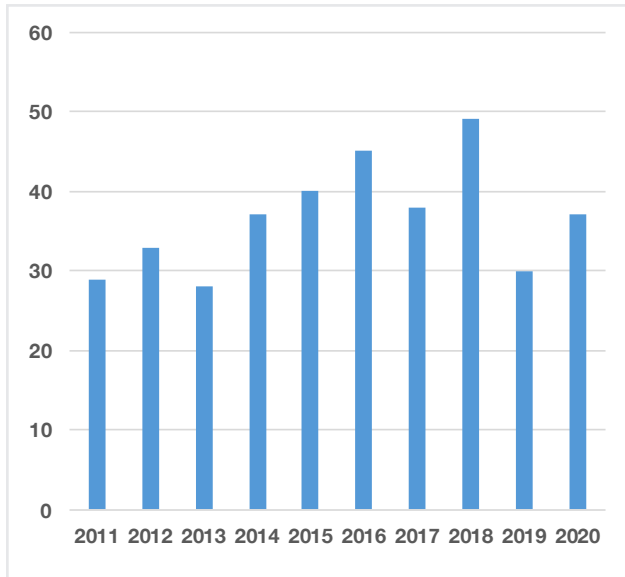


Chart: (below) Publications by Year - 2020 (YTD) (PubMed)

In association with MLabs, MCTP's Molecular Testing Lab (MTL) receives orders for and carries out PCA3, Mi-Prostate Score (MiPS), and to a smaller extent, Cell Search Circulating Tumor Cell (CTC) assays. Since 2010, MTL has processed 16,398 PCA3, 1,527 MPS and 1,580 CTC assays for clinical use, and 3,231 PCA3 and 3,231 MPS assays for research samples. In FY20, MTL processed 204 PCA3, 58 MPS assays for clinical use and 401 PCA3 and 401 MPS assays for research use.

MTL also procures biological samples such as urine, blood, and tissue for ongoing clinical and research projects. Since 2010 MTL has procured 1,580 tissue, 4,965 Urine, 5,093 serum, 5,063 EDTA plasma and 4,924 DNA. MTL supports the following clinical studies and research projects:

- **UMCC 2013.117:** A Randomized Phase II Study of Androgen Deprivation Therapy with or without PD 0332991 in RB-Positive Metastatic Hormone-Sensitive Prostate Cancer
- **ENACT Study:** A Clinical trial assessing the efficacy of enzalutamide in men with prostate cancer on active surveillance
- A Randomized Phase II trial of Abiraterone, Olaparib, or Abiraterone + Olaparib in Patients with Metastatic Castration-Resistant Prostate Cancer with DNA Repair Defects (c16-168)
- **UMCC 2016.106:** A Phase I Trial of Neoadjuvant Stereotactic Body Radiotherapy Prior to Radical Prostatectomy for High Risk

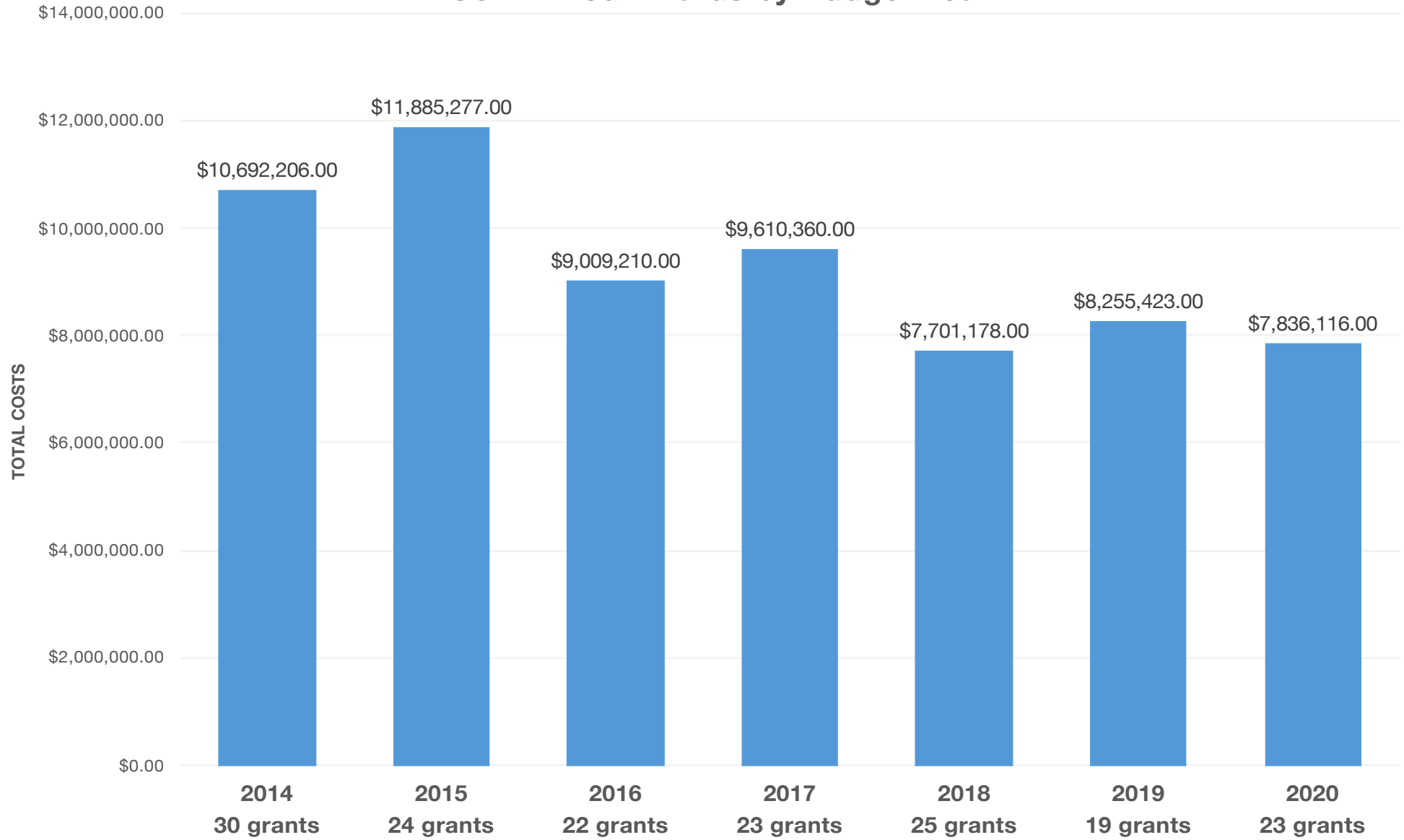
Prostate Cancer

- **HUM00117711:** Targeted Early Detection Program in Men at High Genetic Risk for Prostate Cancer
- **HUM00148970:** EDNRN Prostate MRI Biomarker Study and Reference Set.
- **HUM00188437:** Interstitial assessment of architectural heterogeneity in prostate cancer ex vivo
- **MI-ONCOSEQ (clinical sequencing program):** The Tissue/ Informatics Core has been critical for the success of this program. The Core supports this study by participating in biospecimen procurement from biopsies and preparing samples to undergo sequencing in a CLIA-certified facility.
- Collaborative project, "Validation of Mitochondrial Markers for Prostate Cancer" with Samantha Maragh (National Institute of Standards and Technology).
- Collaborative project with Dr. Marc Goldstein, PI (Weill Cornell) to determine if the sensitivity and specificity of a semen PCA3 assay is superior to that of the current PCA3 urine assay.
- **SABOR Study NCI:** Collaboration with Dr. Michael Liss to improve ways to diagnose and follow patients already diagnosed with prostate cancer.

Academic Activities

Members of the MCTP published 40 papers from July, 2019 – June, 2020, several in high-impact journals (*Cell*; *Nature*; *European Urology*). Our publications are highly cited with an overall H-index of 126 for Dr. Chinnaiyan (Web of Science®). Dr. Chinnaiyan was also elected as member of the National Academy of Sciences.

Committed Awards by Budget Year



Michigan Medicine Laboratories (MLabs)



30

Jeffrey L. Myers, MD
Director, MLabs Reference Laboratory



Julia Dahl, MD
Associate Director, MLabs Reference Laboratory

Michigan Medicine Laboratories (MLabs) is a full-service reference laboratory that leverages the combined strengths of our faculty, trainees, staff, and state-of-the-art laboratories. We value our vital role as the conduit that allows access for patients around the world to Michigan Medicine expertise. We strive to be a trusted partner to all, building strong relationships with pathologists, hospital laboratories, skilled nursing facilities, physician offices, and specialty physicians across Michigan and the nation. Our highly effective collaborations put the needs of the patient at the top of all we do, aligning us strongly with the Michigan Medicine mission, “to advance health to serve Michigan and the world.”

The significant disruption to healthcare caused by COVID-19 had drastic consequences for MLabs. As follow-up visits were postponed, new biopsies were put on hold, and cancer testing, in many cases, was not ordered, we saw a measurable decline in volume and revenue. Total activity showed year-over-year decline of 8% measured as total number of accessioned cases (304,183) and -7% measured as total billable tests (462,259). Total gross charges fell 4.6% as compared to FY19. Before the pandemic, year-over-year activity was positive at approximately 3%. The good news; comparing June 2019 to June 2020, total accessions shows a 13.3% increase, which is an early indicator that MLabs’ volume is on the rise and expected to continue growing into FY21.

MLabs response during the pandemic included:

- Partnering closely with and coordinating testing for the most vulnerable population in our community housed in skilled

nursing facilities averaging 600 PCR tests per week, published in the *Journal of the American Geriatrics Society*. DOI: 10.1111/jgs.16869

- Supporting Mid-Michigan, Metro Health, and the VA with testing capacity as testing platforms and supplies were unattainable by many
- Successful rapid transition of staff to remote work while at the same time providing increased support to other pathology divisions via phone call management, increased hours of operation, and supply chain

Significant accomplishments in FY20 despite the pandemic include:

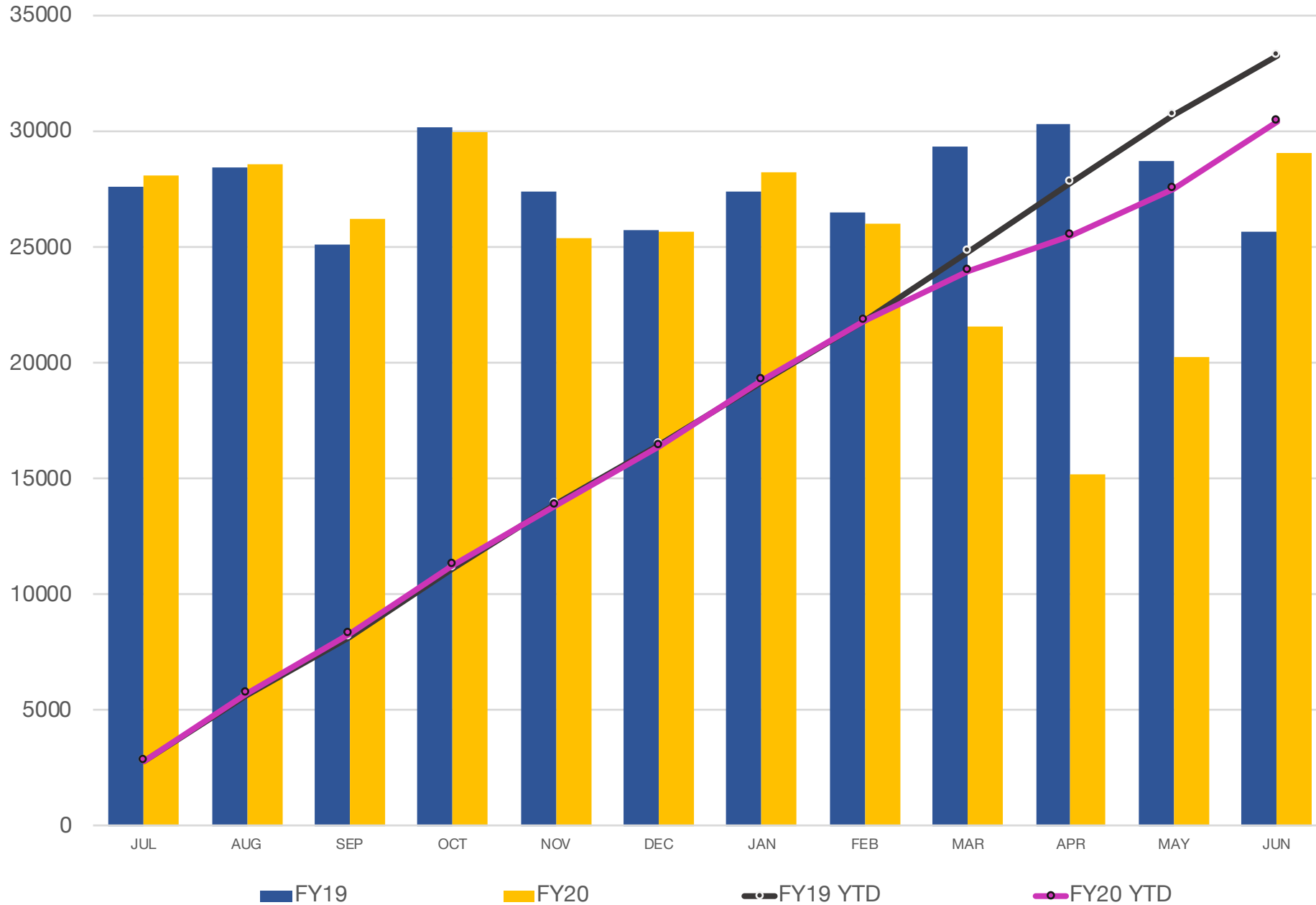
- Building on a one-day learning collaborative which included senior emeritus members of the team that built Mayo Clinic Laboratories in the 1970s, a strategic initiative was kicked off in December, 2019; *Michigan Medicine Laboratories – A Strategy for Transformation And Revolution (M-STAR)*. Fueled by the conviction that there is a substantial gap between MLabs’ current capacity to deliver laboratory services and the opportunity to do that with a greater focus on hospital reference laboratory, consultation, and esoteric molecular diagnostic services, the project team was tasked with transformation. The goal: to develop a business plan to support breakthrough improvement in Michigan Medicine Laboratories’ (MLabs) capacity to serve the interests of Michigan Medicine and to advance health in the region, the nation, and the world. The team achieved significant progress, but was put on hold at the

start of the pandemic. A reboot of the project will occur in FY21.

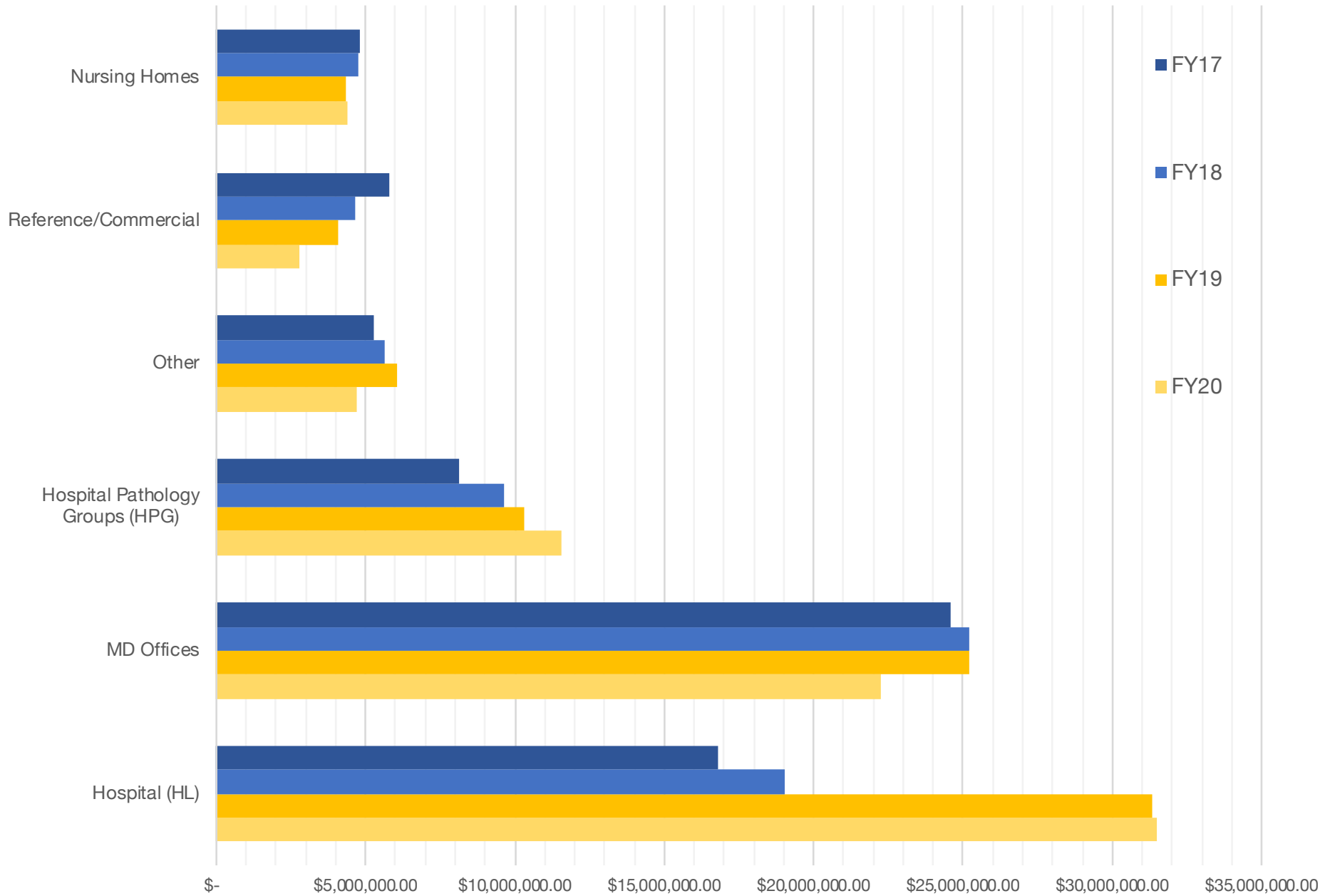
- May 2020 saw the successful completion of the Salesforce Business Development project. Modifications including implementation of the Pardot marketing application and Salesforce Engage, configuration updates to Opportunities and Leads, and updates to support activity tracking and client manual document automation. These enhancements have allowed MLabs to increase marketing and sales efforts with actionable data in the form of real time dashboards and reports centered around pipeline management, ROI tracking, and base business maintenance and growth.
- MLabs' new modern website was launched in June 2020, featuring large images with a full screen layout and clean streamlined look and feel. The new site enhances our brand credibility with interactive news and related articles that are searchable. The responsive platform allows scaling to any screen size and is mobile friendly. Multiple CTA (Call to Action) icons enhance the user engagement and capture potential customer email/contact information and interests. This beautiful new site paves our way to increase digital marketing, a major goal for FY21.



MLabs Total Accessions YOY Change (-8%)



Total Gross Charges by Market Segment, FY17 - FY20



Veterans Affairs

Pathology & Laboratory Medicine



34

Stephen Chensue, MD, PhD
 Director, Veteran's
 Administration Hospital
 Laboratories, VA

The Pathology and Laboratory Medicine Service of the Veterans Affairs Healthcare System, in Ann Arbor, Michigan, is staffed by pathologists with a joint appointment at the University of Michigan Medical School. The VA Ann Arbor is a designated cancer center providing regional full-service clinical laboratory testing. They support Anatomic Pathology services in Surgical Pathology, Cytopathology and Telepathology for VA Medical Centers in Battle Creek, Saginaw, Detroit, and Northern Indiana. In addition, chemistry and hematology testing is offered at our Toledo, Ohio laboratory, and point-of-care testing is offered in Flint and Jackson, Michigan community outpatient clinics. Data presented below is for the year that ended December 31, 2019.

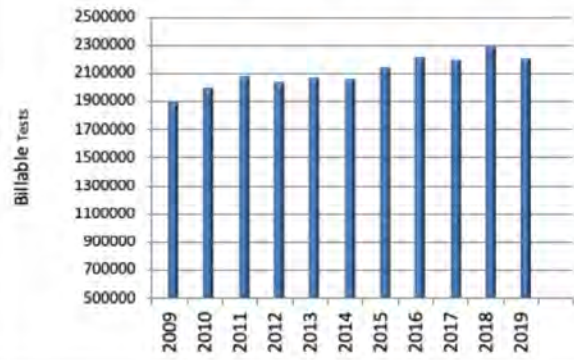
Clinical Pathology workload in the Ann Arbor laboratory has current average annual growth rate of 2% since 2009. The rate of increase at the main facility was blunted by a workload shift to our expanded branch laboratory at the Toledo outpatient facility. Anatomic Pathology workload continues to increase at an average rate of 6% per year since 2009. The VHA establishes high standards of quality and timeliness. Laboratory faculty and staff work hard to meet these standards, meeting clinical pathology STAT specimen turnaround time goals in all sections at >95% of the time. Our outpatient phlebotomy team serviced 85% of patients in less than 10 minutes with >95% of patients indicating they are satisfied with their service on satisfaction surveys. In Anatomic Pathology, surgical pathology reporting exceeded targets in 2019. Cytology reporting fell short due to loss of screening staff but addition of new staff in 2020 should correct this. When compared to similar VA medical centers, the VA Ann Arbor workload was the highest among those facilities in 2019.

Pathologist productivity is likewise among the highest with the lowest pathologist labor expense per billable test.

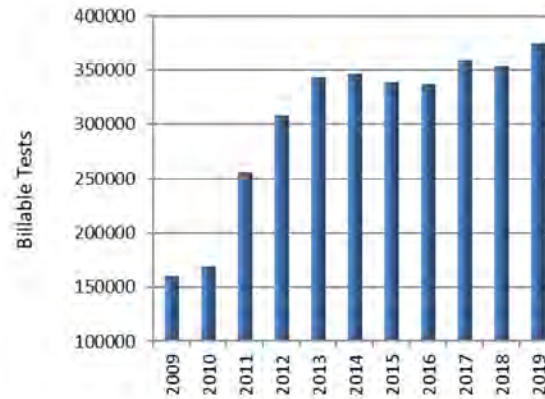
In 2019-2020, the main laboratory underwent a major renovation of its Anatomic Pathology division to create a state-of-the-art fully modular open space plan with incorporation of full bar code tracking from specimen arrival to slide archiving. As part of a major modernization effort, the VA Ann Arbor laboratory has installed an integrated digital camera system at grossing stations and at pathologist microscopes. Captured gross and microscopic images are automatically collected in case files for viewing at any computer workstation. Our cytology section is in the process of implementing remote robotic microscopy to allow pathologists to perform rapid aspiration evaluations (ROSE) from their offices. In 2021, the VA Ann Arbor will convert to a Cerner-based information system.

| Service | Accessions | Target | %Meeting |
|--------------------|------------|---------------------|----------|
| Surgical Pathology | 14,294 | 95% reported <2d | 95.2% |
| Non-Gyn Cytology | 2,959 | 95% reported <2d | 94.0%* |
| Gyn Cytology | 1,711 | 95% reported <14d | 87.8%* |
| Frozen Section | 523 | 95% reported <20min | 98.8% |
| Autopsy | 6 | 100% completed <30d | 100% |

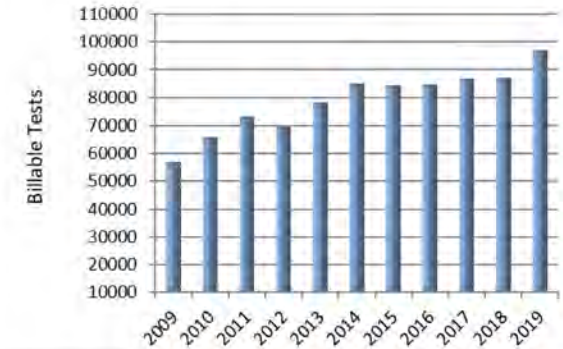
VA Ann Arbor Clinical Pathology Billable Workload



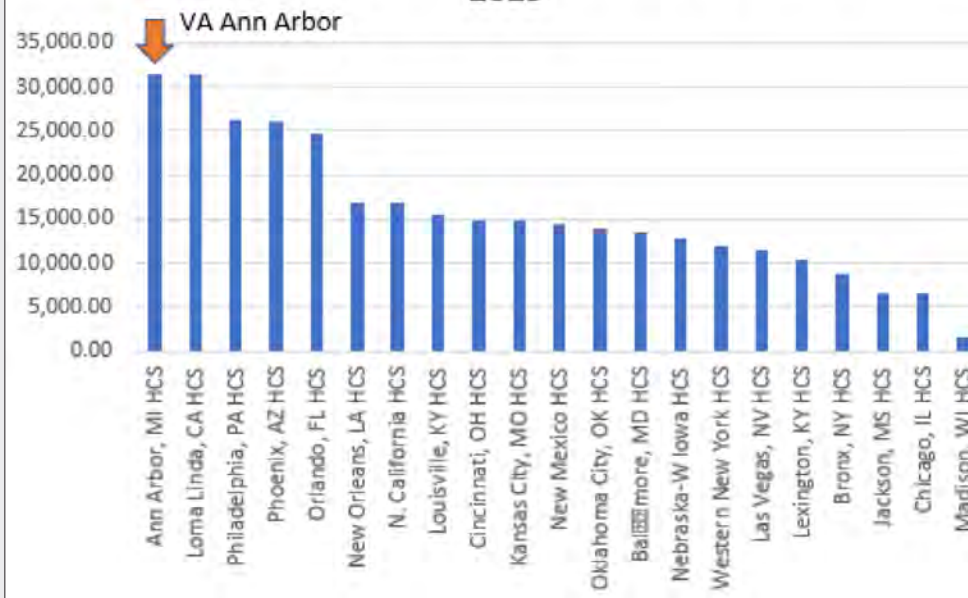
VA Toledo Laboratory Billable Clinical Workload



Ann Arbor Pathologist Workload



Pathologist RVU Workload Ranked by VA 1b Facility 2019



Research Mission

It has been another highly productive year for Experimental Pathology (EP). The EP faculty include the entire spectrum of emerging young investigators to established senior faculty who occupy ~62,000 sq. ft. of research space in numerous buildings across the medical campus. We are proud of the accomplishments of this diverse group of EP faculty whose research focus spans broadly from inflammation and immune responses, to cancer biology, and aging. Results emanating from the division are at the forefront of cutting-edge research which bridges new basic discoveries with the clinical practice of medicine. Discoveries have been in basic biology, disease pathogenesis, and therapeutics. Success of this division is further evidenced by outstanding grant funding, high impact publications, patents, and prestigious faculty awards.

EP division faculty received \$35,805,236 in grant funding the past academic year, which is an 8% increase from the previous year. This successful research funding trend has not only been sustained, but has continued to increase over the past five years. We have the second highest number of R01 grants awarded to experimental pathology faculty at the national level. With inclusion of other federal grant dollar amounts, we rank number 9 in the nation. These numbers clearly support the high productivity of EP faculty in spite of a very challenging national funding climate and the pandemic. A large fraction of the funds were awarded from federal sources (NIH, DoD) with additional funds from non-profit organizations and industry (Figure 1). Successful research awards include eighteen NIH grants (R01 to U01 grants and subcontracts), two Department of Defense (DoD) grants and eighteen foundation/industry grants (Figure 2: See right page). EP faculty also continue to be outstanding mentors, which is reflected in research fellowship and career

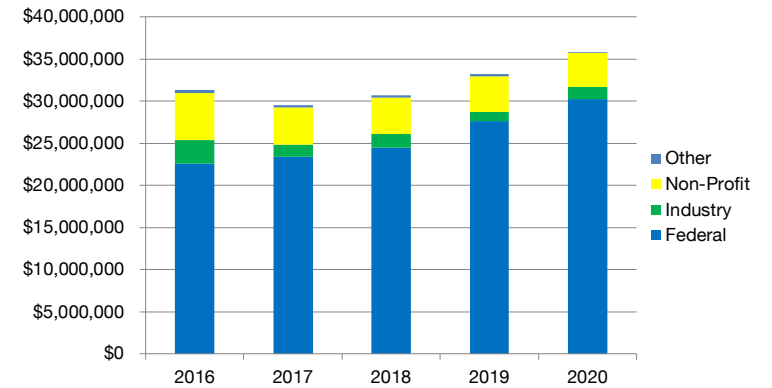


Figure 1: Funds awarded from federal, non-profit, and industry.

development awards that were received by trainees in a number of faculty laboratories. Members of our clinical divisions (AP/CP) participated on many of these extra-mural grant-funded initiatives as well.

In addition to independent PI grants, EP training awards include one career-development and six fellowship grants from the NIH and foundations. In keeping with these successful funding metrics, grant indirect costs excelled in the medical school and faculty have high dollar density of research space that, on the average, continues to be above \$130/sq. ft. Innovation and research success of EP faculty is further reflected in 39 patent applications and 38 issued patents, 12 new invention reports, and 6 new commercialization agreements. A summary of these faculty achievements is shown in Figure 3. (See on pg. 37)

Asma Nusrat, MD
Director, Experimental Pathology

| National Institute of Health (NIH) | |
|------------------------------------|----------------------------------------------------------|
| Type of Grant | Faculty Name |
| R01 | Cierpicki, Tomasz |
| R01 | Grembecka, Jolanta Hodgin, Jeffrey Hodgin, Jeffrey |
| R01 | Kleer, Celina |
| R01-Subcontract | Lieberman, Andrew |
| R35 | Lukacs, Nicholas |
| R01-Subcontract | Lukacs, Nicholas |
| R01-Subcontract | Lukacs, Nicholas |
| U01 | Miller, Richard |
| R01-Subcontract | Miller, Richard |
| R01-Subcontract | Miller, Richard |
| R01-Subcontract | Nesvizhskii, Alexey |
| R01 | Nunez, Gabriel |
| R01-Subcontract | Rajendiran, Thekkelnaycke |
| R01 | Venneti, Sriram |
| R56 | Ward, Peter |
| R01 | Zochowska, Anuska |

| Other Governmental Granting Agencies | |
|-------------------------------------------|------------------------------|
| Sponsor | Faculty Name |
| DHHS-Office of the Secretary-Subcontracts | Davenport, Robertson |
| DOD | Pitchiaya, Sethuramasundaram |
| DOD | Udager, Aaron |

| Industry & Nonprofits | |
|---------------------------------------|------------------------------------|
| Sponsor | Faculty Name |
| Prostate Cancer Foundation | Chinnaiyan, Arul |
| Prostate Cancer Foundation TO VA | Chinnaiyan, Arul |
| Prostate Cancer Foundation TO VERAM | Chinnaiyan, Arul |
| Bristol-Myers Squibb | Cieslik, Marcin |
| V Fdn for Cancer Research, The | Cieslik, Marcin / Alva, Ajjai |
| Cancer Research Institute | Cieslik, Marcin / Pitchiaya, Sethu |
| Leukemia and Lymphoma Society | Grembecka, Jolanta |
| Leukemia and Lymphoma Society | Grembecka, Jolanta |
| Takeda Pharmaceuticals | Johnson, Kent |
| The Pablove Foundation | Kumar, Surinder |
| Amer Assoc for Cancer Research | Nikolovska-Coleska, Zaneta |
| Millennium Pharm, Inc. | Nunez, Gabriel |
| St. Baldrick's Foundation | Rual, Jean-Francois |
| University of Pennsylvania | Schultz, Mark |
| Bristol-Myers Squibb | Tien, Jean |
| CS Health Solutions LLC | Varani, James |
| Michael Mosier Defeat DIPG Foundation | Venneti, Sriram |
| American Society of Hematology | Zhang, Xiaotian |

| Trainee and Career Development | |
|--------------------------------|-------------------------------------|
| Sponsor | Faculty Name |
| American Society of Hematology | Ryan, Russell |
| NIH-F99 | Parolia, Abhijit (Chinnaiyan, Arul) |
| NIH-F32 | Laszczyk, Ann (Dressler, Gregory) |
| NIH-F31 | Uddin, Jazib (Hogan, Simon) |
| Crohn's and Colitis Foundation | Raya Sandino, Arturo (Nusrat, Asma) |
| CERN Foundation | Chung, Chang (Venneti, Sriram) |
| Prostate Cancer Foundation | Kregel, Steven (Chinnaiyan, Arul) |

Figure 2: Research Funding

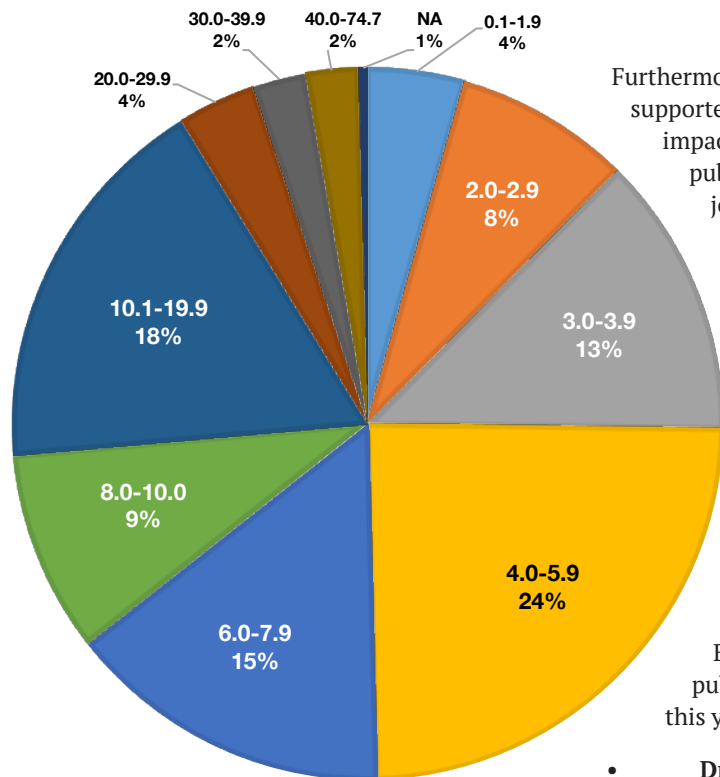


Chart: Manuscripts published in FY20 by journal impact factor.

Furthermore, high research productivity is supported by many new discoveries and high impact publications. 250 manuscripts were published by our faculty in high-impact journals such as *Nature*, *Cell*, *Nature Communications*, *Nature Methods*, *Nature Chemical Biology*, *Journal of Clinical Investigation*, *Science Immunology*, *Proceedings of the National Academy of Sciences*, among many others. 26% of manuscripts were published in journals with an impact factor of greater than 10 and an additional 24% were accepted in journals that have an impact factor of 6-10 (Adjoining figure). These data were assembled using PubMed and EndNote. Among the many outstanding published manuscripts, a few highlights this year include the following:

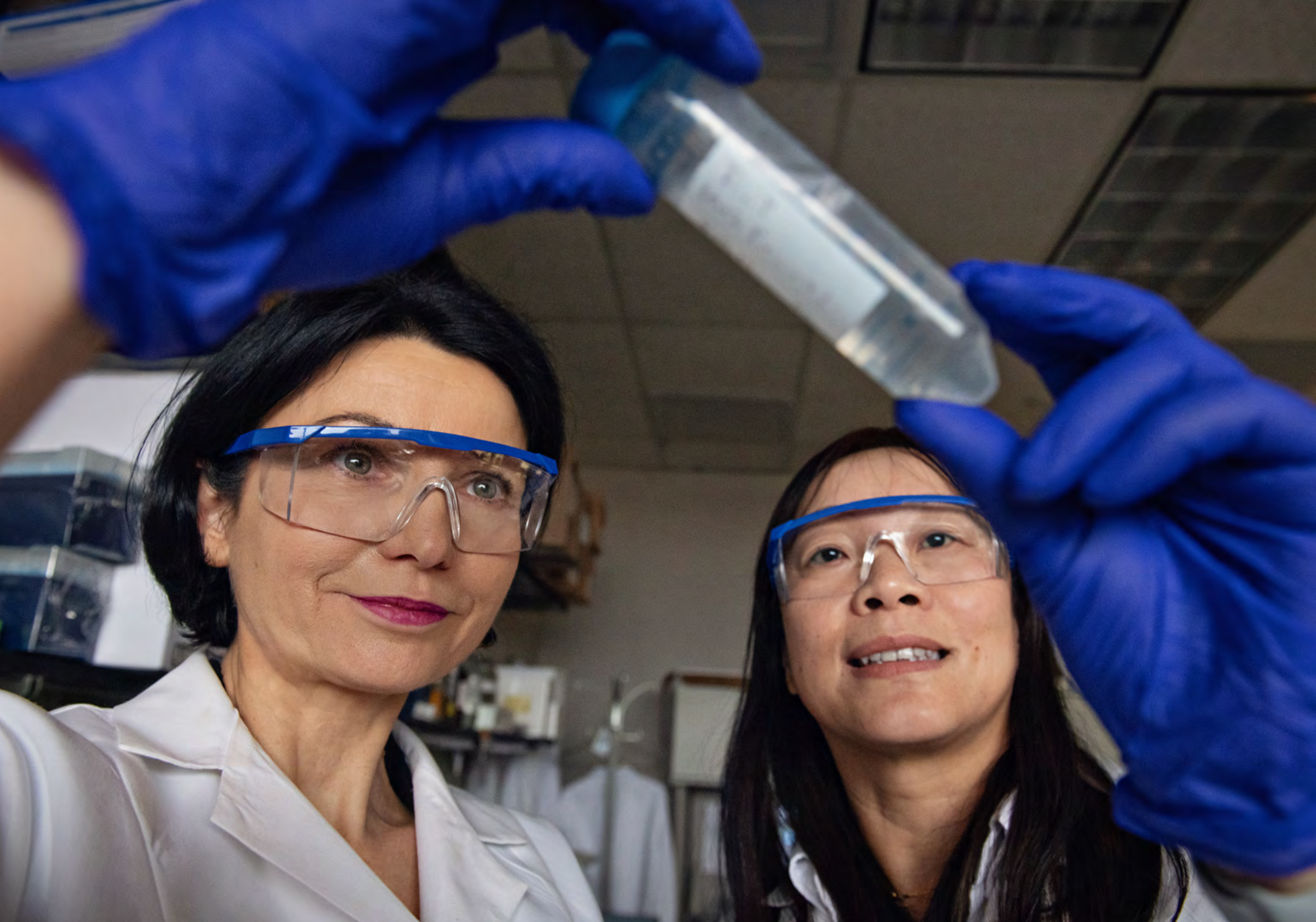
- **Dr. Alexey Nisvizhskii's** high level of productivity includes senior-author manuscripts published in *Nature Communications* (2) and one each in *Nature Methods*, *PNAS*, and *Cell* journals. In these studies, Dr. Nisvizhskii reports cutting-edge proteomic approaches, analysis of cancer proteomes, and development of novel bioinformatics algorithms and software tools for proteomics.
- In an article published in *Nature Chemical Biology*, **Drs. Tomasz Cierpicki** and **Jolanta Grembecka** identified compounds that inhibit NSD1 histone methyltransferase. They also published a *Journal of Clinical Investigation* manuscript that shows remission of a subgroup of leukemia in animal models by a novel small molecule menin inhibitor (MI-3454).
- **Dr. Arul Chinnaiyan** continues to have high productivity and has published many articles addressing cancer biology and biomarkers. In an article published in *Nature Communications*, his group identified an essential role for Argonaute 2 in EGFR-KRAS signaling in pancreatic cancer development. Furthermore,

Dr. Chinnaiyan's study in *Nature* reported distinct structural classes of activating FOXA1 alterations in advanced prostate cancer.

- **Drs. Charles Parkos** and **Asma Nusrat** also had a productive year. Their articles published in the *Journal of Clinical Investigation*, *Proceedings of the National Academy of Sciences*, and *Nature Communications* reported novel mediators and mechanisms involved in controlling mucosal homeostasis and repair. The *Nature Communications* study identified an important role of CD47, a previously unreported "don't eat me signal" in promoting mucosal wound repair.
- **Dr. Celina Kleer** continued to have a productive year studying breast cancer biology. Her recent study showing a quantitative proteomic landscape of metaplastic breast carcinoma pathological subtypes and their relationship to triple negative tumors was published in *Nature Communications*.
- **Dr. Andrew Lieberman's** studies focus on neuroscience. His article in *Nature Communications* demonstrated Hsp70- and Hsp40-mediated inhibition of inter-domain interaction is necessary for transcriptional activity in the androgen receptor.
- **Dr. Gabriel Nuñez** continues to make important discoveries related to microbiota cross-talk with the host immune response. In an article published in *Science Immunology*, his group identified specific gene-microbe interactions that drive development of Crohn's-like disease colitis in mice. His studies suggest that a specific intestinal microbe triggers Crohn's-like disease in the presence of impaired clearance of the bacterium by innate immunity.

Another measure of the faculty's performance are their invited seminars. EP faculty members presented many talks in the past year that include presentations at the institutional, national and international levels. These national/international recognitions were also accompanied by prestigious awards. Indeed, it was a banner year! A few of these awards are listed below:

Dr. Arul Chinnaiyan was elected into the very prestigious National Academy of Sciences. He also received the American Association for Investigative Pathology Rous-Whipple Award which is given



| All Issued Patents | |
|--------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Patent Title | Inventors |
| Phage Microarray Profiling of the Humoral Response to Disease | Xiaoju Wang, Arul Chinnaiyan |
| Recurrent Gene Fusions in Prostate Cancer | Scott Tomlins, Arul Chinnaiyan |
| Stem Cell Factor Inhibitor | Steven Kunkel, Sem Phan, Cory Hogaboam, Vladislav Dolgachev, Nicholas Lukacs |
| 9H-pyrimido[4,5-b]indoles and related analogs as BET bromodomain inhibitors | Longchuan Bai, Jennifer Meagher, Jeanne Stuckey, Arul Chinnaiyan, Angelo Aguilar, Duxin Sun, Yujun Zhao, Donna McEachern, Ting Zhao, Shaomeng Wang, Xu Ran, Ruijuan Luo, Irfan Asangani, Bo Wen, Yang Hu, Liu Liu, Bing Zhou |
| Small Molecule Inhibitors of MCL-1 and Uses Thereof | Hollis Showalter, Zaneta Nikolovska-Coleska, Fardokht Abulwerdi |
| Non-Coding RNAs and Uses Thereof | Arul Chinnaiyan, Felix Feng, John Prensner, Yashar Niknafs, Matthew Iyer |
| Recurrent Gene Fusions in Cutaneous CD30-Positive Lymphoproliferative Disorders | Bryan Betz, Thirunavukkarasu Velusamy, Mark Kiel, Delphine Rolland, Nathanael Bailey, Kojo Elenitoba-Johnson, Megan Lim |
| Systems and Methods for Determining a Treatment Course of Action | Dan Robinson, Arul Chinnaiyan, Yi-Mi Wu |
| SCHLAP-1 ncRNA and Uses Thereof | Arul Chinnaiyan, John Prensner, Matthew Iyer |
| Therapeutic Antibodies and Uses Thereof | Steven Kunkel, Cory Hogaboam, Nicholas Lukacs |
| Methods and Compositions for Inhibiting the Interaction of Menin with MLL Proteins | Szymon Klossowski, Tomasz Cierpicki, Jolanta Grembecka, Duxin Sun, Jonathan Pollock, Dmitry Borkin, Hongzhi Miao |
| Compositions Comprising Thienopyrimidine and Thienopyridine Compounds and Methods of Use Thereof | Andrew Muntean, Tomasz Cierpicki, Jay Hess, Jolanta Grembecka, Duxin Sun, Dmitry Borkin |
| System and Method for Scheduling Appointments | Andrew K. Alexander, Ulysses G. J. Balis, Ronald G. Tompkins |
| Ash1L Inhibitors and Methods of Treatment Therewith | Jing Deng, Szymon Klossowski, Hao Li, Tomasz Cierpicki, Jolanta Grembecka, Hongzhi Miao, Eungi Kim, Trupta Purohit |

Figure 3: Patent Applications. Continued in Appendix on pg. 70 for Invention Reports.

to an active senior scientist with a distinguished career in research who has advanced the understanding of disease. Dr. Chinnaiyan is recognized worldwide as one of the foremost experts in the identification of gene fusions in prostate cancers that now serve as biomarkers and targets for cancer therapy. His studies have also led to the development of a cancer profiling bioinformatics resource (OncoPrint) and his group continues to develop high-throughput clinical sequencing approaches for precision oncology (MI-ONCOSEQ project), as well as RNA-seq methods to decipher lncRNAs in cancer.

Dr. Gabriel Nuñez was elected into the prestigious National Academy of Medicine in recognition of his dedication to outstanding research. He also presented the highly regarded Society of Investigative Dermatology Stone Lecture. Dr. Nuñez's studies identified pattern recognition receptors in the Nod-like receptor (NLR) family, NOD1 and NOD2, that mediate cytosolic sensing of microbial organisms. His seminal studies went on to demonstrate NOD2 genetic variation is associated with susceptibility to Crohn's disease. This was the first genetic variation in IBD, which has now expanded to over 100 genes. Dr. Nuñez has continued to make novel discoveries on how microbiota regulate the immune response in the gut and the skin.

Dr. Asma Nusrat was elected into the competitive Association of American Physicians society.

Dr. Celina Kleer was awarded the AACR Outstanding Investigator Award for breast cancer research. She also received the American Society for Investigative Pathology Outstanding Investigator Award, which is given to mid-career investigators with demonstrated excellence in research in experimental pathology.

At the institutional level, Dr. Kathleen Cho received the highly regarded Dean's Basic Science Award.

EP faculty continue to have important leadership positions on editorial boards, grant review study sections, and national/international scientific societies. Our chair, Dr. Charles Parkos, continues to serve as a board member representing FASEB member societies. In this capacity, he has participated in the FASEB delegation advocating for the importance of scientific funding to senators and congress members in Washington, DC. Dr. Zaneta

Nikolovska-Coleska was elected as president of the International Chemical Biology Society. Dr. Ulysses Balis was appointed as Chair of the American Board of Medical Specialties Digital Information and Technology Advisory Committee which advises government and non-governmental bodies on best practices for Pathology data stewardship and provenance. Dr. Evan Farkash was re-elected Chair of the Transplant Diagnostics Community of Practice for the American Society of Transplantation and Dr. Jiaqi Shi was awarded the magna cum laude Three Pearls Award in the SCBT-MR Annual course.

At the Institutional level, Dr. Thomas Wilson accepted a senior position as the Co-PI of the Michigan Biosciences Initiative (Single-Cell Spatial Analysis Program) in the medical school and has already implemented new cutting-edge technology in this area. Dr. Nick Lukacs serves as the scientific director for the Mary H. Weiser Food Allergy Center (MHWFAC), of which three other pathology faculty are members: Drs. Simon Hogan, Chang Kim and Catherine Ptaschinski. Over the past year, MHWFAC built on foundational programs to create an internationally recognized Food Allergy Research Center. The research areas of expertise of the 7 faculty include vaccine development, targeted intervention, immunopathogenesis, microbiome, and metabolite influence on food allergy. Center members have also begun to expand basic research into clinical studies to build a translational pipeline by examining food allergic patients undergoing food allergen challenge. MHWFAC also established a collaborative regional center with Henry Ford Health System (HFHS) named the Southeast Michigan Food Allergy Consortium (SMFAC). The formation of the regional center brings together the research strength of the MHWFAC with the epidemiology and birth cohort study expertise of HFHS. This regional center has provided members opportunity to apply for and receive a Discovery Center Grant from the Food Allergy Research and Education (FARE) as one of ten centers in the US, thereby having National collaborations and impact. In addition, investigators in the MHWFAC have been successful in acquiring additional funding to support their research (>\$2.5 million) and expand their footprint in the field of Food Allergy. A number of publications related to food allergy have emanated from the center. Of note, the Hogan Lab identified that intestinal epithelial cells can act as antigen passages

and channel food allergens across the epithelium and regulate the onset of food-induced allergic reactions (*J Allergy Clin Immunol.* 2019 Oct;144(4):1058-1073).

Dr. Steven Kunkel serves as the Executive Vice Dean in the Medical School and was appointed as the Chief Scientific Officer for Michigan Medicine. In his prominent leadership position, Dr. Kunkel played a pivotal role in the development and implementation of robust strategic research plans that have facilitated novel directions for many research programs across Michigan Medicine. These have included management of a central bioprepository, research data warehouse/data direct, biomedical research core facilities, fast forward medical innovation program, and the launching of clinical trial support units. Furthermore, Dr. Kunkel played a very important role in the organization of safe research operations during the COVID-19 pandemic.

In closing, EP faculty had another highly successful year and maintained outstanding standards in research funding, publications, awards, and leadership roles.

Education Mission

Education is another of the core missions of the Department of Pathology as part of an Academic Medical Center. The Department is a key provider of learning for medical students, graduate students, dental students, residents, and fellows. Our 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 over the years. In addition, many Pathology faculty members play key roles in education in other clinical departments throughout Michigan Medicine 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.

In FY19, our Education Division relocated to the North Campus Research Complex from the Medical Sciences 1 building. Residents and fellows are now housed in newly renovated space with floor-to-ceiling windows overlooking the park-like setting of the NCRC campus. Located adjacent to the grossing room, and near the clinical laboratories, with several multi-headed teaching microscopes located in nearby rooms, residents and fellows are at the heart of the work being done in Pathology. The faculty suite is located directly above the educational space, ensuring easy access for questions and mentoring opportunities.

Graduate Medical Education – Pathology Residency Program

In FY20, the University of Michigan Pathology Residency Program

was the #1 ranked program in the Midwest and #6 ranked program in the United States. In addition, 100% of our graduates from the past six years indicated that the training they received in our residency program was “excellent.”

| Program Type | Ranking by Reputation | Ranking by Research Output |
|-------------------|-----------------------|----------------------------|
| All U.S. programs | 6 | 9 |
| Midwest programs | 1 | 3 |

Michigan Medicine

For our incoming resident cohort, we received 450 applications to fill 8 open slots. The number of applications increased from 435, in spite of the smaller number of graduating medical students applying to pathology programs across the country. We had an exceptionally-talented pool of applicants and were able to recruit high-caliber residents from a wide geographic region. Seven of our 2020 incoming first-year residents matched in AP/CP and one matched in CP. All eight were highly ranked by UM in the National Residency Matching Program (NRMP) match. Our incoming resident class consisted of medical school graduates from across the United States, including:

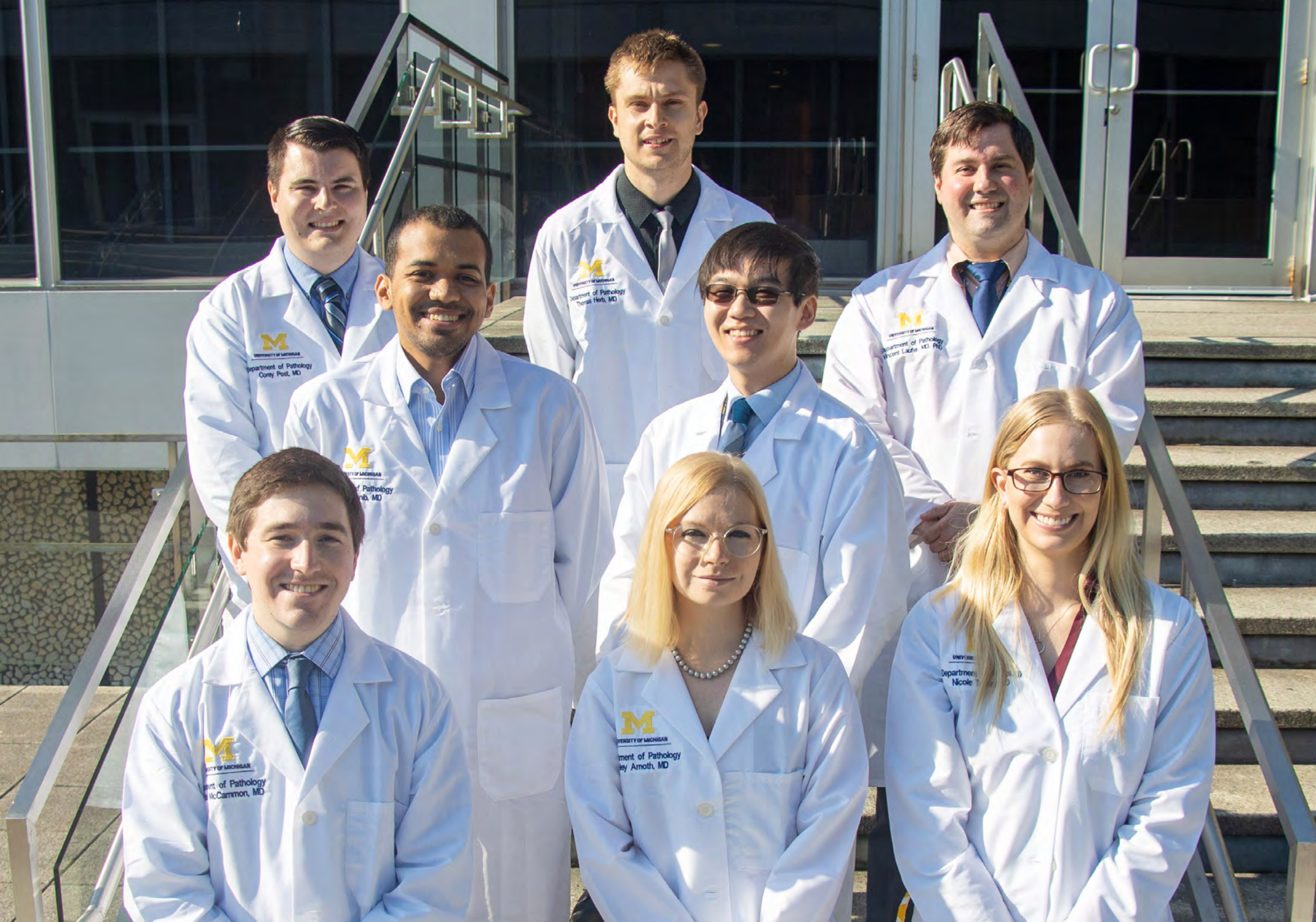
- **Haley M. Amoth, MD** / University of North Dakota School of Medicine and Health Sciences
- **Thomas M. Herb, MD** / Pennsylvania State University College of Medicine
- **Vincent A. Laufer, MD, PhD** / University of Alabama School of Medicine



Carol Farver, MD
Director, Division of Education Programs



Kristine Konopka, MD
Director, Residency Training Program



UNIVERSITY OF MICHIGAN
Department of Pathology
Corey Post, MD

UNIVERSITY OF MICHIGAN
Department of Pathology
[Name obscured], MD

UNIVERSITY OF MICHIGAN
Department of Pathology
Thomas Herb, MD

UNIVERSITY OF MICHIGAN
Department of Pathology
[Name obscured], MD

UNIVERSITY OF MICHIGAN
Department of Pathology
[Name obscured], MD

UNIVERSITY OF MICHIGAN
Department of Pathology
[Name obscured], MD

UNIVERSITY OF MICHIGAN
Department of Pathology
[Name obscured], MD

UNIVERSITY OF MICHIGAN
Department of Pathology
[Name obscured], MD

- **Nathan J. Mc Cammon, MD** / The University of Texas Southwestern Medical School
- **Corey S. Post, MD** / University of Arkansas for Medical Sciences College of Medicine
- **Fysal Shennib, MD** / University of Oklahoma College of Medicine
- **Nicole (Nikki) K. Tomm, MD** / University of Minnesota Medical School
- **Maxwell D. Wang, MD** / Tulane University School of Medicine

Our residency curriculum consists of daily didactic, gross, or slide presentations, 13 AP and 7 CP core subspecialty rotations, quality improvement course, Path 862 Translational Pathology course (combined with PhD students), and ASCP Lab Management University with certification.

A vibrant and varied morning Pathology Educational Series takes place most mornings at 8 am, from September through mid-June. In 2019-2020, there were approximately 110 conferences, most offering CME credit. They were presented by visiting faculty from other institutions, residents, fellows, staff, and departmental faculty. The morning conference series may be the one venue that most often draws together residents, fellows, AP faculty, and CP faculty. At the end of March, these conferences were changed to virtual formats rather than live.

In collaboration with our Division of Quality and Healthcare Improvement, our first- and second-year residents participated in quality improvement and patient safety projects as part of our quality improvement curriculum. Residents worked through web-based learning modules, attended lectures and discussions, and worked in teams on clinically-focused quality improvement projects. Data for knowledge assessment tests indicate a trend toward continuous improvement of the post-test mean scores, with significantly improved post-test over pre-test scores in each of the four years the curriculum has been administered.

Our residents are highly-engaged members of the medical and

pathology communities with many serving in local, regional, and national organizations (*see chart on pg. 67 of the Appendix*).

Six residents successfully completed residency training in FY20. Four are continuing their training at U-M in surgical pathology, gynecologic pathology, dermatopathology, and hematopathology. The remaining two have secured full-time appointments outside of U of M with one returning to fulfill a military appointment.

Key achievements of our graduating residents include:

- All graduating residents earned certificates in Lab Management University
- All graduating residents participated in at least one cycle of the QI curriculum
- All graduating residents participated in a CAP inspection or mock inspection
- Two graduating residents completed the Healthcare Administration Scholarship Program, a 2-year certificate-level program covering various topics in healthcare administration, culminating in a senior administrative project.
- Our 5-year certification rate is 96% for first-time takers.

Pathology Fellowship Program

The Department of Pathology offers 9 ACGME-approved fellowships with 16 approved positions plus an additional 8 clinical fellowship programs offering 11 positions.

On July 1, 2019, we welcomed:

- Blood Banking and Transfusion Medicine Fellow
Zeinab Moussa, MD
- Breast Pathology Fellow
Helen Worrell, MD
- Chemical Pathology Fellow
David Manthei, MD, PhD



Emily McMullen, MD
Chief Resident



Laura Griesinger, MD
Assistant Chief Resident



Ania Owczarczyk, MD, PhD
Assistant Chief Resident



Amanda Kitson, MD
HO IV



Chelsea Styles, MD
HO IV



Burke Van Norman, MD
HO IV



Nicholas Zoumboros, MD
HO IV



Krista Chain, MD
HO III



Ashley Bratt, DO
HO III



Cisley Hines, MD
HO III



Alex Taylor, MD
HO III



Margaret Fang, MD
HO II



Efrain Gutierrez-Lanz, MD
HO II



Justin Kelley, MD, MPH
HO II



Lauren Kroll-Wheeler, MD
HO II



Tim Miller, MD
HO II



Catherine Perez, MD
HO II



William Perry, MD, MPH
HO II



Batoul Aoun, DP
HO I



Geoffrey Halling, MD
HO I



Ryan Landvater, MD
HO I



David Nai, MD
HO I



Emile Pinarbasi, MD, PhD
HO I



Jaclyn Plotzke, MD
HO I



Julianne Szczepanski, MD
HO I



Katelyn Zebrowski, MD
HO I



Haley Amoth, MD
Incoming HO I



Thomas Herb, MD
Incoming HO I



Vincent Laufer, MD, PhD
Incoming HO I



Nathan McCammon, MD
Incoming HO I



Corey Post, MD
Incoming HO I



Fysal Shennib, MD
Incoming HO I



Nicole Tomm, MD
Incoming HO I



Maxwell Wang, MD
Incoming HO I

2019-2020 Pathology Residents



Madelyn Lew, MD
 Director, Medical School
 Pathology Education Curriculum

- Cytopathology Fellows
Craig Cousineau, DO, MPH and Brian Soles, MD
- Dermatopathology Fellow
Carole Bitar, MD
- Forensic Pathology Fellow
Teresa Nguyen, MD
- Gastrointestinal Pathology Fellow
Sara Hall, MD
- Genitourinary Pathology Fellow
Eman Abdulfatah, MBBCh, MSc
- Gynecologic Pathology Fellow
Abubaker Elshaikh, MD
- Hematopathology Fellows
Laura Baugh, DO, PhD and Lauren Stanoszek, MD, PhD
- Molecular Genetics Fellow
Jonathan Mowers, MD, PhD
- Neuropathology Fellows
Kyle Conway, MD (year 2) and Yelena Fudym, MD
- Pathology Informatics Fellow
Jacob Abel, MD
- Pediatric Pathology Fellow
Caroline Simon, MD
- Pulmonary Pathology Fellow
Laurence Briski, MD
- Surgical Pathology Fellows
Aaron Belknap, MD, Michella Whisman, MD, and Shula Schechter

Medical Student Teaching

The Department has a long history of playing an integral role in pre-clinical medical student education. In Foundations of Medicine

2, one of the first sequences encountered by medical students in the Scientific Trunk, we introduce the foundational principles of Pathology – Cell Injury & Death, Inflammation, and Neoplasia. This lays the groundwork upon which students build in subsequent organ-based blocks. Lectures and laboratories are conducted by many pathology faculty members including Madelyn Lew, Scott Owens, Evan Farkash, Scott Bresler, Alexandra Hristov, Allecia Wilson, Kristine Konopka, Paul Killen, Aaron Udager, Karen Choi, Jiaqi Shi, Angela Wu, Tom Giordano, Andrew Sciallis, May Chan, Charles Ross, Laura Cooling, Sandra Camelo-Piragua, Andrew Lieberman, Stephanie Skala, and Paul Harms. Under the direction of Dr. Madelyn Lew, Director of Medical Student Education for the Department of Pathology, our faculty members are working to continue integrating pathology content with other clinical and basic science elements in blocks and to incorporate new interactive methods of delivering education material.

In the *Surgery & Applied Sciences Clerkship*, students partake in a week-long pathology rotation that exposes them to various facets of pathology. For this clerkship, Madelyn Lew has utilized feedback from students, house officers, and faculty to re-design the curriculum, to incorporate educational grossing and microscopic sessions directed specifically to medical students. Madelyn Lew, Kristina Davis, and Stephanie Skala will be working together to launch the revamped curriculum in January 2021. Using these sessions along with case-based small group sessions, web-based interactive modules, and supplemental electronic resources, students will consolidate foundational principles learned in the Scientific Trunk, enhance their understanding of clinicopathologic correlations, and increase lab stewardship.

In their third and fourth years of the medical school curriculum, students enroll in the Branches curricula. In the Branches, pathology faculty participate as mentors and career advisors for the Diagnostics & Therapeutics Branch as well as Science Consultants for Branch students preparing their Patient Based Scientific Inquiry (PBSI). Branch students can also participate in a variety of integrated electives that include multiple disciplines to enhance their understanding of disease process, presentation, and management within the pathology department.



Eman Abdulfatah, MBBCh, MSc



Jacob Abel, MD



Laura Baugh, DO, PhD



Aaron Belknap, MD



Carole Bitar, MD



Lawrence Briski, MD



Kyle Conway, MD



Craig Cousineau, DO, MPH



Abubaker Eishaikh, MD



Sara Hall, MD



David Manthei MD, PhD



Zeinab Moussa, MD



Jonathan Mowers, MD, PhD



Teresa Nguyen, MD



Shula Schechter, MD



Caroline Simon, MD



Brian Soles, MD



Lauren Stanoszek, MD, PhD



Michella Whisman, MD



Helen Worrell, MD

Graduating Fellows 2019-2020

| Fellow | New Position | Institution |
|-------------------|---------------------------------------|--------------------------------------------------|
| Eman Abdulfatah | Assistant Professor | Michigan Medicine, Ann Arbor |
| Jacob Abel | Molecular Genetic Pathology Fellow | Michigan Medicine, Ann Arbor |
| Laura Baugh | Molecular Genetic Pathology Fellow | University of Colorado, Aurora, CO |
| Aaron Belknap | Genitourinary Pathology Fellowship | Michigan Medicine, Ann Arbor |
| Carole Bitar | <i>Pending</i> | — |
| Lawrence Briski | Assistant Professor | University of Miami, Miami, FL |
| Kyle Conway | Assistant Professor | University of Iowa, Iowa City, IA |
| Craig Cousineau | Pathologist | Michigan Diagnostic Pathologists, Southfield, MI |
| Abubaker Elshaikh | Assistant Professor | Baylor College of Medicine, Houston, TX |
| Sara Hall | Pathologist | Great Lakes Pathologists, Milwaukee, WI |
| David Manthei | Assistant Professor | Michigan Medicine, Ann Arbor |
| Zeinab Moussa | Medical Director | CSL Plasma, Jackson, MI |
| Jonathan Mowers | Pathologist | Michigan Diagnostic Pathologists, Southfield, MI |
| Teresa Nguyen | Assistant Professor | Michigan Medicine, Ann Arbor |
| Shula Schechter | Gastrointestinal Pathology Fellowship | Michigan Medicine, Ann Arbor |
| Caroline Simon | Pediatric Pathology Fellowship | Michigan Medicine, Ann Arbor |
| Brian Soles | Pathologist | PSA Banner Baywood Hospital, Mesa, AZ |
| Lauren Stanoszek | Assistant Professor | University of Toledo, Toledo, OH |
| Michella Whisman | Bone & Soft Tissue Fellowship | Michigan Medicine, Ann Arbor |
| Helen Worrell | Pathologist | Beaumont Hospital, Troy, MI |



Zaneta Nikolovska-Coleska, PhD
Director of Molecular and Cellular
Pathology Graduate Program

Pathology Elective Rotation

The *Pathology Elective* experience, under the direction of Dr. Madelyn Lew, allows students to take a closer look at the daily practice of academic pathologists across multiple subspecialties. Throughout this rotation, students select cases to write-up in order to enhance their understanding of clinicopathologic correlations. Additionally, students are required to write an in-depth paper about a topic within Pathology that correlates to their own personal or career interests. While many of the students rotating in our elective may choose other fields of practice, a distinct subset take part in our Career Exploration elective to evaluate Pathology as a possible career choice. For these students, individualized mentoring is provided by faculty in the department.

Molecular and Cellular Pathology Graduate Program

The Molecular and Cellular Pathology Graduate Program (MCP) is one of the Program in Biomedical Sciences (PIBS) graduate programs and is supported through the Department of Pathology. The MCP Graduate Program, under the direction of Dr. Zaneta Nikolovska-Coleska, has 40 Pathology research mentors/labs from which to choose and 20 students performing their PhD thesis research in Pathology Department laboratories during FY20.

In August 2019, our new MCP and PIBS students participated in a half-day event to discuss the program and to learn about available research rotation projects. Once the students selected their laboratory, they were encouraged to work with their mentors to attend mentoring sessions offered by Rackham's Office of Student Success and to prepare their mentoring plan. At the first thesis committee meeting, students present their proposal written in an R21 format.

Each year, the Director of the MCP meets with the students to discuss their progress. In addition, students are invited to an annual MCP Student Council meeting to hear students' feedback, opinions, and suggestions. This is to ensure students remain on track and their needs are being adequately addressed during their graduate studies.

Students are also engaged with outreach and professional

development activities to build their mentoring skills with younger students and undergraduates. In FY20, the students participated in:

- Science Olympiad tutor
- Developing Future Biologists
- miLEAD Consulting
- Michigan Medicine No One Dies Alone program
- UM Museum of Natural History, Science Communications Fellow
- MiSciWriters
- ComSciConversations

In addition, the students organized the Department Research Symposium, held on November 15, 2019. They invited Dr. Robert Roeder, The Rockefeller University, as their keynote speaker.

To address the social needs of the MCP students, a number of events are held each year, including a traditional Student/Faculty fall picnic at Island Park, a happy hour student/faculty mixer during the school year and an ice cream social in the summer.

During this fiscal year, four students successfully completed their preliminary exams, which allowed them to pass to candidacy during their second year and begin to focus on their research thesis work. (See *Appendix pg. 75*) In addition, six students graduated with their PhD:

| Graduate | Current Company |
|-----------------------|--------------------------------------------------------|
| Carrie-Anne Malinczak | Postdoctoral Fellow, University of Michigan |
| Carl Engelke | Medical Student, University of Michigan Medical School |
| Andi Cani | Postdoctoral Fellow, University of Michigan |
| Sabra Dhomerji | Postdoctoral Fellow, Stanford University |
| Jacqueline Mann | Postdoctoral Fellow, University of Pittsburgh |
| Paloma Garcia | Unknown |

Our graduate students continue to be successful in obtaining prestigious research awards and extramural grants during their graduate studies. The following awards were received this year:

| Student Name | Award |
|-----------------|-----------------------------------------------------------|
| Samantha Kemp | NIH F31 fellowship |
| Abhijit Parolia | NIH/NCI F99/K00 pre-doc to post-doc transition fellowship |
| Abhijit Parolia | AACR Scholars-In-Training Award |
| Abhijit Parolia | PIBS Excellence in Research Award |
| Abhijit Parolia | MCP Outstanding Research Award |
| Michael Pitter | National Cancer Institute Diversity Award |

Training grants were received by several MCP students including: Angela Guo and Alexander Monovich from Training in the Biomedical Research of Aging; Jessica McAnulty, Brian Basinski and Alec Chu from Training Program in Translational Research. Two students, Samantha Kemp and Rita Avelar obtained Rackham travel awards, to attend the AACR special conference in pancreatic cancer and the AACR Advances in Ovarian Cancer Research meetings, respectively, and present their research work.

The MCP students regularly publish their research work in high-impact peer-reviewed journals. This year three first-author manuscripts were published by the following students: Abhijit Parolia and colleagues in *Nature*, 2019 and *Molecular Oncology* 2019; and Siva Kumar Natarajan and colleagues in *Cancers*, 2019. Eleven co-author manuscripts were published by the following students: Rita Avelar et al. *Oncogene*, 2020 and *Nature Communications*, 2020; Derek Dang et al. *Neuro-Oncology*, 2020; Sanjana Eyunni et al. *Nature Communications*, 2020; Angela Guo et al. *Scientific Reports*, 2020 and *Science Advances*, 2020; Samantha Kemp et al. *Cancer Discovery*, 2020; Thaddeus Kunkel et al. *BMC Medicine*, 2019; Sahiti Marella et al, *Journal of Allergy and Clinical Immunology*, 2020; Jessica McAnulty et al. *Nature Communications*, 2020 and Abhijit Parolia et al. *Molecular Cell*, 2020.

Translational Pathology Training Grant

The NIH NIGMS T32 Training Program in Translational Research, directed by Drs. Andrew Lieberman and Zaneta Nikolovska-Coleska, was funded and started on July 1, 2016 and supported 4 pre-doctoral trainees for year 4 of the 5-year cycle.

| Trainee | Academic Program | Mentor | Years Trained |
|--------------------|--------------------------------|-----------------------|---------------|
| Thaddeus Kunkel | Molecular & Cellular Pathology | Dr. Andrew Lieberman | 2nd |
| Filipe Cerqueira | Microbiology & Immunology | Dr. Nicole Koropatkin | 2nd |
| Jessica McAnulty | Molecular & Cellular Pathology | Dr. Analisa DiFeo | 1st |
| Anna Michmerhuizen | Cellular & Molecular Biology | Dr. Corey Speers | 1st |

Strongly affiliated with the T32 TPTR Program

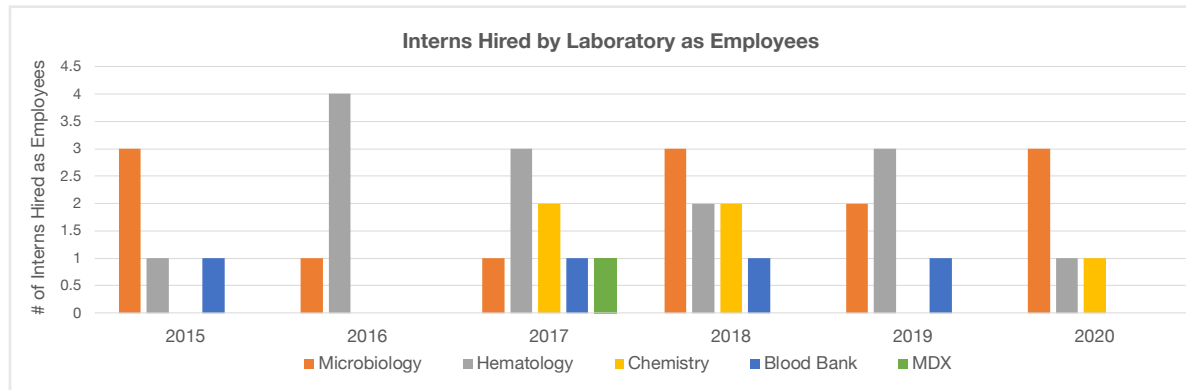
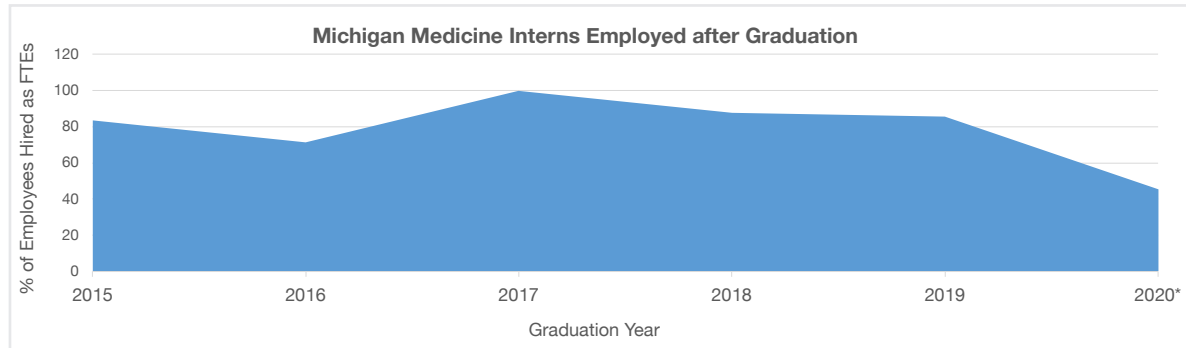
| | | |
|------------------|--------------------------------|---------------------------------------------------------------|
| Andi Cani | Molecular & Cellular Pathology | Dr. Scott Tomlins |
| Hanjia Guo | Molecular & Cellular Pathology | Dr. David Lombard |
| Lucas Huffman | Neuroscience | Dr. Roman Giger |
| Samantha Kemp | Molecular & Cellular Pathology | Drs. Marina Pasca di Magliano, Howard Crawford & Celina Kleer |
| Karson Kump | Chemical Biology | Dr. Zaneta Nikolovska-Coleska |
| Shawn Whitefield | Microbiology & Immunology | Dr. Evan Snitkin |

This year, the first three trainees funded by the T32 training program graduated and successfully continued their careers in the biomedical research workforce focusing on translational research:

- Shawn Whitefield is a clinical microbiology fellow at University of North Carolina
- Andi Cani, recipient of the UM Precision Health Scholars Award in 2018, is a postdoctoral fellow at University of Michigan
- Karson Kump, recipient of the American Association for Cancer Research Scholar-in-Training Award 2020, is a consultant at Health Advances.

Postdoctoral Research Fellows

The department is also home to 68 postdoctoral research fellows working in more than 20 laboratories within Pathology. These research fellows are training under the supervision of their faculty



mentors, who provide them with funding and laboratory space to continue their research efforts until they are able to become successful, independent investigators. Each postdoctoral fellow's training is unique to the needs of the fellow, their research interest, and the mentoring of their faculty lead.

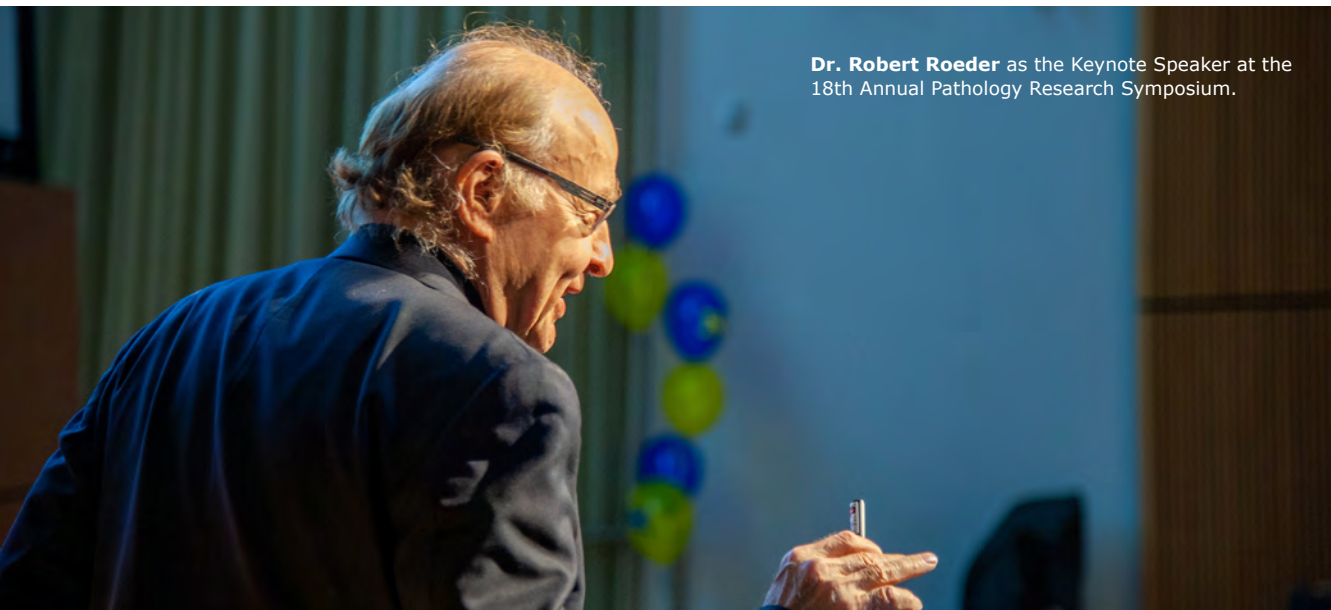
Medical Laboratory Scientists

The Department of Pathology's Education Division has been training Medical Laboratory Scientists for decades. Currently, two internship classes are offered annually with two students selected from each of these National Accrediting Agency for Clinical Laboratory Science (NAACLS) accredited universities: Eastern Michigan University, Ferris State University, Michigan State University, Wayne State University, Michigan Technological University, and Grand Valley State University. To be able to graduate from a NAACLS accredited medical laboratory science program, students must complete an internship in the field following their classroom programs. This makes them eligible to sit for the American Society for Clinical Pathology (ASCP) exam to be certified to work in a clinical laboratory.

Interns rotate through each of our labs in pathology, with schedules customized to meet the needs of each program and to ensure the proportion of time spent in each lab is consistent with coverage on the ASCP exam. Since 2015, a full 85% of interns have been hired to work in our labs.

Conferences and Symposia

- **New Frontiers in Pathology**, October 31 – November 2, 2019. A James French honored lecturer was Dr. Robert H Young, a Robert E. Scully Professor of Pathology from Harvard Medical School. His lecture provided a fascinating history of and differential diagnoses for granulosa cell tumors, Sertoli cell tumors, yolk sac tumors, and dysgerminoma.
- **18th Annual Pathology Research Symposium**, November 15, 2019. The symposium featured a keynote speaker, Dr. Robert Roeder, Arnold and Mabel Beckman Professor, The Rockefeller University, talks and posters by our students and faculty, as well as a career panel with experts from different career paths.



Dr. Robert Roeder as the Keynote Speaker at the 18th Annual Pathology Research Symposium.

- **3rd T32 Retreat**, November 14th, 2019. At this event the trainees presented their translational research projects and the keynote speaker was Wafik El-Deiry, MD, PhD, FACP, Associate Dean of Oncological Sciences, Warren Alpert Medical School, Brown University.
- **11th Annual CHAMP Research Symposium**, February 7, 2020. The keynote address was given by Dr. David Klimstra, the James Ewing Alumni Chair of Pathology at Memorial Sloan Kettering Cancer Center, who presented “*Diagnostic, Prognostic, and Theragnostic Assessment of Pancreatic Neuroendocrine Neoplasms.*” Following the keynote address, Dr. Laurie Griesinger, the 2020 Giesen Award recipient, gave this year’s Giesen Lecture for her abstract “*Molecular Profiling of Penile Intraepithelial Neoplasia (PeIN) Highlights Subtype-Specific Recurrent and Unique Oncogenic Driving Alterations.*”
- **Mucosal Immunology Symposium**, March 6, 2020. The Department of Pathology hosted the 2020 Mucosal Immunology Symposium in collaboration with the Society for Mucosal Immunology and the Mary H. Weiser Food Allergy Center. Dr. Nicholas Lukacs, Scientific Director of the Mary H. Weiser Food Allergy Center, gave the featured keynote address. Dr. Lukacs discussed the importance of pursuing a topic that you love within the field of science.

A number of other symposia were canceled or postponed due to the coronavirus pandemic.

In addition, research seminar series are held weekly highlighting research from our own faculty and trainees as well as research conducted by invited guest lecturers. This year were invited the following speakers: David Shechter, PhD (Albert Einstein College of Medicine); Roberd Bostick, MD, MPH (Emory University); D. Joseph Jerry, PhD (University of Massachusetts – Amherst); Mary Armanios, MD (Johns Hopkins University); Daniel Promislow, PhD (University of Washington); Bjoern Schwer, MD, PhD (University of California, San Francisco); Rozalyn Anderson, PhD (University of Wisconsin); Joseph Bauer, PhD (University of Pennsylvania); Paul Monga, MD (University of Pittsburgh); Ning Dai, PhD (Rutgers University); Daniel Starczynowski, PhD (Cincinnati Children’s Hospital); Jinfang (Jeff) Zhu, PhD (NIH); Tanja Gruber, MD, PhD (St. Jude Children’s Research Hospital).

Videos: (below) See more videos from the department’s YouTube account: www.youtube.com/umichpath



Watch Recap: New Frontiers in Pathology 2019



Watch Recap: Mucosal Immunology Symposium 2020



Watch Recap: 11th Annual CHAMP Research Symposium

Pathology Informatics



Ulysses Balis, MD
Director, Pathology Informatics

The Division of Pathology Informatics (PI), which serves as one of the functional units of the overall Pathology Department, serves the tripartite missions of the department, including clinical operations support, original research, and education. As an informatics division, it is somewhat unique among contemporary academic pathology departments, in that it maintains both its own embedded teams of technical staff IT specialists and associated IT infrastructure, while still maintaining active dialog and alignment with the Health Enterprise’s central IT group. This unique governance model allows the division to maintain its critically needed self-autonomy with respect to project oversight and prioritization, while at the same time leveraging consistent best-practice IT standards and methodologies, as determined by the health system at large. It affords the division both the ability to carry out internal prioritization of the department’s many projects, as well as the ability to independently carry out original IT development efforts.

In addition, the division hosts its own active thrusts in fundamental areas of information technology, machine vision, and deep learning research, including computational imaging of WSI subject matter, asset tracking solutions, computational pathology, natural language processing, and medical information interoperability. Fundamentally, PI operates as a service unit within the greater department, covering a wide range of operational, strategic, and educational functions, with these various missions tied together by a centrally-governed team of superbly-trained information technology specialists who, at the same time, possess substantial familiarity with the clinical lab and its associated workflows.

The division is comprised of 3 faculty, one informatics fellow, and 43 full- or part-time staff. The critical mass of three full-time informatics faculty has allowed for the continued assignment of effort towards both intramural and extramural academic endeavors, with it still being the case that U-M’s PI division remains the largest and fully Clinical Informatics-boarded Pathology Informatics academic unit in the US.

The 2020–2021 academic year was particularly challenging for the informatics division, in that routine operational responsibilities were challenged by the incremental requirements of supporting the department’s response to the COVID-19 pandemic. One area where the division expended significant efforts was in the formulation of a real-time, web-accessible dashboard to allow for simplified viewing of COVID testing performance metrics. Based on use of the R programming environment, which is well recognized for its rapid prototyping capabilities, informatics division was able to stand up not one, but an entire portfolio of real-time operational metrics surrounding COVID testing in the course of three weeks. In the latter part of the academic year, the initial COVID dashboard was extended to also include geospatial metrics papers concerning infection rates in the state of Michigan, as well as metrics concerning the recently added serologic testing for COVID.

This past academic year was also a very busy period for our operations division, which carried forward a number of remaining tasks associated with the department’s recent relocation to the NCRC campus, with example projects being the completion of workstation installations (over 100) and peripheral device installations in both the lab and office areas (over 1500 devices). In tandem, the Informat-

ics Division continued in its mission of supporting the PRR project (phase 2) by virtue of its participation with IT and AV planning efforts, as well as the design and procurement of over 70 incremental desktop workstations intended for the new space at University Hospital. Additionally, the Informatics Desktop Team was an integral component of the ongoing instrumentation and workstation staging efforts at University Hospital, as PRR phase 2 commenced.

This past year, the Informatics Division completed a number of operational projects in partnership with the enterprise-at-large, including:

- Label Printer deployment at ten locations throughout University Hospital and the greater health system
- Configuration of label printers on COVID floors, and subsequent removal of printers from COVID floors.
- Fundamental reengineering and improvement of the SoftID specimen label format
- Assistance, at the enterprise level, of engaging the vendor and identifying and swapping out affected Zebra Power Bricks, which had been identified as a potential fire risk.
- Upgraded or replaced all PC's in the department to allow for uninterrupted operation on the Windows 10 platform: >100 faculty machines and >600 lab and research machines
- Conversion of the on-site legacy data backup for the prior Cerner-based PathNet LIS lab information system archive to a cloud-based repository (Cerner Charon Solution)
- Phlebotomy cart refurbishment (> 40 carts)
- Continued in its provisioning of routine daily operational support, which included 700 new account requests, ~5,000 HIM-originated patient identity merges, ~1500 MLabs-originated patient identify merges, >6,000 patient demographic identify changes, and 12,475 gross images' metadata updated in SoftPathDX.

In terms of academic efforts, the Informatics Division witnessed an exceptionally productive year, with continuing funding support from two NIH center grants, and two new awards (Balis Co-I for one and PI for the other), including an unrestricted grant from Agilent for \$55,000 to support bridging technologies for transcriptomic histology investigations. Faculty of the division published more than 25 publications, and delivered 10 national or international invited keynote presentations. Technology generated by faculty of the division resulted in three disclosures and one awarded patent, over the preceding academic year. The division continues in its tradition of having not one, but two, faculty members on the Clinical Informatics test examination committee, and one faculty member serving on the American Board of Medical Specialties, as its chair of the Digital Information Technology Advisory Committee. Finally, the Division serves as the co-secretariate for the International Pathology Informatics Summit, the premier annual meeting covering all topics of Pathology Informatics.

Division of Quality & Healthcare Improvement



Scott Owens, MD
Director, Division of Quality and Health Improvement

The Division of Quality and Health Improvement (DQHI) continued to serve the Department of Pathology and Michigan Medicine patients with a variety of quality improvement projects in FY20. Winter/Spring 2020, however, saw DQHI affected by the unprecedented COVID pandemic, bringing changes and challenges to our Divisional operations and structure, as well as opportunities to rethink how we work. In response to the mandates for physical and social distancing, DQHI personnel have been working largely off-site since March, 2020, but with little in the way of disruptions or slowdowns in progress. In response to the fiscal challenges posed by decreased clinical activity, the DQHI Manager position has been temporarily reduced to 0.8 FTE, our full-time Data Scientist position has been put on hold until FY21, and safety/preparedness and compliance activities (positions occupied by Jennifer Bell and Andrea Arlen) have been moved out of DQHI and into Anatomic and Clinical Pathology operational management, respectively. Details are discussed in the appropriate sections that follow. In addition to these changes, the DQHI team provided *ad hoc* support for the Department and the institution more broadly during the crisis, with members pitching in to do everything from specimen transport to volunteering in the laboratories.

Education

Under the leadership of Brian Tolle, first- and second-year residents again undertook the annual Quality (QI) Curriculum in partnership with the Education Division. This endeavor was interrupted by the COVID crisis after completion of about half of the scheduled sessions, but learners were able to get a good start on their background

work and selected projects before the hiatus. Plans are underway for this cohort (now second- and third-year residents) to complete these projects in the first half of FY21. In addition, current first- and second-year residents will start the new iteration of the curriculum, including some content updates provided by the institutional Quality Department, in the second half of FY21. Plans are being finalized with Dr. Kristine Konopka, Director of Residency Programs, for the appropriate time in the Pathology Education Series to deliver this content.

Patient Asset Management Initiative (PAMI)

Amy Mapili continued her leadership in FY20 as overall program manager of this departmental initiative aimed at stewardship of patients' physical and digital assets while they are in our care. This year's activity continued a focus on further implementation of PathTrack throughout the enterprise. PathTrack is a digital application developed by our partners in Pathology Informatics that has the ability to interact with the laboratory information system (Soft) to accurately track the movement of assets throughout the Department. This year, with additional work by Jeff Lott and the Pathology Informatics team, PathTrack was deployed for the first time outside of the main medical campus, at Brighton Center for Specialty Care. Continued work is underway that will bring the tool up throughout the enterprise, including off-site locations throughout the State. A robust remote training procedure was developed after the start of the COVID pandemic so that user training at off-site locations could be accomplished with appropriate social distancing. Up- and downstream asset management activities (e.g., specimen ordering and

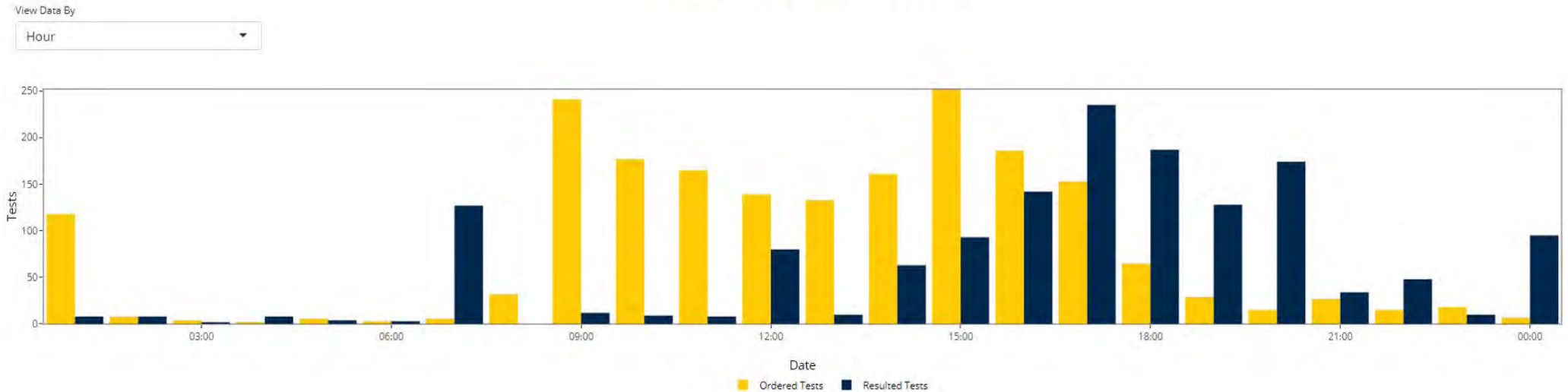
Tests Ordered
1,962

Tests Resulted
1,488

Tests Resulted Positive
117

Percentage Positive
8%

Historical Testing Volumes (All)



collection practices, results reporting, and slide/block archiving and retrieval) are being evaluated for the next phase(s) of the project.

MSTAR

Amy Mapili and Lukas Hager worked in partnership with Michigan Medicine Laboratories (MLabs) leadership on the MSTAR project, with Amy providing project management work for the “Data” cohort/work stream and Lukas providing data analytics and statistical guidance. Lukas also provided data analytics support to the MSTAR consultant team more broadly.

Laboratory Stewardship Initiative/Committee

Spearheaded by Project Manager Jeff Lott, this initiative continues to involve a partnership with leaders in Internal Medicine and the

Michigan Program on Value Enhancement (MProVE; ihpi.umich.edu/featured-work/michigan-program-value-enhancement), centered on the Laboratory Stewardship Committee (LSC), a sub-committee of the institutional Lab Formulary Committee, co-chaired by Jeffrey Warren, MD (Pathology) and Timothy Laing, MD (Rheumatology). Dr. Ashwin Gupta, a Clinical Lecturer and Hospitalist in Internal Medicine with both experience in and enthusiasm for quality initiatives and test utilization-centered projects, shares leadership of the LSC with Lee Schroeder, MD, PhD, Associate Professor of Pathology and Director of Point-of-Care Testing. During FY20, work continued on projects involving partnerships with stakeholders in Internal Medicine and Pathology:

Chart: (above) COVID-19 Laboratory Testing Dashboard.

- In partnership with medical and nursing leadership, as well as MiChart support, a stool charting process to ensure that appropriate patients (i.e., those who have had at least three non-solid stools) are tested for *C. difficile* colitis, has been developed and is in the early phases of deployment.
- Costly and low-yield in-patient thrombophilia testing has effectively been ended as a result of the work of the Laboratory Stewardship Committee.
- Evidence-based reflex ordering systems for anti-nuclear antibody (ANA) and thyroid hormone testing have been deployed. Data analysis/dashboards are being utilized to track usage of these algorithms and to guide P-D-C-A cycles to assess appropriate utilization and further interventions.
- A test utilization dashboard for feedback to providers is in continued development, in partnership with Dr. Hitinder Gurm in Cardiology.
- Duplicative laboratory-based ionized calcium (ICAL) testing is targeted for elimination for those patients who receive an ICAL result on arterial blood gas analysis.
- An effort to eliminate serum amylase testing for patients suspected of having acute pancreatitis is underway in its early phases. Serum lipase alone is the preferred method for diagnosis, as outlined in national “Choosing Wisely” guidelines.

Data Science

Lukas Hager continued his contributions to both the knowledge base and skillset of the DQHI team and a number of data projects during FY20. In addition to supporting the work outlined above in the Laboratory Stewardship section, Lukas worked on exploring the use of data to distribute surgical pathology workload based on case/block/slide volume and personnel availability, using the gastrointestinal (GI) pathology service as a prototype. This was enthusiastically supported by the Director of the GI service as well as the Director of Surgical Pathology. As the COVID crisis took hold,

Lukas’s substantial expertise in data analysis and “Shiny app” coding was leveraged to create dashboards to monitor COVID testing and other key data points for departmental operations (*See pg. 55*). Feedback from our partners in Pathology Informatics indicated that Lukas’s contributions were crucial to the success of these efforts.

During the fourth quarter of FY20, Lukas communicated to DQHI leadership that he was successfully admitted to a Ph.D. program in Economics at the University of Washington, and would matriculate in the Fall of 2020. In light of the financial challenges created by the pandemic, the decision was made to leave the Data Scientist position unfilled for FY21 and to begin recruitment for July 2021 at a later date. In the interim, Lukas will provide part-time support remotely (approximately 8 hours/week), with an ideal goal of leveraging this work to synergize with his Ph.D. studies.

Compliance, Accreditation, Quality, and Safety

FY20 saw the addition of Eleanor (Ellie) Mills as Quality Assurance Coordinator for DQHI. Ellie immediately became involved in a number of places and projects throughout the Department, including in the residents’ QI curriculum, root cause analyses in the operational sphere for CP and AP stakeholders, auditing of the usage of reporting templates/synoptic reports for surgical pathology specimens, and others. During the first half of FY20, Ellie was able to work with Andrea Arlen and Jenny Bell on a laboratory risk assessment tool that could be used to guide quality improvement projects in the laboratories, as well. As mentioned above, the COVID pandemic and subsequent financial response brought significant changes to this part of the DQHI team, with Andrea Arlen moving to the CP division under the management of Kristina Martin, and Jennifer Bell moving to the AP division under the management of Christine Rigney.

COVID19 PCR Tests Ordered and Resulted Compared to Test Capacity as of 2020-10-21



Chart: COVID-19 PCR Tests Ordered and Resulted Compared to Test Capacity as of October 21, 2020.

Finance & Administration



Martin Lawlor
Director, Finance and
Administration

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The Division of Finance and Administration, which is under the auspices of the Office of the Chair, is responsible for the business, operational, and fiscal affairs of the Department of Pathology, as mandated by the policies of the Chair, Michigan Medicine, and the University. In this section, key achievements of the Finance and Administration team are highlighted as well as the supporting services provided by this division. Mr. Martin Lawlor served on various departmental, health system, university, and professional committees including the Ambulatory Care Operating Committee, Cancer Center Ambulatory Care Coordinating Group (co-chair), Executive Committee for the Joint Venture Hospital Laboratories (chair), and the Association of Pathology Chairs – Pathology Department Administrators Committee.

Some key divisional highlights for this academic year include:

- Developed a plan for COVID-19 testing, including multiple testing platforms, and setup testing collection sites – including a tent site at NCRC.
- Developed safety protocols for COVID-19, including social distancing policies and mask compliance policies.
- Continued to make progress on the PRR project by starting the remodeling of the University Hospital clinical laboratories. This is a multiphase project.
- Worked closely with Dr. Parkos and the vice chairs for a very successful recruitment year with many new recruits, including the new Director of Anatomic Pathology.

- Developed and executed a Department-wide economic recovery plan as mandated by Michigan Medicine leadership.

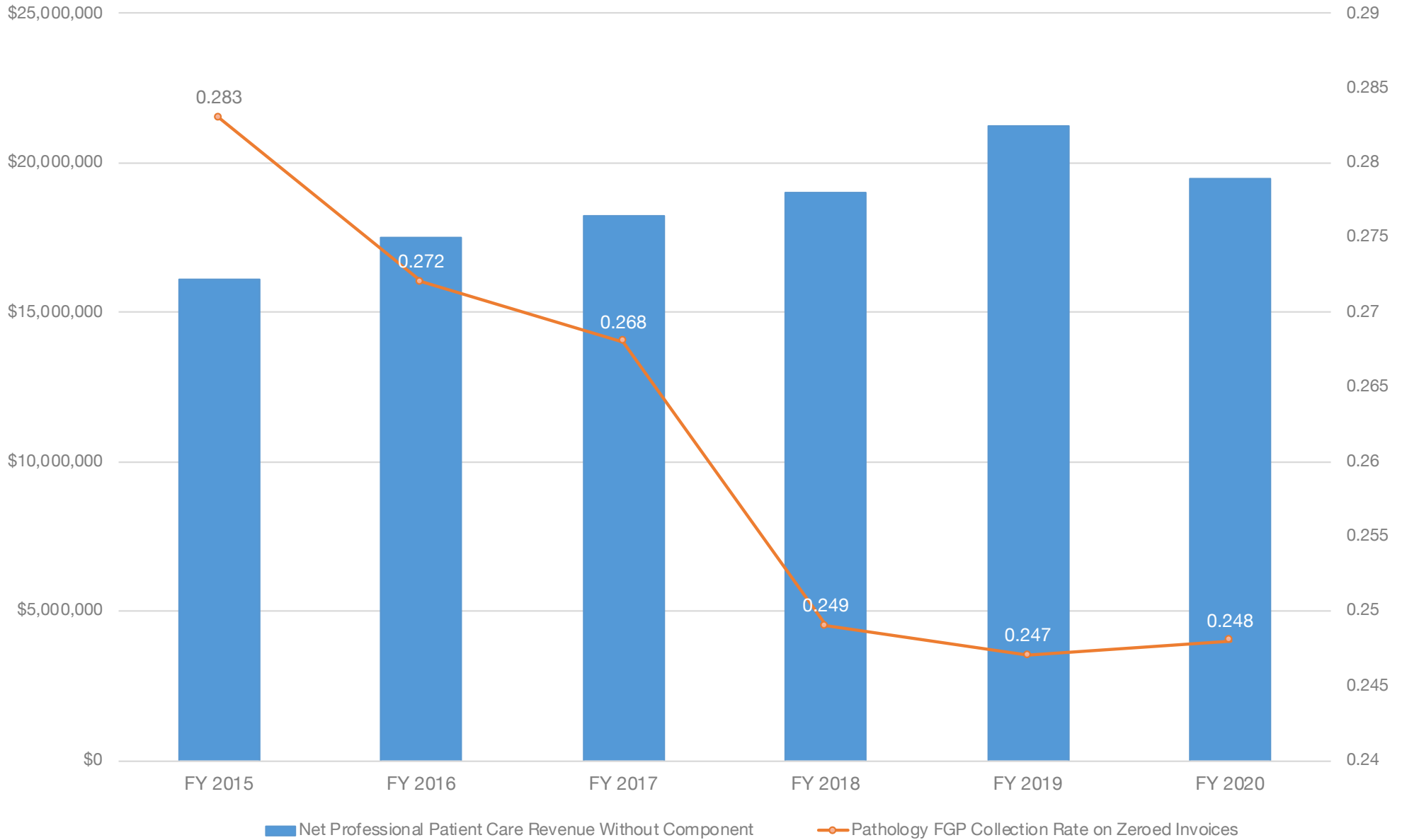
Administrative Support Center

The administrative support center is divided into support services for the pathology laboratories; academic and business affairs; and human resources, faculty affairs, and education.

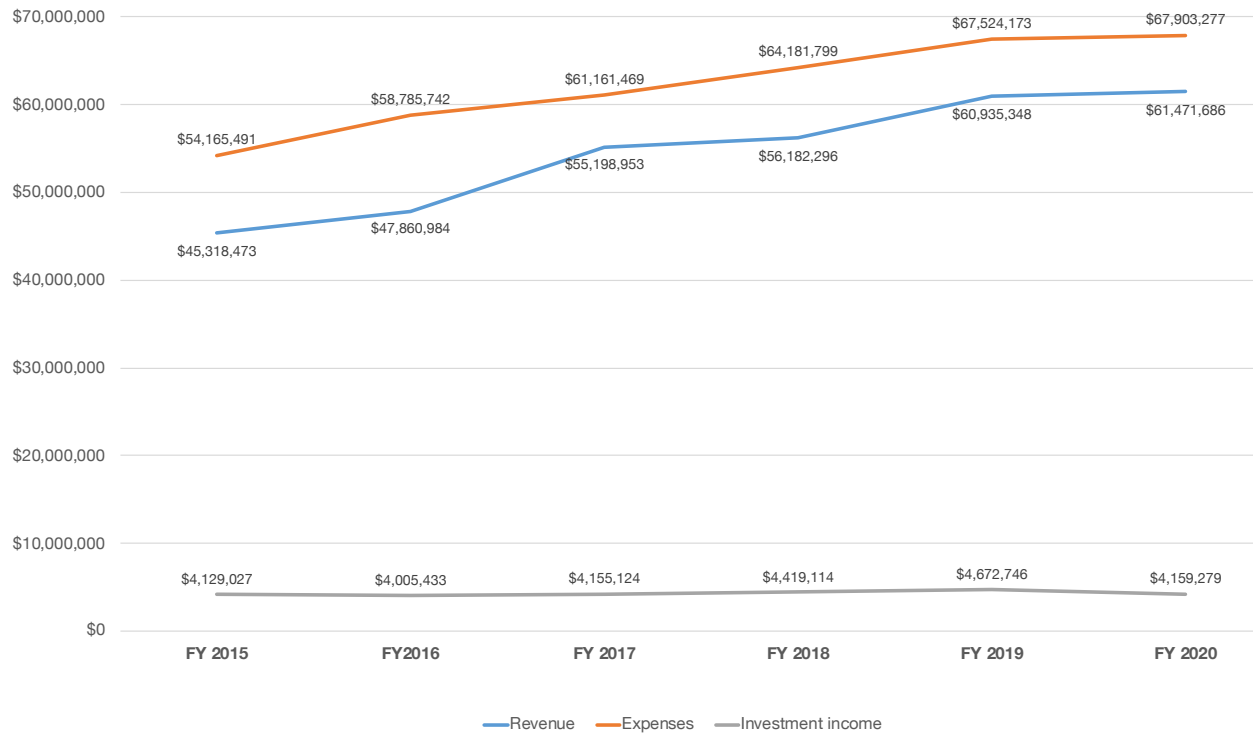
Pathology Laboratories

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 operating expenditures were \$145 million. Pathology is responsible for 9.1% of total hospital gross revenue and 3.6% of total expense. Gross revenue and expenses were impacted by the COVID-19 pandemic. Gross revenue was down 3.31% when compared to FY19 as a result of the forced shutdown of most clinical activities not directly related to the care of COVID patients during the early days of the pandemic. Pathology was instrumental in the development and deployment of testing for the active COVID-19 virus, as well as antibody testing. As such, we were able to mitigate gross revenue losses in other areas as a result of the substantial amount of COVID testing we did from March – June 2020. Microbiology saw a 22.7% increase in gross revenue during the year and most of that increase occurred in the final four months of the fiscal year. Expenses were similarly impacted as a result of increased spending on reagents and supplies tied to COVID-19 testing.

Net Professional Patient Care Revenue Without Component Billing



Pathology Only Revenue and Expense Trend



The administrative support center team worked diligently in FY20 to prepare for and undertake the remodeling of the University Hospital clinical laboratories. The renovation of these spaces were paused during the early months of the pandemic, but began again in earnest over the summer. Led by the PRR team, with the support of the Pathology Informatics team, the renovations proceeded on a modified schedule and without excess disruption. Throughout FY20, our facilities managers and the PRR team diligently addressed issues as they arose, especially with unanticipated issues surrounding logistics of maintaining clinical laboratory operations in the midst of the renovations.

Members of the administrative support center team served as

departmental liaisons with nursing, the office of clinical affairs, office of clinical safety, biomedical engineering, and hospital finance. They served on the quality month committee, pathology diversity, equity and inclusion committee, pathology patient and family advisory council, pathology social media committee, and others. The team addressed patient safety issues, and cooperated on process improvement initiatives with partners such as the Rogel Cancer Center, UH operating rooms, and various medical procedure units.

FY20 Pathology Income Statement

| REVENUE | FY19 | FY20 |
|---------------------------------------------------|---------------------|---------------------|
| Patient Care Revenues | \$20,225,741 | \$19,785,095 |
| UMHS Service Payments | \$8,469,599 | \$10,916,413 |
| Net Total Research (Directs & Indirects) | \$22,187,567 | \$21,498,647 |
| Gifts and Other Income (Wayne/Washtenaw ME, etc.) | \$10,052,440 | \$9,271,532 |
| Total Revenue | \$60,935,347 | \$61,471,687 |

EXPENSES

| | | |
|---------------------------------|---------------------|---------------------|
| Total Salaries | \$49,906,093 | \$51,284,891 |
| Total Non-Payroll Expense | \$17,618,080 | \$16,618,387 |
| Total Operating Expenses | \$67,524,173 | \$67,903,278 |

| | | |
|-----------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Operating Margin (Loss) | (\$6,588,826) | (\$6,431,591) |
| Non-Operating Income and Expense (Includes Investment Income, UMHS Margin Sharing, Departmental Commitments, etc.) | \$5,925,912 | \$8,998,765 |
| Total Margin | (\$662,914) | \$2,567,174 |

Office of Academic and Business Affairs – Medical School

The office of academic and business affairs – medical school, is responsible for all administrative and academic operations associated with the Department, including management of department finances

(budgets, contracts, research grants, forecasts, and analyses), as well as clinical billing (professional and technical front-end operations), in collaboration with the Chair and Administrative Director. Mr. David Golden 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.

The office also manages the Michigan Medicine and All Funds expenditures and forecast processes. Key departmental metrics include:

- Total Medical School All Funds expenditure for FY20 were \$77.9 million and Hospital expenditures were \$145 million.
- Hospital technical gross revenue for FY20 was \$835.7 million, compared to \$864.2 million in FY19, a decrease of 3.3%.
- Professional fee gross charges were \$72.1 million in FY20 compared to \$90.3 Million in FY19.
- Overall gross charges for Pathology's group practice were down 20.0% (\$18.2 million).
- In FY20, our faculty received 56 awards from the NIH and ranked 9th in the nation in funding by the NIH, down from 5th in FY19, and 5th in the nation when considering number of awards received. Total grants submitted in FY20 was \$25,043,287, a decrease of approximately 28% from FY19. Our total sponsored research spending in FY20 was \$32.5 million, down from \$32.7 million in FY19.

Business Affairs

Business Affairs is responsible for oversight of all accounting and financial transactions for the Department as well as ensuring appropriate hospital and medical school funds flows. Our billing office handles all send-out, component, and MLabs billing, and any inter-departmental, MLabs or Hospital patient billing error corrections. The grants management office handles the day-to-day management of research funds to ensure compliance with funder requirements,

and to ensure the funds are distributed appropriately both within Pathology as well as across internal and external research groups.

Business Affairs is also responsible for Hospital and Medical School financial reporting and budget preparation for the Department and in administering numerous contracts, including those for the Washtenaw and Wayne County Medical Examiner's Office contracts. As part of the budgeting process, they also develop and maintain the capital equipment process, prepare financial analyses, produce numerous *ad hoc* reports. They also oversee the Pathology Renovation and Relocation project to ensure contract terms are met, budgets are managed, and capital investments are approved according to Michigan Medicine and Pathology procedures, and facilities are prepared for the renovation of University Hospital spaces to occur in late FY21 and FY22. In addition, all faculty and staff effort and funding changes are processed through this unit.

Finance

The Department of Pathology is in a strong financial position and continues to thrive under the leadership of Dr. Charles Parkos and Mr. Martin Lawlor, with endowments and FFAE to support our clinical, research, and educational missions, exceeding \$93.6 million. In FY20, we experienced a smaller gap between our revenues and expenses, with revenues at \$67.8 million, up 2% over FY19 and expenses at \$77.9 million, up 0.6% over FY19, mostly due to decreased staffing needs associated with the pandemic. This resulted in an operating loss of \$10.0 million. The loss was mostly offset by non-operating income (investments, dean's contributions, and other institutional support payments). Including our non-operating income, FY20 ended with a net loss of \$699K. In contrast, in FY19 we experienced a loss of \$2.5 million, as our non-operating income was lower than in prior years.

Michigan Medicine has long-range expansion and upgrades budgeted, including Pathology's Renovation and Relocation Project, that requires greater-than-average net budget increases as compared to those seen over the past decade. As a result, there is significant pressure on Departments to reduce expenses and increase revenues. While our revenues continue to grow, the collection rate is near its lowest point in the past 15 years at just 24.8% of charges. Pathology



Thomas Morrow
Administrative Manager, Clinical Operations



Kristina Martin
Manager, Clinical Operations



Christine Rigney
Assistant Administrator,
Operations, Division of Anatomic Pathology



David Golden
Director, Finance



Christine Shaneyfelt
Financial Analyst Senior,
Hospital



Mike McVicker
Financial Analyst Senior,
Medical School



John Harris
Manager, Research Administration

faculty and staff FTEs have remained relatively flat at 1,205.3 in FY20 versus 1,210.7 in FY19. The combination of the pandemic and the economic recovery plan has forced us to do more with less staffing. Increased workloads and decreased collection rates pose challenges for meeting Michigan Medicine targets for the Department. As a result, filling vacant staff positions has become more difficult. We are grateful to our staff, who have stepped up to the plate to take on additional duties to ensure the missions of Pathology continue to meet and exceed expectations.

We have outstanding faculty and staff who continue to support exceptional scholarship and clinical care. Our Clinical services continue to grow and maintain the highest quality. New educational opportunities continue to attract top trainees and our future looks bright as we move forward into our new facilities, designed for the future. Overall, FY20 has been a tremendous year for our department.

Human Resources, Faculty Affairs and Education

Our Staff Human Resources Team provides support for Pathology's hospital laboratories (approximately 809.17 FTEs) and Medical School support staff, including our research programs (approximately 240.5 FTEs). This includes processing all new hires, promotions, merit increases, orientation, as well as transfers when staff move to other departments, or terminations for those who leave our institution. They also help to coordinate employee recognition events and awards.

Faculty Affairs is responsible to coordinate appointments, reappointments, and promotions for our 173 active faculty and the 29 supplemental appointments in the Department. In FY20, sixteen new faculty joined the Department of Pathology while we bid farewell to fifteen faculty members. Thirteen of our faculty successfully completed the promotion process, *see table to the right*.

Our faculty received numerous awards in recognition of their achievements in academics, research, and clinical service: (*See Appendix on pg 70.*)

The Education Office includes the Residency and Fellowship Training Programs (26 residents and 24 fellows in 9 ACGME and 7 non-ACGME

Faculty Promoted in FY20

| Name | New Rank | Division |
|-------------------------------|------------------------------|----------|
| Andjelkovic-Zochowski, Anuska | Professor | EP |
| Heider, Amer | Clinical Associate Professor | AP |
| Jeruss, Jacqueline | Associate Professor | AP |
| Jing, Xin | Clinical Professor | AP |
| Liu, Yifan | Research Associate Professor | EP |
| Mehra, Rohit | Clinical Professor | AP |
| Qiao, Yuanyuan | Assistant Research Scientist | MCTP |
| Rual, Jean-Francois | Associate Professor | EP |
| Shi, Jiaqi | Clinical Associate Professor | AP |
| Stamatovic, Svetlana | Associate Research Scientist | EP |
| Sung, Lok Man | Clinical Associate Professor | AP |
| Venneti, Sriram | Associate Professor | EP |
| Wilson, Allecia | Clinical Associate Professor | AP |
| Rajendiran, Thekkelnaycke | Associate Research Scientist | MCTP |
| Schroeder, Lee | Associate Professor | CP |
| Wang, Xiaojun (George) | Associate Research Scientist | MCTP |
| Wu, Yi-Mi | Associate Research Scientist | MCTP |

programs), the Medical Student Education Teaching Programs for the M1 and M2 laboratories, and the M4 Clerkship Program, as well as the Molecular and Cellular Pathology PhD program with 20 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. The department also holds two NIH training grants (PIs Nicholas Lukacs, PhD; Andrew Liberman, MD, PhD, Zaneta Nikolovska-Coleska, PhD) which support 4 pre- and 6 post-doctoral trainees. The education office performs the human resource functions for the department's graduate students (31 including 6 non-MCP students with Pathology mentors and 4 training grant trainees).

Office of the Chair

The staff in the Office of the Chair coordinates the Advances in Forensic Medicine and Pathology conference, which was held for its ninth year in FY20. They also reconcile departmental purchasing cards, renew medical licenses, process CME requests for faculty, coordinate and develop departmental communications including the *Inside Pathology* magazine and the Annual Report, and prepare numerous reports and presentations for various meetings. In addition, they provide support to the Chair and Department Administrator, including scheduling, travel arrangements, data collection, event planning, correspondence, committee support, and faculty recruitment.

Community Service

In support of our mission as a non-profit healthcare provider, our faculty and staff engage in numerous service activities throughout the year. Some of the activities our faculty and staff engaged in this year included:

Local Activities (UM, Ann Arbor or Michigan)

- Relay for Life Teams to raise funds for cancer treatment
- Assisted MetroHealth in validating the Verify-Now assay for aspirin and Plavix-specific platelet aggregation
- Gift of Life Michigan board and committee memberships
- Patient and Families Advocacy Committee (PFAC)
- Numerous Medical School and Health System committee leadership/membership, see our list of new leadership positions.
- High school genetics, ethics, Doctors of the Future, and other programs as well as volunteering to coach or direct athletic programs
- High School Ethics Bowl judge
- Service on multiple non-profit boards of directors

National

- Assisted in multiple inspections for College of American Pathologists (CAP), American Association of Blood Banks (AABB), American Society for Histocompatibility and Immunogenetics (ASHI)

- Serving on multiple national and international professional organization boards and committees, see our list of new leadership positions added in FY20.

International

- Exploring transport solutions for patient samples in remote African villages to laboratory testing facilities
- Developing Essential Diagnostic Test List for low resource settings
- Implementing comprehensive 8-marker flow cytometry to accurately diagnose acute pediatric and adult leukemia patients in low-middle income countries, implementing it in Addis Ababa, Ethiopia
- Cervical cancer screening initiative in India

Employee Recognition

The Department of Pathology recognizes the valuable contributions made by our faculty and staff alike. In FY20, we recognized the years of service for faculty and staff who have served for 10, 20, 30, and even 40 years, as well as those who received Above and Beyond Awards, as nominated by their peers. (*Appendix on pg. 76*) The number of employees who have been in the department for over 20 years speaks to the dedication of the employees as well as to the collegial atmosphere of our Pathology Department.

This year we also honored our retirees. (*Appendix on pg 76.*)



Sarah Dudley-Short
Manager, Faculty Affairs

Pathology Relocation & Renovation Project



Christine Baker
Project Manager, PRR

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The Pathology Relocation and Renovation (PRR) Project is a multi-year, multi-phase project embracing the opportunities to relocate a large section of the department into new off-site space at the North Campus Research Complex (NCRC) and to renovate and right-size critical functions within University Hospital. Christine Baker has been with the Department of Pathology for more than six years, and leads this project. She facilitates and manages the tasks needed to design and activate the new spaces, and serves as the liaison to colleagues within Michigan Medicine Facilities and Operations as well as the construction teams led by the Architecture, Engineering, and Construction group.

Construction for Phase 1 of the PRR, which was over 140,000 square feet of newly renovated space at NCRC, finished in FY18. The activation of the new space completed in November 2018. This included several major clinical laboratories as well as key administrative divisions.

The design of Phase 2, the renovation of the laboratory and support spaces at UH, formally finished in 2017, but further revisions and re-phasing continued through early 2019. Phase 2 of PRR is a unique endeavor and challenge—all current labs must remain operational while the new laboratory space is constructed and then activated. The first design effort included a complicated, 19-phase plan, which was revised and edited to reduce the duration of the entire project. Phase 2 now has 5 unique and distinct construction phases, followed by duration of activation.

To prepare for the beginning of Phase 2, temporary spaces were constructed in early FY20 through January 2020, enabling larger



sections of empty laboratory and office space to be available for the construction teams; this was part of the strategy that was devised during the extensive re-phasing of the project. The space was quickly activated, and the resulting empty spaces were turned over for the formal beginning of construction for Phase 2 in late January 2020.

The first construction phase in Phase 2 was scheduled to complete near the end of FY20, but was delayed due to the governor's restriction on non-essential activity related to COVID safety measures. Once construction activities resumed, the timeline was revised and extended out through the first quarter FY21.

Once activated, this first phase will include new laboratory space for Hematology and Chemistry. It also includes a new automation line for the Hematology laboratory, replacing their current line.

The subsequent phases of PRR will build out the remaining sections of the Core Lab, including a new automation line for Chemistry, new Specimen Processing space, new Anatomic Pathology space, and new space for the Microbiology stat-functions. It also includes a Transfusion Medicine neighborhood, with new- and updated space for the Blood Bank, Cellular Therapy, and Apheresis. Finally, the space for the Phlebotomy team and other support spaces will be updated in the final phases of the project.



| Anatomic Pathology Case Volumes | | | | | | | |
|------------------------------------------------|---------------|---------------|---------------|---------------|---------------|----------------|----------------|
| Cytopathology Case Volumes | FY16 | FY17 | FY18 | FY19 | FY20 | 1-YR | 5-YR |
| FNA by Pathologist w/ ROSE | 184 | 169 | 164 | 183 | 142 | -22.40% | -22.83% |
| FNA, No ROSE | 710 | 659 | 687 | 842 | 767 | -8.91% | 8.03% |
| FNA, w/ ROSE | 2,298 | 2,171 | 2,101 | 2,102 | 1,788 | -14.94% | -22.19% |
| Gyn Case | 23,604 | 23,295 | 23,003 | 23,580 | 18,608 | -21.09% | -21.17% |
| Non-Gyn Case | 6,854 | 6,660 | 7,392 | 8,128 | 7,432 | -8.56% | 8.43% |
| Total | 33,650 | 32,954 | 33,347 | 34,835 | 28,737 | -17.51% | -14.60% |
| Dermatopathology Case Volumes | | | | | | | |
| Derm In-House | 16,205 | 15,774 | 16,327 | 15,979 | 13,470 | -15.70% | -16.88% |
| Derm Outside | 6,958 | 7,687 | 7,170 | 7,400 | 6,517 | -11.93% | -6.34% |
| MLabs Derm | 8,409 | 12,238 | 10,398 | 9,748 | 7,549 | -22.56% | -10.23% |
| Total | 31,572 | 35,699 | 33,895 | 33,127 | 27,536 | -16.88% | -12.78% |
| Hematopathology Case Volumes | | | | | | | |
| Hemepath In-House | 1,980 | 1,856 | 1,939 | 2,301 | 2,657 | 15.47% | 34.19% |
| Hemepath Outside | 2,733 | 2,434 | 2,604 | 2,704 | 2,346 | -13.24% | -14.16% |
| Total | 4,713 | 4,290 | 4,543 | 5,005 | 5,003 | -0.04% | 6.15% |
| Neuropathology Case Volumes | | | | | | | |
| Muscle In-House | 175 | 156 | 139 | 86 | 78 | -9.30% | -55.43% |
| Muscle Outside | 194 | 179 | 203 | 266 | 218 | -18.05% | 12.37% |
| Neuro In-House | 748 | 846 | 773 | 834 | 741 | -11.15% | -0.94% |
| Neuro Outside | 380 | 450 | 496 | 521 | 597 | 14.59% | 57.11% |
| Total | 1,497 | 1,631 | 1,611 | 1,707 | 1,634 | -4.28% | 9.15% |
| Ophthalmic Case Volumes | | | | | | | |
| Ophthalmic In-House | 1,276 | 1,248 | 1,311 | 1,455 | 1,367 | -6.05% | 7.13% |
| Ophthalmic Outside | 59 | 61 | 56 | 52 | 73 | 40.38% | 23.73% |
| Total | 1,335 | 1,309 | 1,367 | 1,507 | 1,440 | -4.45% | 7.87% |
| Pediatric and Perinatal Pathology Case Volumes | | | | | | | |
| Fetal Exams | 163 | 178 | 215 | 230 | 215 | -6.52% | 31.90% |
| Peds Autopsy | 30 | 33 | 37 | 27 | 24 | -11.11% | -20.00% |
| Peds In-House | 3,276 | 3,514 | 3,564 | 3,747 | 3,307 | -11.74% | 0.95% |
| Peds Outside | 341 | 351 | 432 | 477 | 406 | -14.88% | 19.06% |

(continued)

| | | | | | | | |
|------------------------------------|---------------|---------------|---------------|---------------|---------------|----------------|----------------|
| Placentas | 1,832 | 1,834 | 2,071 | 2,148 | 1,894 | -11.82% | 3.38% |
| Total | 5,642 | 5,910 | 6,319 | 6,629 | 5,846 | -11.81% | 3.62% |
| Renal Case Voumes | | | | | | | |
| Renal In-House | 1,180 | 1,099 | 1,294 | 1,413 | 943 | -33.26% | -20.08% |
| Renal Outside | 47 | 35 | 48 | 37 | 36 | -2.70% | -23.40% |
| Total | 1,227 | 1,134 | 1,342 | 1,450 | 979 | -32.48% | -20.21% |
| Technical Only Case Volumes | | | | | | | |
| Technical Only | 1,616 | 1,933 | 2,072 | 2,007 | 1,673 | -16.64% | 3.53% |
| Technical w/ Interpretation | | | | 160 | 460 | 187.50% | |
| Total | 1,616 | 1,933 | 2,072 | 2,167 | 2,133 | -1.57% | 31.99% |
| Outside Case Volume | | | | | | | |
| Breast | 1,756 | 1,602 | 1,765 | 1,737 | 1,541 | -11.28% | -12.24% |
| Cardiac | 20 | 9 | 13 | 20 | 21 | 5.00% | 5.00% |
| Cytology | 1,454 | 1,353 | 1,372 | 1,196 | 1,192 | -0.33% | -18.02% |
| Dermatopathology | 6,958 | 7,687 | 7,170 | 7,400 | 6,517 | -11.93% | -6.34% |
| Endocrinology | 552 | 600 | 598 | 613 | 551 | -10.11% | -0.18% |
| Gastrointestinal | 4,942 | 4,963 | 5,088 | 5,220 | 5,043 | -3.39% | 2.04% |
| Genitourinary | 1,771 | 1,872 | 2,038 | 2,148 | 1,959 | -8.80% | 10.62% |
| Gynecologic | 1,285 | 1,443 | 1,480 | 1,696 | 1,571 | -7.37% | 22.26% |
| Head & Neck | 1,198 | 1,192 | 1,300 | 1,366 | 1,255 | -8.13% | 4.76% |
| Hematopathology | 2,733 | 2,434 | 2,604 | 2,704 | 2,346 | -13.24% | -14.16% |
| InterDepartmental Consult | | | 370 | 635 | 356 | -43.94% | |
| Misc. Outside Case | 542 | 8 | 31 | 22 | 9 | -59.09% | -98.34% |
| Muscle | | 1 | 14 | 33 | 29 | -12.12% | |
| Neuropathology | 380 | 450 | 496 | 521 | 597 | 14.59% | 57.11% |
| Ophthalmic | 59 | 61 | 56 | 52 | 73 | 40.38% | 23.73% |
| Pediatric | 341 | 351 | 432 | 477 | 406 | -14.88% | 19.06% |
| Pulmonary | 2,674 | 2,811 | 2,971 | 3,184 | 2,712 | -14.82% | 1.42% |
| Renal | 47 | 35 | 48 | 37 | 36 | -2.70% | -23.40% |
| Soft Tissue | 1,263 | 1,343 | 1,507 | 1,630 | 1,481 | -9.14% | 17.26% |
| Total | 27,975 | 28,215 | 29,353 | 30,691 | 27,695 | -9.76% | -1.00% |

Table 1 : Anatomic Pathology Case Volumes 2016-2020 (From pg. 8)

| Clinical Pathology Billed Test Volumes | | | | | | | | |
|------------------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|--------------|--------------|
| | FY15 | FY16 | FY17 | FY18 | FY19 | FY20 | 1 Yr. | 5 Yr. |
| Clinical Chemistry and Toxicology | | | | | | | | |
| Chemical Pathology | 2,300,846 | 2,545,505 | 2,861,047 | 2,990,055 | 3,165,847 | 2,985,204 | -5.7% | 29.7% |
| Special Chemistry | 615,414 | 659,007 | 642,556 | 650,105 | 714,738 | 649,436 | -9.1% | 5.5% |
| Clinical Chemistry and Toxicology | 2,916,260 | 3,204,512 | 3,503,603 | 3,640,160 | 3,880,585 | 3,634,640 | -6.3% | 24.6% |
| Transfusion Medicine | | | | | | | | |
| Pathology Blood Bank/Bone Marrow | 275,738 | 286,206 | 308,550 | 316,719 | 328,279 | 327,949 | -0.1% | 18.9% |
| Blood Procurement | 93,207 | 67,765 | 61,994 | 64,254 | 66,414 | 59,056 | -11.1% | -36.6% |
| Transfusion/Apheresis | 9,590 | 2,165 | 1,804 | 1,965 | 2,008 | 2,132 | 6.2% | -77.8% |
| Total | 378,535 | 356,136 | 372,348 | 382,938 | 396,701 | 389,137 | -1.9% | 2.8% |
| Other Clinical Laboratories | | | | | | | | |
| Hematology/Coagulation | 79,130 | 78,958 | 78,390 | 87,062 | 105,598 | 99,902 | -5.4% | 26.3% |
| Flow Cytometry | 8,104 | 8,283 | 8,399 | 9,296 | 12,313 | 11,709 | -4.9% | 44.5% |
| Cytogenetics | 25,051 | 24,152 | 21,085 | 23,801 | 23,480 | 19,157 | -18.4% | -23.5% |
| Histocompatibility | 476,481 | 488,490 | 520,905 | 549,418 | 571,808 | 566,888 | -0.9% | 19.0% |
| Clinical Microbiology and Virology | 20,384 | 20,736 | 15,899 | 17,026 | 20,106 | 17,860 | -11.2% | -12.4% |
| Molecular Diagnostics | 116,160 | 141,648 | 129,294 | 126,650 | 151,392 | 141,665 | -6.4% | 22.0% |
| Reference Tests | 2,312 | 2,084 | 2,487 | 1,355 | 393 | 248 | -36.9% | -89.3% |
| MCTP | 1,874,185 | 1,951,045 | 1,997,349 | 2,051,306 | 2,153,658 | 2,085,345 | -3.2% | 11.3% |
| Total | 5,168,980 | 5,511,693 | 5,873,300 | 6,074,404 | 6,430,944 | 6,109,122 | -5.0% | 18.2% |

Table 2 : Clinical Pathology Billed Test Volumes (From pg. 18)

Table 3 (Right): Transfusion Medicine Number. (From pg. 21)

| Transfusion Medicine | | | | | | | |
|----------------------------------------------|---------------|---------------|---------------|---------------|---------------|---------------|-------------|
| Blood Bank Main Laboratory | FY15 | FY16 | FY17 | FY18 | FY19 | FY20 | Change |
| Red Blood Cells | 28,667 | 26,515 | 30,905 | 32,004 | 33,065 | 31,040 | -6% |
| Random/Pooled Platelets | 47,264 | 20,959 | 6,009 | 6,080 | 5,880 | 51 | -99% |
| Apheresis Platelets | 873 | 6,394 | 10,120 | 10,648 | 11,000 | 13,640 | 24% |
| Plasma | 8,688 | 6,642 | 6,997 | 7,267 | 7,073 | 6,676 | -6% |
| Cryoprecipitate | 4,979 | 6,011 | 6,437 | 7,404 | 7,840 | 6,676 | -15% |
| Total Components Transfused | 90,471 | 66,521 | 60,462 | 63,403 | 64,858 | 58,475 | -10% |
| Immunohematology Reference Lab | | | | | | | |
| Antibody Identifications | 1,107 | 1,081 | 1,376 | 1,240 | 1,153 | 1,516 | 31% |
| ABO Resolution | 150 | 156 | 111 | 187 | 233 | 312 | 34% |
| BMT | 322 | 247 | 203 | 320 | 319 | 284 | -11% |
| Eulates | 184 | 176 | 227 | 215 | 255 | 265 | 4% |
| Adsorptions | 241 | 317 | 464 | 319 | 402 | 547 | 36% |
| Titers | 259 | 303 | 324 | 295 | 477 | 484 | 1% |
| Special Antigen Typing | | | 6,314 | 5,896 | 6,137 | 6,384 | 4% |
| Total Activity* | 2,763 | 2,801 | 9,861 | 9,097 | 10,624 | 11,402 | 7% |
| <i>*Includes procedures not listed above</i> | | | | | | | |
| Cellular Therapies Laboratory | | | | | | | |
| Collections Processed | 518 | 415 | 452 | 427 | 452 | 454 | 0% |
| Bags Frozen | 614 | 542 | 718 | 619 | 608 | 703 | 16% |
| Transplants, Autologous | 137 | 116 | 122 | 136 | 130 | 113 | -13% |
| Transplants, Allogeneic | 45 | 45 | 36 | 32 | 54 | 43 | -20% |
| Transplants, Unrelated | 69 | 61 | 44 | 67 | 75 | 64 | -15% |
| CAR-T Products | | | 4 | 12 | 54 | 24 | -56% |
| Total Transplants | 251 | 222 | 202 | 235 | 259 | 220 | -15% |
| Apheresis Service | | | | | | | |
| Therapeutic Plasmapheresis | 1,313 | 1,389 | 1,207 | 1,220 | 1,310 | 1,416 | 8% |
| HPC Collections | 386 | 416 | 370 | 345 | 308 | 346 | 12% |
| Donor Pre-Evaluations | 258 | 243 | 219 | 255 | 308 | 236 | -23% |
| LDL Apheresis | 212 | 124 | 89 | 106 | 94 | 95 | 1% |
| RBC Exchange | 96 | 120 | 103 | 112 | 170 | 175 | 3% |
| CART-T Collections | | | 4 | 12 | 33 | 20 | -39% |
| Total Procedures | 2,218 | 2,407 | 2,024 | 2,074 | 2,206 | 2,288 | 4% |

Faculty Awards 2019-2020

| Faculty | Award Name | Organization |
|------------------------------|----------------------------------------------------------|--------------------------------------------------|
| Arul M. Chinnaiyan, MD, PhD. | Elected Member | National Academy of Science |
| | Rous-Whipple Award | American Association for Investigative Pathology |
| Kathleen R. Cho, MD | Dean's Basic Science Award | University of Michigan Medical School |
| Celina G. Kleer, MD | Outstanding Investigator in Breast Cancer Research Award | American Association for Cancer Research |
| | Outstanding Investigator Award | American Association for Investigative Pathology |
| Gabriel Nuñez, MD | Elected Member | National Academy of Medicine |
| | Stone Lecturer | Society of Investigative Dermatology |
| Asma Nusrat, MD | Elected Member | Association of American Physicians |
| Jiaqi Shi, MD | MAGNA Cum Laud Three Pearls Award | SCBT-MR Annual course |

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New National Leadership Positions - 2020

| Faculty | Role | Organization |
|--------------------------------|-----------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Ulysses G. J. Balis, MD | Chair | American Board of Medical Specialties Digital Information and Technology Advisory Committee |
| Evan A. Farkash, MD | Chair of the Transplant Diagnostics Community of Practice | American Society of Transplantation |
| Zaneta Nikolovska-Coleska, PhD | President | International Chemical Biology Society |
| Charles M. Parkos, MD, PhD. | Board Member | Federation of American Societies for Experimental Biology |

Table 5-8 (Above): List of Faculty Awards received 2019-2020. (From pg. 62) Followed by New National Leadership Positions and Leadership Appointment from pg. 62. Then the Inventions Report continued from pg. 40.

Table 9 (Right): Full list of Departmental and Institutional Committee Service.

New Department Leadership Appointments

| | | |
|-------------------------|--------------------------|------------------------------------------------------------------------|
| Steven L. Kunkel, PhD | Executive Vice Dean | Medical School |
| | Chief Scientific Officer | Michigan Medicine |
| Nicholas W. Lukacs, PhD | Scientific Director | Mary H. Weiser Food Allergy Center |
| Thomas E. Wilson, PhD | Co-PI | Michigan Biosciences Initiative (Single-Cell Spatial Analysis Program) |

Invention Reports

| Title | Inventors |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| Essential Diagnostics Database | Lee Schroeder |
| A Computer Algorithm for Automated Diagnosis of Whole Frozen Brain Tumor Slides | Daniel Orringer, Sandra Camelo-Piragua, Todd Hollon, Siri Khalsa |
| Monoclonal Antibody GM35 | Charles Parkos, Matthias Kelm, Jennifer Brazil |
| SETDB2 Antibody | Yali Dou, Bo Zhou |
| Mobile Apps for on Demand Specimen Transport | Lee Schroeder |
| Inhibitors of Class I Phosphoinositide 3-Kinases (PI3Ks) Activate Chaperone-Mediated Autophagy (CMA), an Important Anti-Neurodegeneration and Metabolic Regulatory Pathway. | Richard Miller, Samuel Endicott |
| Intercellular Junction Proteins and Food Allergy | Asma Nusrat, Vicky Garcia Hernandez, Simon Hogan, Amnah Yamani |
| Targeting Activin Pathway to Treat Pancreatic Cancer | Jiaqi Shi |
| IFN- α -Tethered Hydrogels Enhance Mesenchymal Stem Cell-Based Immunomodulation and Promote Tissue Repair | Asma Nusrat, Miguel Quiros Quesada |
| TCR-FISH: A Novel Method for Spatially and Clonally Resolved Profiling of Tumor-Infiltrating Lymphocytes | Marcin Cieslik, Sethuramasundaram Pitchiaya |
| Development of GAS41 Inhibitors | Tomasz Cierpicki, Jolanta Grembecka, Dymytrii Listunov, Brian Linhares, Alyssa Winkler |
| Human RNases as Antiviral Agents for CoV2 and other Enveloped RNA Viruses | Dan Robinson, Yi-Mi Wu |

Departmental and Institutional Committee Service

| | | |
|-----------------------------------------------------------------|-------------------------------------------------------|---------------------------------------------------------------------------|
| ACGME Self-Study Committee | Cytopathology Director Faculty Search Committee | Pathology Relocation and Renovation (PRR) Project Resident Representative |
| Advisory Committee on Promotions and Tenure | Histocompatibility Director Search Committee | (PRR) Executive Steering Committee |
| Advisory Council for Patient and Family Centered Pathology Care | Histology Committee | (PRR) Project Committee |
| Blood Transfusion Committee | House Officer Quality and Safety Council | Pathology Social Media Team Member |
| Clinical Pathology Director Search Committee | Laboratory Communications Committee | Phlebotomy Working Group |
| Clinical Pathology Operations Director Search Committee | Laboratory Formulary Committee | Program Evaluation Committee |
| Clinical Pathology Operations Committee | MLabs Executive Committee | Search Committee for Anatomic Pathology Director |
| Clinical Pathology Quality Assurance Committee | Pathology Diversity, Equity, and Inclusion Committee | Search Committee for HLA and Blood Bank Associate Director |
| Clinical Pathology Symposium Planning Committee | Pathology Document Control Vendor Selection Committee | Search Committee for Toxicology/Chemistry Faculty |
| Cytogenetics Faculty Search Committee | Pathology Executive Committee | |

Professional Society Membership and Engagement

| | | |
|---------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| A. James French Society of Pathologists | American Society of Dermatopathology | International Society of Urological Pathology |
| Academy of Clinical Laboratory Physicians and Scientists | American Society for Histocompatibility and Immunogenetics | Michigan Association of Medical Examiners |
| American Academy of Family Physicians | American Society of Hematology | Michigan Society of Pathologists |
| American Association for Clinical Chemistry | American Society for Microbiology | Michigan State Medical Society |
| American Association of Blood Banks | Association for Molecular Pathology | National Association of Medical Examiners |
| American Association for Cancer Research | College of American Pathologists and Residents' Forum | Pan American Society for Clinical Virology |
| American Association for the Advancement of Science | Hans Popper Hematopathology Society | Rodger C. Haggitt Gastrointestinal Pathology Society |
| American Board of Pathology | Infectious Diseases Society of America | Society for Hematopathology |
| American Medical Association, and Resident & Fellow Section Delegates | International Association of Therapeutic Drug Monitoring and Clinical Toxicology | South Central Association for Clinical Microbiology |
| American Society for Bioethics and Humanities (ASBH) | International Society of Bone and Soft Tissue Pathology | United States and Canadian Academy of Pathologists, and Resident Advisory Subcommittee and Ambassadors |
| American Society for Clinical Oncology | International Society of Gynecological Pathologists | Washtenaw County Medical Society |
| American Society for Clinical Pathology, and Resident Representatives, Resident Council and Chair of the Resident Council | International Society for Heart and Lung Transplantation | |
| American Society for Clinical Oncology | International Society of Laboratory Hematology | |

Ongoing Clinical Trials/Studies Supported by MI-ONCOSEQ

| NCT ID | Clinical Trial | PI | Total Patients | Sites |
|---------------|----------------|------------|----------------|------------------------------------------------------------------------------------------------------------|
| NCT00261456 | UMCC 2018.050 | Alva | 30 | University of Michigan, Memorial Sloan Kettering, Johns Hopkins, Washington University St Louis, UCSF |
| NCT03456804 | UMCC 2019.031 | Heath | 7 | Karmanos |
| NCT03562507 | UMCC 2018.052 | Alva | 8 | UM |
| NCT03101566 | UMCC 2017.026 | Sahai | 89 | University of Michigan, Emory, University of Texas Southwestern, Wisconsin, Northwestern, UT Southwestern |
| NCT03287050 | UMCC 2017.069 | Alva | 3 | University of Michigan |
| NCT03242915 | UMCC 2017.057 | Gadgeel | 30 | University of Michigan, Karmanos, Montefiore Medical Center, Rush University, Henry Ford, Cleveland Clinic |
| SU2C/PCF | VA Multisite | Chinnaiyan | 248 | University of Washington, University of Michigan, Karmanos, Royal Marsden Hospital |
| POPCAP-VA/PCF | Multisite | Alva | 26 | Ann Arbor VA, Bay Pines VA, Jesse Brown VA, James Haley VA |
| N/A | UMCC 2018.044 | Sahai | 21 | University of Michigan, Vanderbilt University |

Table 10: Ongoing Clinical Trials/Studies Supported by MI-ONCOSEQ. (From pg. 27)



| Graduate Student Thesis Defense and Current Positions | | | | | |
|-------------------------------------------------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------|--------------------------------|
| Name | Defense Date | Thesis Title | Mentor(s) | Current position | Current Company |
| Carrie-Anne Malinczak | 10/21/19 | <i>Long-Term Immune System Alterations Following Early-Life RSV Infection</i> | Nicholas Lukacs | Postdoctoral Fellow | UM Department of Pathology |
| Carl Engelke | 11/22/19 | <i>The Association of PARP1 Enzymatic Inhibition and Chromatin Complex Formation with Radiosensitization by PARP Inhibitors and Their Combination with ATR Inhibition in Pancreatic Cancer</i> | Theodore Lawrence and Arul Chinnaiyan | Medical Student | UM Medical School |
| Andi Cani | 12/5/19 | <i>Precision Medicine Approaches to Hormone-Driven Cancers: Breast Cancer Single Circulating Tumor Cell Genomics and Prostate Cancer Transcriptomic Biomarkers</i> | Scott Tomlins and Arul Chinnaiyan | Postdoctoral Fellow | UM Int Med-Hematology/Oncology |
| Sabra Djomehri | 12/18/19 | <i>Quantitative proteomic and mutational landscape of metaplastic breast carcinoma and generation of a 3D organoid model of neoplastic progression</i> | Celina Kleer | Postdoctoral Fellow | Stanford University |
| Jacqueline Mann | 12/19/19 | <i>Identification of PDL1 Drivers in Models of Head and Neck Squamous Cell Carcinoma by Genome Wide Screening</i> | Chad Brenner and Alexey Nesvizhskii | Postdoctoral Fellow | University of Pittsburgh |
| Paloma Garcia | 3/6/20 | <i>Differential Contribution of Pancreatic Fibroblast Subsets to the Pancreatic Cancer Stroma</i> | Marina Pasca di Magliano and Gabriel Nunez | Interviewing for positions | |

Table 11: Graduate Student Thesis Defense and Current Positions 2019-2020. (From pg. 48)

| Years of Service Recognition - 2020 | | |
|-------------------------------------|----------------------|-------------------|
| 10 Years | | |
| Carla Bigham | Xiaojun Jing | Judy Poore |
| Ja'Nee Bolden | Megan Jordan | Cody Sanch |
| Janet Bolterman | Beverly Kopko | Sunita Shankar |
| Danyell Carpenter | Tamara Kutter | Marc Stafford |
| Galina Chtraklin | Jeffrey Lott | Terri Tallmadge |
| Stephen Collins | Jinghui Luo | Lisa Taulbee |
| Tanya Coyle | April Oler | Brent Temple |
| Brooke Dougherty Reyes | Nadine Patterson | Katherine Thomas |
| Jaclyn Epple | Natalie Perry | Nicholas Wesener |
| 20 Years | | |
| Brooks Barnes | Beth Lawless | Sue Scott |
| Jennifer Bodary | Margaret Mahlmeister | Yinhong Shen |
| Tara Borchardt | Holly Longo-Minor | Abdulsalam Soofi |
| Stacey Curtis | Hongzhi Miao | Rita Spiegelberg |
| Saravana Dhanasekaran | Yu Ning | Reshunda Triplett |
| Jill Gosselin | Theresa Pace | Michelle Vinco |
| Hugh Gregg | Christine Rigney | Yali Zhai |
| 30 Years | | 40 Years |
| Ellen Bassett | Sunita Punjabi | Robin Kunkel |
| David Golden | Ann Rosin | |
| Jacquelyn Goodman | Yinru Sieracki | 50 Years |
| Nanci Lefebvre | Laura Smith | Kathleen Hustler |
| Catherine Niemiec | Kent Traylor | |
| Linda O'Brien | | |

| Above and Beyond Award Recipients | | |
|---------------------------------------------------------------|------------------------|------------------|
| Anatomic Pathology | | |
| David De Le Espriella | Monique Micallef | Christine Rigney |
| Kelli Farhat | Lisa Neal | Natalie Toth |
| Matthew Gabbeart | Linda O'Brien | |
| Sharon Kerr | Nadine Patterson | |
| Clinical Pathology | | |
| Alena Carr | Lorrie Gosselin | Scott McClellan |
| Mary Conniff | Kathleen Gower | April Oler |
| Kimberly Fera | Sheri Hukan | Dena Ryan |
| Laura Gable | Jodi Kennedy-Stanfield | Annette Rush |
| Michelle Garrasi | Beth Lawless | Denise Sulavik |
| Group Award: Staff Performing COVID Nasal Swab Testing | | |

| Experimental Pathology | MLabs | Education Program |
|------------------------|-------------|-------------------|
| Chelsea Decker | Karla Bialk | Pamela Howard |
| Mary Skinner | | |
| Christina Watson | | |

| Pathology Informatics | Finance & Administration |
|-----------------------|--------------------------|
| Ivan Holland | Yvonne Bidwell |

Table 12-13 (Above): Years of Recognition and Above and Beyond Award Recipients (From pg 63.)

Table 14 (Right): Retired Faculty and Staff 2019-2020 (From pg. 63).

| Retired 2019-2020 | | | |
|--------------------|-----------------------------|-------------------|------------------|
| Name | Unit | Retirement Date | Years of Service |
| Vicki Perzynski | Heme/Coag Unit | July 6, 2019 | 40.0 |
| Noreen Clisham | Specimen Processing | August 6, 2019 | 12.3 |
| Kathleen Cullen | Microbiology | August 13, 2019 | 46.1 |
| Eileen Sinclair | Special Chemistry | September 7, 2019 | 17.2 |
| Linda Lapsley | Microbiology | October 12, 2019 | 29.0 |
| David Rohrkemper | Blood Bank | November 28, 2019 | 32.9 |
| Jeanette Jeffreys | Clin. Lab Administration | December 3, 2019 | 37.7 |
| Melvina Grayson | Specimen Processing | December 11, 2019 | 43.7 |
| Mary Jo Bishop | Surgical/Necropsy Path | December 14, 2019 | 28.7 |
| Sue Stern | Chemical Pathology | December 19, 2019 | 41.5 |
| Diana LeBlanc | Pathology Satellite Support | December 21, 2019 | 15.4 |
| Audrey Williams | Outpatient Phlebotomy | December 21, 2019 | 34.4 |
| Lois Hancock | Transfusion/Apheresis | December 27, 2019 | 24.7 |
| Peter Ward | Professor of Pathology | January 2, 2020 | 39.6 |
| Christine Offord | Special Chemistry | January 11, 2020 | 27.3 |
| Donna Bush | Special Chemistry | January 25, 2020 | 36.0 |
| Jane Spinner | Depression Center | February 8, 2020 | 11.0 |
| Timothy Williams | Histocompatibility | February 25, 2020 | 11.1 |
| Iulian Mioc | Specimen Processing | February 29, 2020 | 14.2 |
| Thomas Morrow | Clin. Lab Administration | February 29, 2020 | 46.2 |
| James Varani | Professor of Pathology | March 2, 2020 | 39.7 |
| Ruth Miller | Chemical Pathology | April 1, 2020 | 18.8 |
| Jeanette Gohl | Clin. Lab Administration | May 23, 2020 | 16.8 |
| Kathy Davis | Pathology Informatics | May 30, 2020 | 41.9 |
| Gerald Davis | Heme/Coag Unit | May 30, 2020 | 44.1 |
| Shannon St. Andrew | Chemical Pathology | May 30, 2020 | 32.3 |
| Tsehay Teklegzi | Chemical Pathology | June 6, 2020 | 14.5 |
| Kathryn Gardner | Pathology Satellite Support | June 27, 2020 | 34.9 |



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