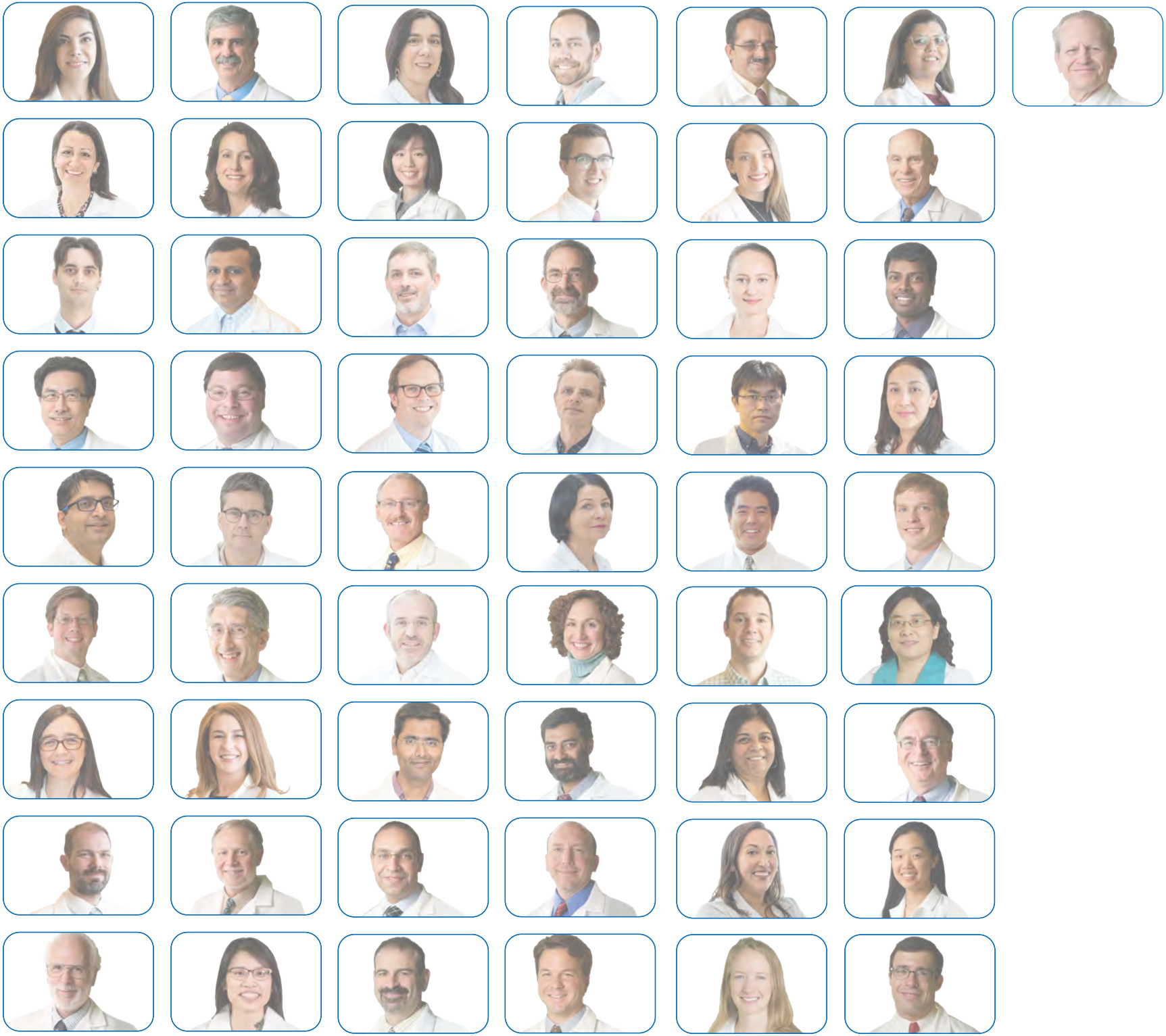
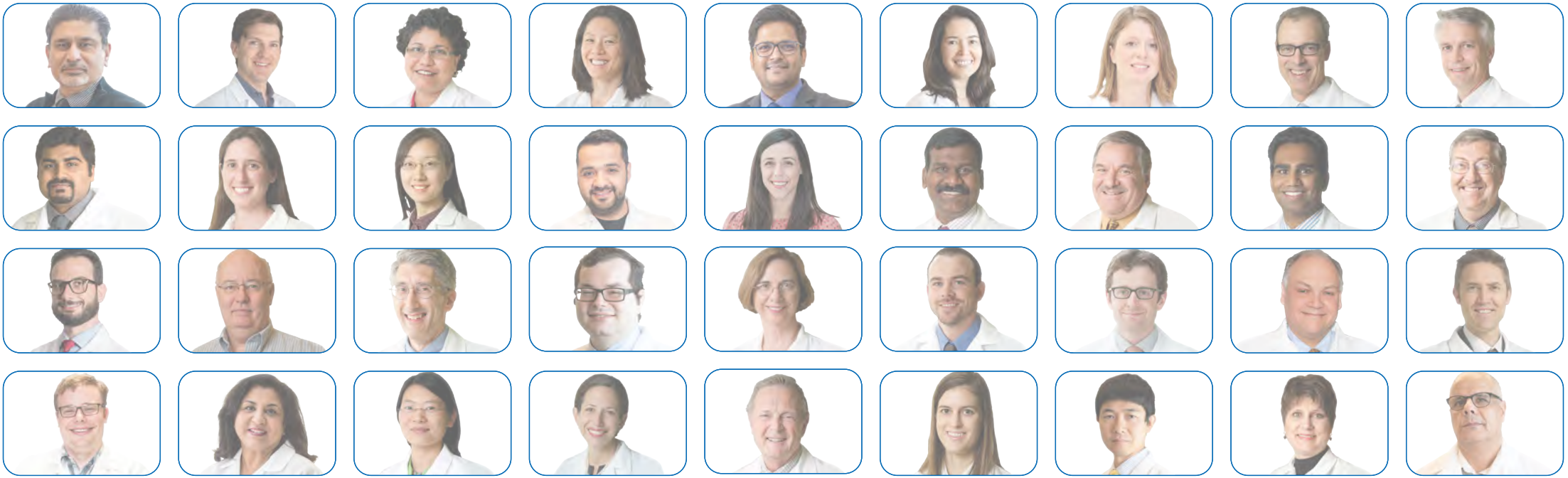
Annual Report

2021

Department of **Pathology**

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN





Annual Report compiled by Pathology Communications: Lynn McCain, Editor; Brent Temple, Design and Layout; and Camren Clouthier, Photography. A special thanks to the many contributors who provided the content for this report.

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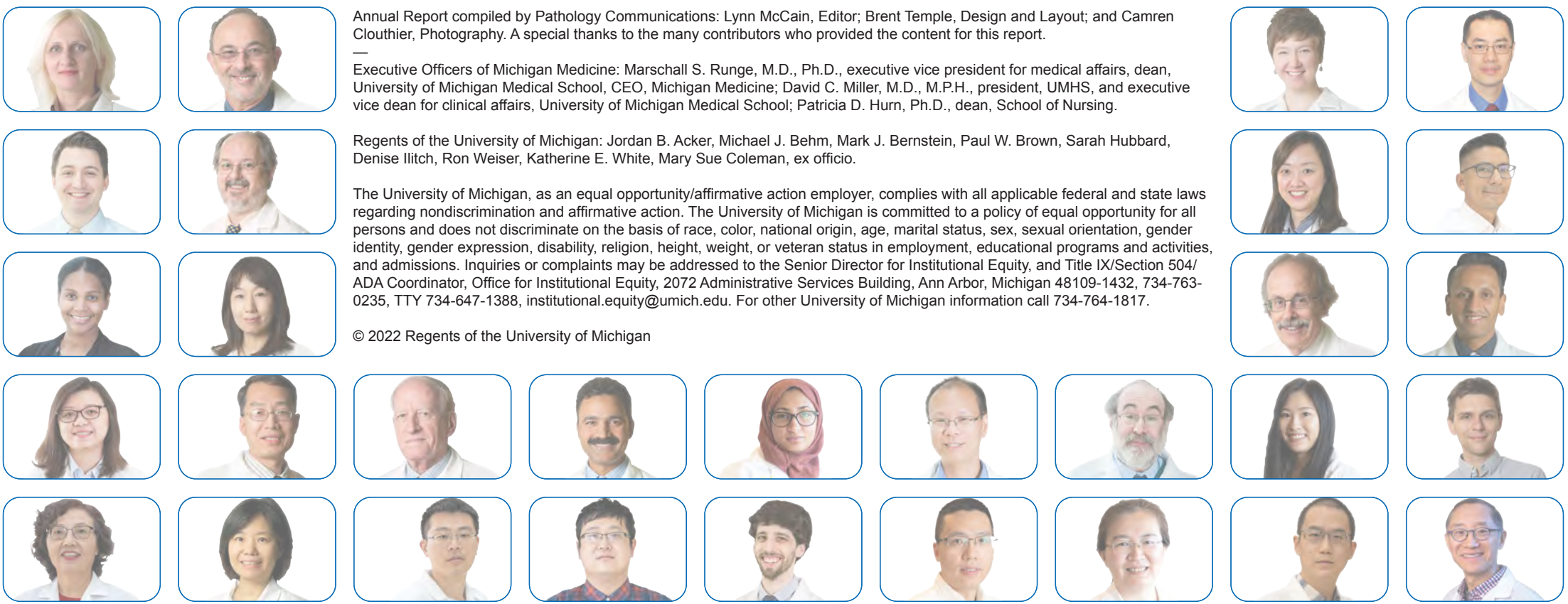

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Message From the Chair

When COVID-19 first arrived in Michigan in March 2020, it was immediately clear that the virus had the potential to spread rapidly and make many people very sick. The impact of Covid-19 on our personal lives, department, communities, country, and world has been profound and unprecedented in modern history. Many of these impacts were devastating – the severity of illness and huge loss of life, isolation, job losses, fear, and despair changed all of our lives. Yet there have been many heroes amongst us resulting in countless acts of kindness and compassion, increased awareness of disparities, unprecedented development of vaccines and therapeutics as well as new ways to deliver healthcare.

I am proud of the faculty, staff, and trainees of our Department of Pathology. Time and again, we were faced with seemingly insurmountable obstacles and were able to pull together as a team to succeed. In the face of fear and exhaustion, our staff, trainees, and faculty exhibited courage. When overwhelmed, they conquered through teamwork, creativity, and perseverance. Day in and day out, members of our department served the patients of Michigan Medicine and the surrounding region with kindness, compassion, and a commitment to excellence.

Late in Fiscal Year 2020 (FY20), national shutdowns led to a significant decrease in non-COVID clinical activity, resulting in decreased caseloads in Pathology. In Fiscal Year 2021 (FY21), clinical services were largely restored in the health system and caseloads rebounded, approaching pre-pandemic levels. There were resurgences in the pandemic, with COVID cases exceeding levels seen in the first wave. Throughout this year, our faculty, staff, and trainees worked diligently to ensure all patients received high quality care in a timely fashion in spite of high demand and sustained shortages of supplies and labor. Their hard work and personal sacrifice are embedded in each number you will see in this report.

Our research faculty and staff experienced a lengthier shutdown than some other units. This resulted in significant delays in experimental progress on research projects essential for funded grants as well as new proposals. As a result, the department experienced a modest decrease in our overall grant dollars. However, the shutdown allowed our faculty to plan for new research projects and do a lot of writing that resulted in submission of additional grant applications and new manuscripts. The result was impressive with 571 manuscripts published, a 128% increase over the prior year. Among these papers were 36 manuscripts related to COVID research from our clinical pathology, anatomic pathology, and experimental pathology faculty, demonstrating the deep talent and commitment of our faculty to finding answers about a novel and devastating virus.

Our education team developed novel content that could be delivered remotely, ensuring the ability of trainees to continue to learn and develop. New curriculum was developed for medical student education, and 22 of our faculty participated in employing this new teaching strategy. Having taken advantage of the new technologies enabling increased remote work, our residents and fellows

are better prepared than ever for digitally based pathology of the future. Our staff exhibited flexibility, creativity, and dedication to ensure tasks were completed, and the department's missions of patient care, education, and research moved forward.

This report provides you with a glimpse into the challenges and the achievements we experienced together as a Department. As you read, I am sure you will be just as proud as I am of all that we have accomplished as a team throughout the pandemic.

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 FY21 the Department of Pathology received over $1,901,298 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:

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Assistant Director of Development
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PEOPLE

206 Faculty

- **49** / Instructional
- **95** / Clinical
- **37** / Research
- **25** / Supplemental
- **77** / Student Temps

1,057 Staff

8 Direct Reports

18 Dotted Line Reports

CDA

COVID-19

9 Diagnostic Tests Developed & Validated → **503,459** Tests Performed

4 Serology Test Developed & Validated → **13,403** 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

$76.8M
MS Annual Expense Budget

$177.9M
UMHS Annual Expense Budget

Ranked #9 In Funding Received by NIH in 2020

Received 41 Awards from NIH between 2020-2021

$32M
Sponsored Spending in 2020

14.9% ↑
Growth in Billable Tests

Research Space Occupies
65,598SQFT
$346 DC/SF
$154 IDC/SF

22 / PhDs
21 / Fellows
64 / Post Doc Fellows
26 / Residents

Clinical

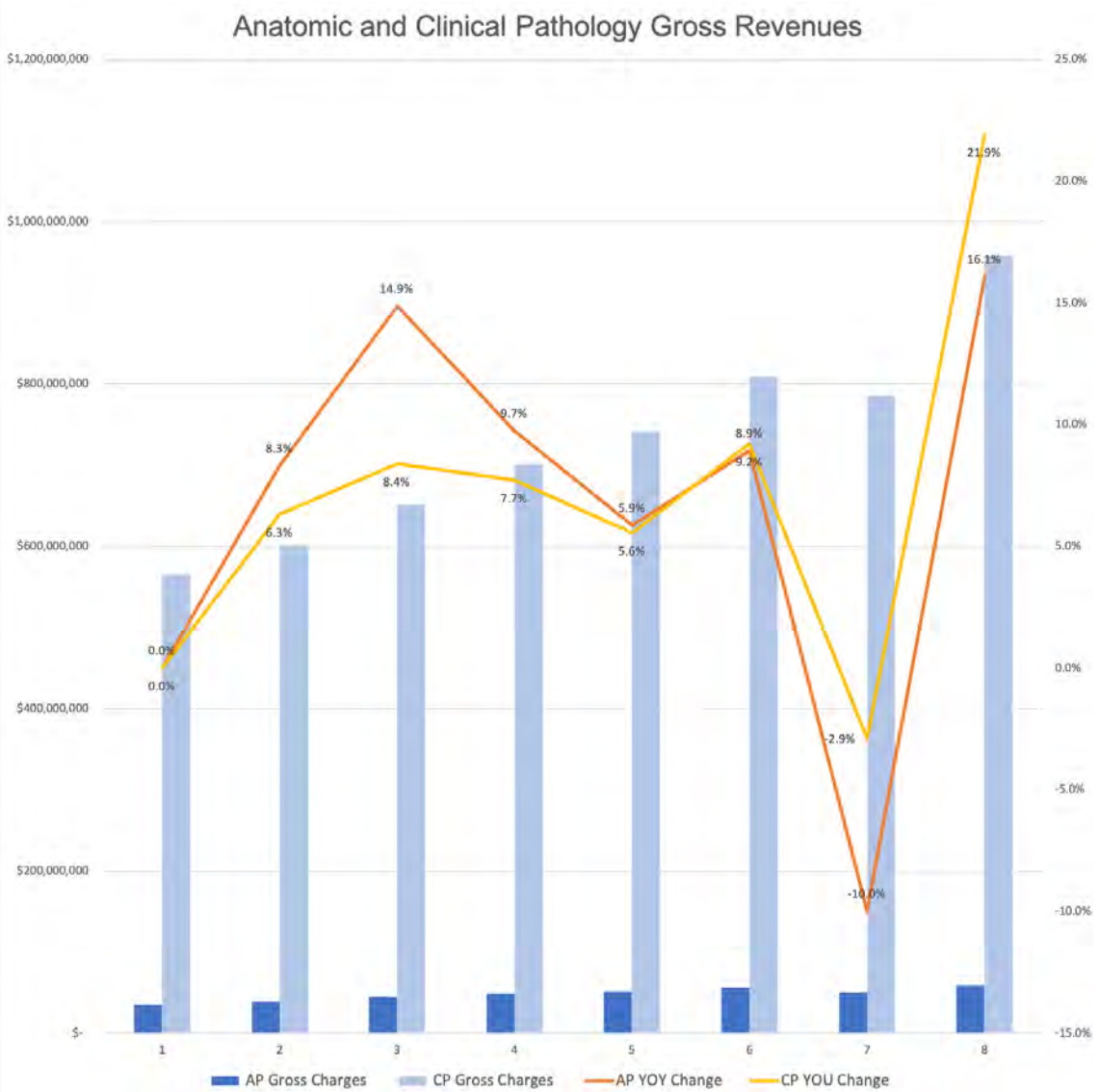
Outpatient Phlebotomy in all Health Centers

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 Pathology

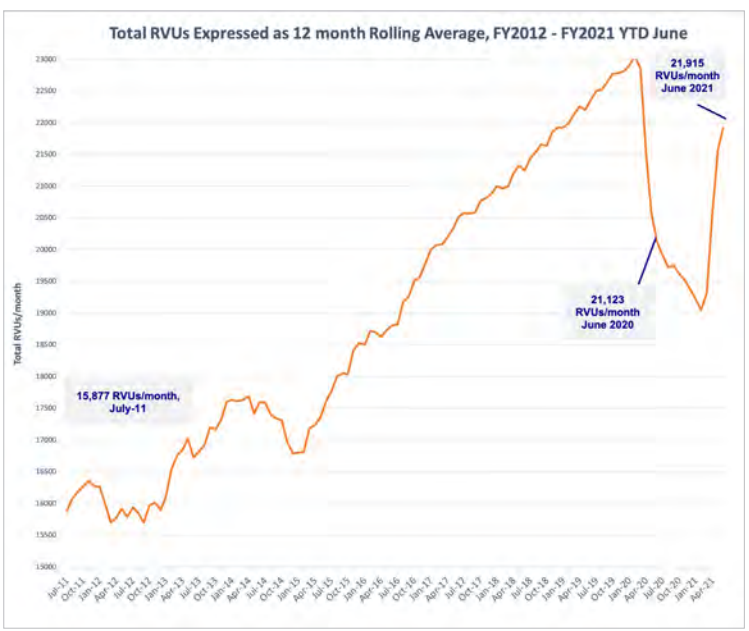
Liron Pantanowitz, MD, MHA

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

Anatomic Pathology (AP) deals with testing of tissues, solid tumors, and cells as well as autopsies and forensics. AP experienced an increase in volume of 10.73% from a total of 136,431 cases from FY20 to 151,065 cases for FY21. The increase in specimens was attributed to a partial clinical service recovery from the COVID-19 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 Director. Most of these services support weekly multidisciplinary tumor boards and conferences.



Clinical Activities

RVU Trends in Anatomic Pathology

Total RVU's generated by AP in FY21 expressed as a 12-month rolling average were 21,915 RVU's/month. This represents a 14.36% increase over FY20 and reflects a steady recovery from the COVID-19 pandemic. 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. *(See chart to the left)*

FTE Trends in Anatomic Pathology

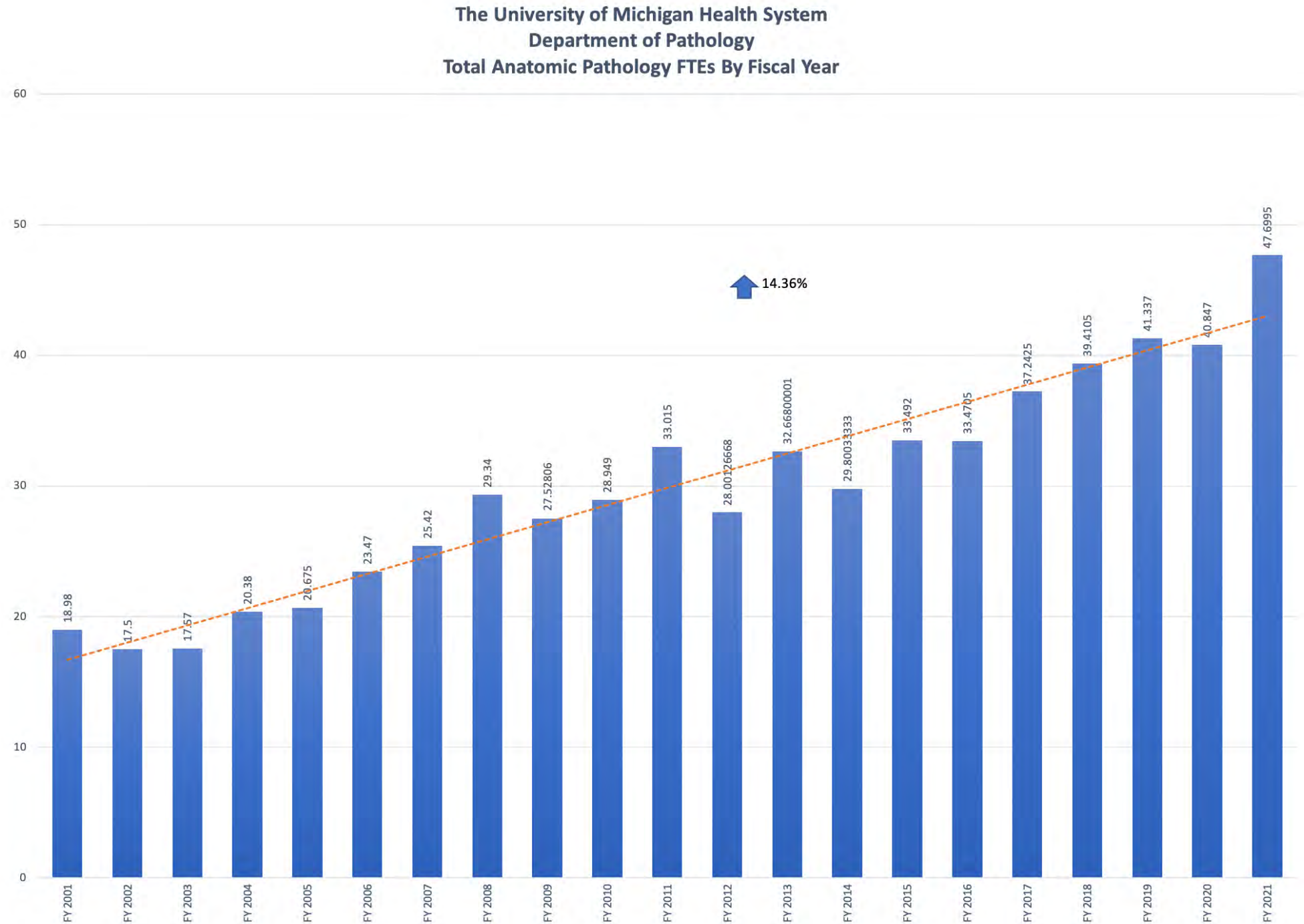
Total clinical FTEs for AP faculty was 47.70 in FY21 compared to 40.85 in FY20, representing 14.36% year-over-year increase. Over a five-year time period, AP staffing has increased 28.1% from 37.24 FTEs to 47.70 FTEs to meet the demands of our growing AP service workload and complexity. This included faculty with dual fellowships and hybrid skillsets in an AP subspeciality paired with molecular pathology.

RVU and FTE Trends in Anatomic Pathology

Total work RVUs/FTE in FY21 showed a 23.61% decrease. On average, each clinical FTE in AP generated 709 RVUs/month in FY21 compared to 928 in FY20. However, these data vary for different AP services and the figures are negatively impacted by a drop in case volume as a consequence of the COVID-19 pandemic.

Surgical Pathology

The Surgical Pathology section encompasses a general sign-out service and multiple subspecialty services, each with its own service director. The clinical service provided by surgical pathology faculty includes frozen section coverage at University Hospital (UH), adult


The University of Michigan Health System
Department of Pathology
Total Anatomic Pathology FTEs By Fiscal Year
60
50
40
30
20
10
0
14.36%
18.98
17.5
17.57
20.38
20.675
23.47
25.42
29.34
27.52806
28.949
33.015
28.00126668
32.66800001
29.80033333
33.492
33.4705
37.2425
39.4105
41.337
40.847
47.6995
FY 2001
FY 2002
FY 2003
FY 2004
FY 2005
FY 2006
FY 2007
FY 2008
FY 2009
FY 2010
FY 2011
FY 2012
FY 2013
FY 2014
FY 2015
FY 2016
FY 2017
FY 2018
FY 2019
FY 2020
FY 2021

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

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 continued to be leveraged to remotely 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 FY21, 13,037 general specimens were processed, which represents an increase of 3.62% over the prior year. However, this service has experienced a 3.86% overall decrease when compared to specimen volumes from five years ago, and this trend likely reflects a negative impact on workload due to the COVID-19 pandemic.

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, increased by 14.5% with 1,696 cases received in FY21. This consult service has shown an overall 26% increase compared to specimen volumes from five years ago. There are accordingly now five dedicated faculty scheduled to cover this service.

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 also features a consultation service that assists with diagnostically challenging cases from the US and abroad. In FY21, the Breast Pathology service processed 3,358 cases which represents a 30.26% growth compared to FY20 and 44.80% growth compared to five years ago.

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 330 challenging consult cases in FY21, which is similar to FY20 and represents a 13% increase 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. The Gastrointestinal/Hepatobiliary Service completed 22,026 in-house cases in FY21, which is a 12.15% increase compared to FY20. Case numbers show a 7.40% decrease compared to five years ago which can be attributed to a revision in our workflow in 2017 where specimens accessioned as two cases (upper and lower gastrointestinal tract) were combined into one case. While case numbers decreased, specimen counts increased at the same rates shown in the past four years.

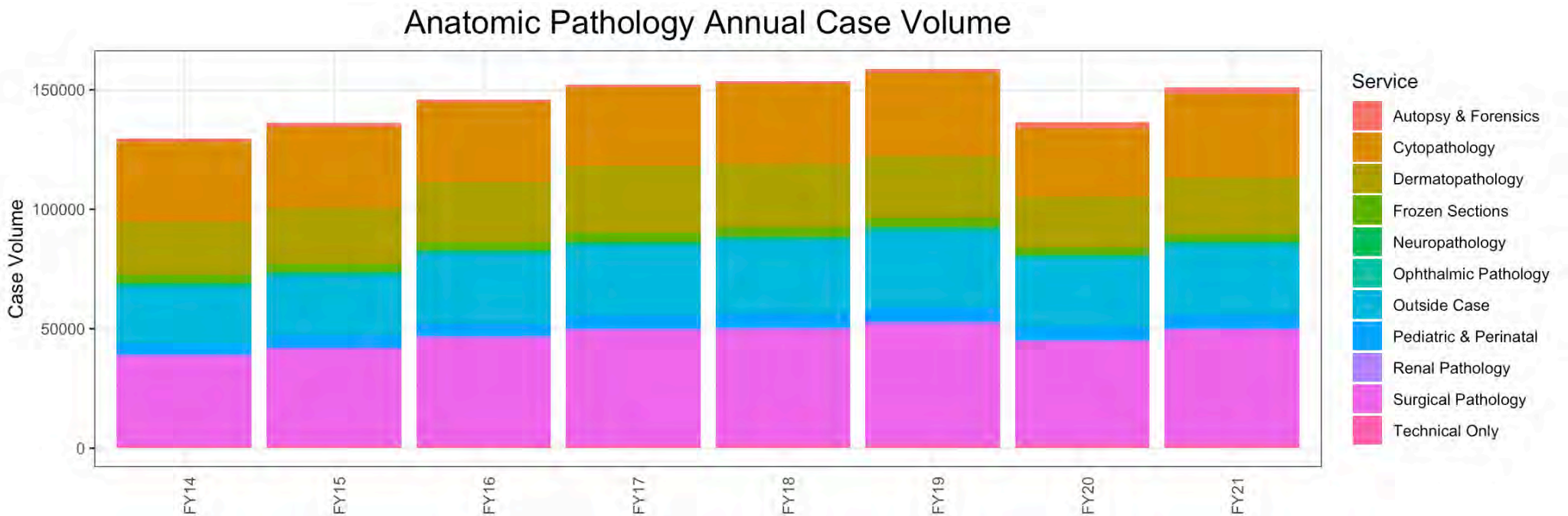
Genitourinary Pathology

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 processed 3,676 cases in FY21, which was up 3.62% over the prior year. Overall, GU specimen volumes are up 9.24% compared to specimen volumes from five years ago.

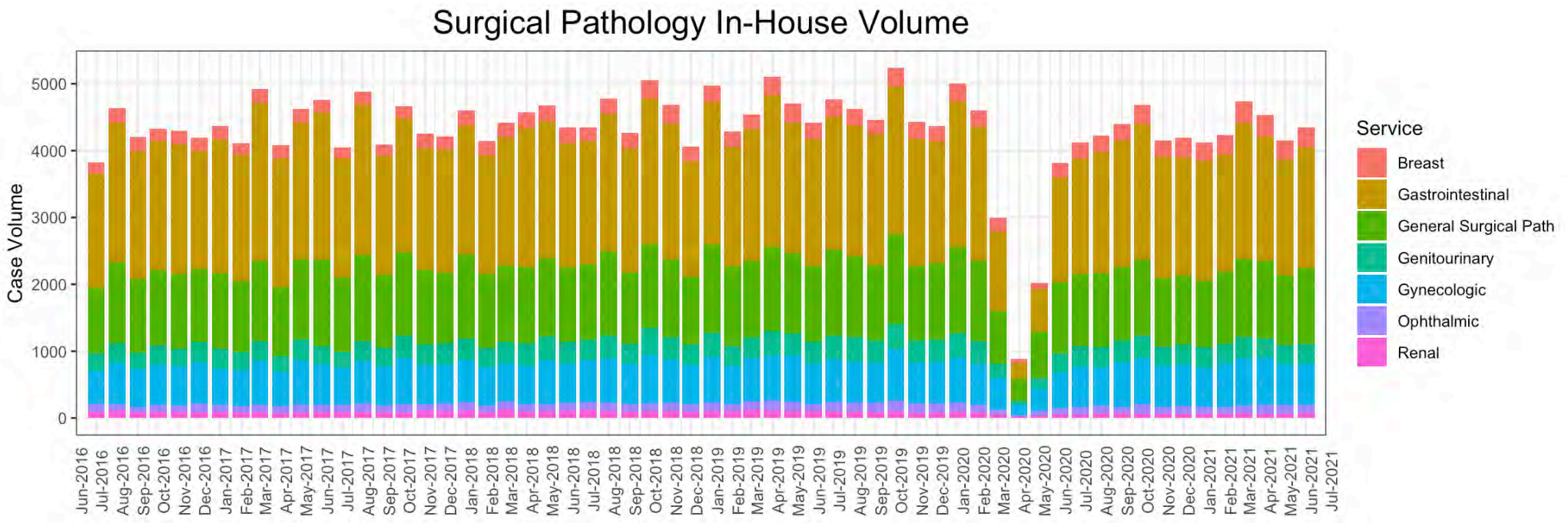
Gynecologic Pathology

Gynecologic Pathology (GYN) is the subspecialty that deals with the study and diagnosis of disease involving the female genital tract. The GYN service processed 7,599 cases in FY21, which is a 14.94% increase over the prior year. This represents a 9% increase compared


PATHOLOGY



AP Service	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21	1-YR	5-YR
Autopsy & Forensics	1,452	1,913	1,031	1,024	1,202	1,722	2,472	2,499	1.09%	144.04%
Cytopathology	33,351	33,553	33,650	32,954	33,347	34,835	28,737	35,305	22.86%	7.13%
Dermatopathology	22,086	23,403	24,600	28,000	26,715	25,720	21,017	23,707	12.80%	−15.33%
Frozen Sections	3,442	3,431	3,596	3,567	3,719	3,620	3,162	3,073	−2.81%	−13.85%
Neuropathology	817	803	759	825	782	789	682	710	4.11%	−13.94%
Ophthalmic Pathology	1,090	1,255	1,252	1,220	1,289	1,424	1,353	1,384	2.29%	13.44%
Outside Case	23,590	24,535	28,695	29,021	30,298	31,471	28,338	28,664	1.15%	−1.23%
Pediatric & Perinatal	4,509	5,193	5,141	5,407	5,723	5,973	5,297	5,645	6.57%	4.40%
Renal Pathology	1,204	1,130	1,180	1,099	1,294	1,413	943	811	−14.00%	−26.21%
Surgical Pathology	36,697	39,502	44,314	46,989	47,191	49,460	42,297	47,146	11.46%	0.33%
Technical Only	1,288	1,499	1,608	1,923	2,062	2,165	2,133	2,121	−0.56%	10.30%
TOTAL	**129,526**	**136,217**	**145,826**	**152,029**	**153,622**	**158,592**	**136,431**	**151,065**	**10.73%**	**−0.63%**



AP Service	FY17	FY18	FY19	FY20	FY21	1-YR	5-YR
Breast	2,319	2,479	2,927	2,578	3,358	30.26%	44.80%
Gastrointestinal	23,787	23,114	23,709	19,639	22,026	12.15%	−7.40%
General Surgical Path[1]	13,561	13,842	14,134	12,581	13,037	3.62%	−3.86%
Genitourinary	3,365	3,734	3,974	3,545	3,676	3.70%	9.24%
Gynecologic	6,966	7,212	7,739	6,611	7,599	14.94%	9.09%
Ophthalmic	1,248	1,311	1,455	1,367	1,397	2.19%	11.94%
Renal	1,096	1,239	1,281	877	807	−7.98%	−26.37%
TOTAL	**52,342**	**52,931**	**55,219**	**47,198**	**51,900**	**9.96%**	**−0.84%**

1 "General Surgical Path" is comprised of Endocrine, Bone, Soft Tissue, Head & Neck, and Pulmonary

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

Jeffrey Myers, MD
Director, Pulmonary/Thoracic Pathology

Raja Rabah, MD
Director, Pediatric Pathology

Raiv Patel, MD
Director, Dermatopathology

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 1,303 cases in FY21, which was a 3.82% increase over FY20 and represents a 9.31% increase compared to specimen volumes from five years ago.

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, the Pulmonary Pathology service evaluated 2,564 complex consultation cases, which represents a 5.46% decrease over FY20 and an 8.79% decrease compared to specimen volumes from five years ago.

Case Volume

Case volume for all Surgical Pathology services in FY21 includes all in-house specimens and extramural consultations (transfer and private consults). This case volume for Surgical Pathology was 51,900, which represents a varied year-over-year increase for different subspecialties. This represents a 9.96% increase over the prior year.

Frozen Sections

Despite COVID-19 related constraints on performing surgery, the frozen section case volume for FY21 was 3,073, representing a decrease of 2.81% compared to FY20.

Turnaround Time

Turnaround time, defined from when a specimen is received in pathology until the case is signed out, decreased an average of 7.72% compared to one year ago. This can be attributed to several measures including leveraging informatics for better tracking of turnaround time and delayed cases, as well as immediate notification of faculty about late cases.

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

The pediatric surgical pathology case volume of 6,190 for FY21 reflects a 5.87% increase compared to FY20 and a 4.74% increase compared to specimen volumes from five years ago. Placental exams decreased by 3.6% to 1,825 cases in FY21 and shows a 0.5% decrease over five years. Pediatric fetal exams were up 19% and pediatric autopsies had no change from FY20.

Turnaround Time

Average turnaround time for pediatric surgical pathology cases was 2.2 days in FY21, which decreased by 6.3% in the last year. These turnaround times also demonstrate that cases in FY21 were signed out 6.4% more quickly compared to five years ago.

Dermatopathology

Dermatopathology focuses on the study of cutaneous diseases at a microscopic and molecular level. The dermatopathology service utilizes light microscopy, immunofluorescence, and molecular testing.

Case Volume

The Dermatopathology service experienced an overall 9.3% increase in FY21 and handled a total of 30,094 cases. This included a 16.8% increase in specimens from Michigan Medicine patients (“in house” cases) which accounted for 51% of the cases seen. Cases from

patients outside of Michigan Medicine ("MLabs cases") were also up 5.7% in FY21.

Turnaround Time

Overall turnaround time for dermatopathology cases averaged 3.35 days, showing on average a 2.4% increase over FY20. This included an improvement of 0.7% for in-house cases and a decrease of 8.23% for MLabs' dermatopathology 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 FY21 there were a total of 1,952 cases signed out compared to 1,634 cases in FY20, representing a 19.5% increase. Over a five-year period, this service has witnessed a 20% increase in neuropathology cases. Both in-house and outside neuropathology cases (transfers and consults) increased in FY21, as did in-house muscle cases. From July 1, 2020 - June 30, 2021, we examined at brain cutting 83 hospital cases and 45 dementia cases collected through the Michigan Alzheimer's Disease Research Center (ADRC).

Turnaround Time

Turnaround time for neuropathology cases decreased on average to 5.52 days, showing a 2.6% improvement from FY20 and a 5.7% improvement compared to five years ago.

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 1,472 cases in FY21, representing a 2.2% increase over the prior year and a 12.5% increase over the past five years.

Turnaround Time

Ophthalmic Pathology turnaround time averaged 3.27 days showing a decrease of 32.6% in FY21 and a 42.9% decrease over five years.

Renal Pathology

The Renal Pathology service focuses on the diagnosis and characterization of medical diseases (non-tumor) of the kidneys.

Case Volume

Medical renal biopsy case volume decreased to 845 in FY21, representing -14.3% and -26.4% change in one- and five-year-over-year volumes, respectively. The decline was driven in part by a FY20 kidney transplantation hold and changes in transplantation surveillance biopsy practices, both related to COVID-19.

Turnaround Time

For medical renal biopsies, the overall turnaround time was 11.7 days in FY21, representing a marked (63%) improvement compared to last year and even greater (71%) decrease compared to five years ago.

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 follow-up visits due to inadequate sampling. Our cytopathology team are also skilled at performing palpation-guided and ultrasound-guided FNA themselves.

Case Volume

Our cytopathology service processed 35,305 cases in FY21 which was up 22.9% from FY20 and up 7.1% compared to five years ago. Gynecologic Pap tests represented the bulk of these cytopathology

Andrew Lieberman, MD, PhD
Director, Neuropathology

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							
	FY17	FY18	FY19	FY20	FY21	1-YR	5-YR
Brain Cases	76	52	70	52	42	−19.23%	−44.74%
Livingston Autopsies		80	99	123	137	11.38%	--
Livingston Exams		3	9	26	28	7.69%	--
UH (Adult) Autopsies	148	152	167	164	128	−21.95%	−13.51%
UH (Peds) Autopsies	33	37	27	24	24	0.00%	−27.27%
Washtenaw Autopsies	408	330	351	344	378	9.88%	−7.35%
Washtenaw Exams	51	70	62	67	104	55.22%	103.92%
TOTAL	**716**	**724**	**785**	**800**	**841**	**5.12%**	**17.46%**

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

Wayne County ME Office Case Volume							
	FY17	FY18	FY19	FY20	FY21	1-YR	5-YR
Full Autopsies	2,359	2,417	2,318	2,116	2,901	37.10%	22.98%
Externals	867	855	865	891	562	−36.92%	−35.18%
TOTAL	**3,226**	**3,272**	**3,183**	**3,007**	**3,463**	**15.16%**	**7.35%**

Table: *Wayne County ME Office Case Volumes.*

cases. There were 7,868 non-gynecologic cytopathology cases in FY21 in addition to 3,053 FNAs which included percutaneous and endoscopic aspirations.

Turnaround Time

Turnaround times in cytopathology have remained excellent. The average turnaround time for all cytology cases was 1.68 days in FY21, which was very similar to last year and not that different from several years ago.

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.

Case Volume

Case volumes of autopsies performed in the UH morgue were up 5.12% from FY20 and showed a 17.5% increase over the past five years. Case volumes of autopsies performed at the Wayne County Medical Examiner's Office increased by 15% from the previous year and increased by 7.3% over the past five years.

Turnaround Time

Autopsy and Forensic turnaround times demonstrated an average of 55.2 days to finalize an autopsy, representing a 13% overall increase compared to last year and 87% increase compared to FY17.

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

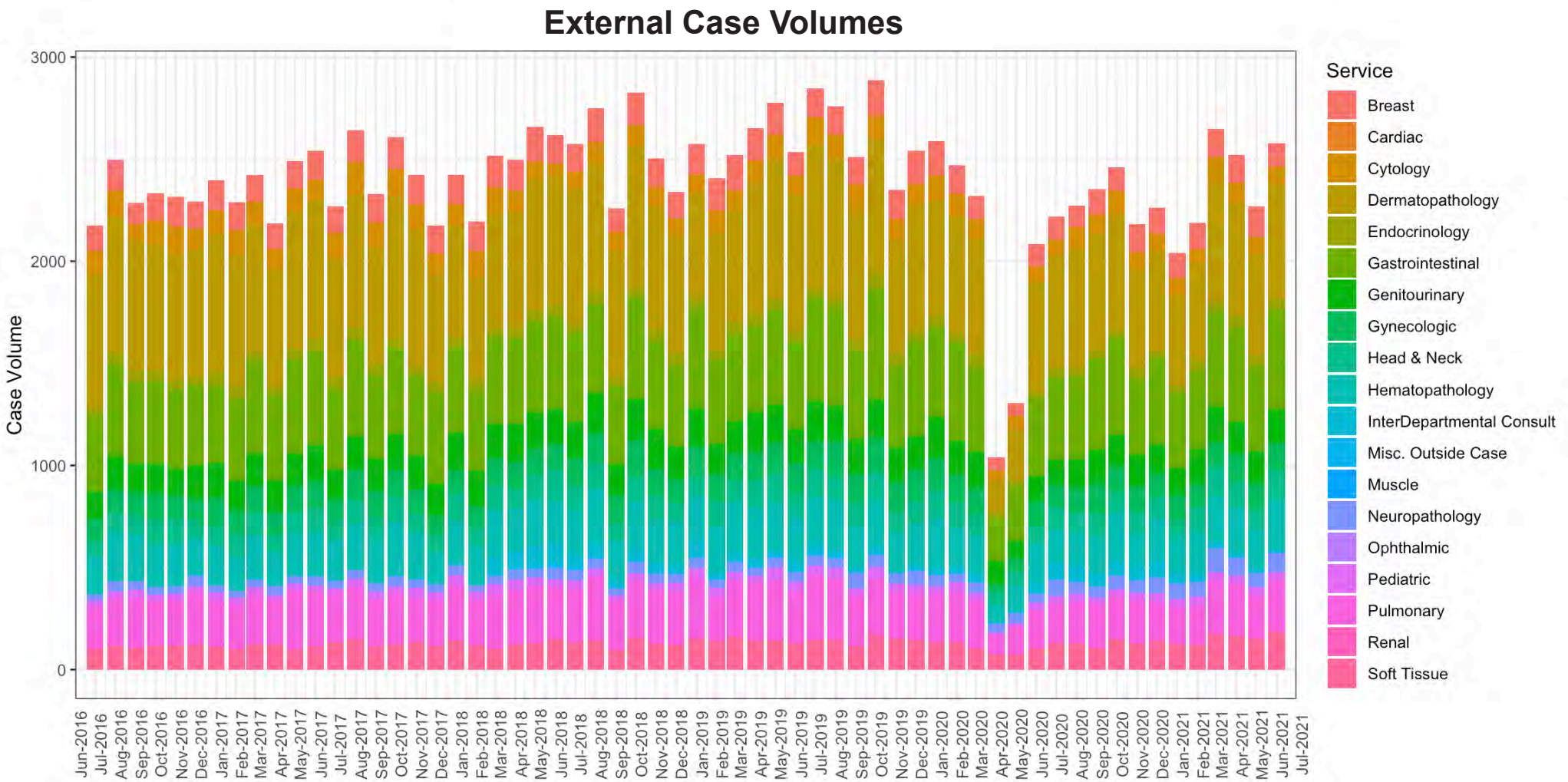


Chart: *External Case Volumes. For figures table, see Appendix* ***pg. 66****.*


EXIT

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 FY21 the extramural AP consultation practice total case volume was 27,997, which represents a 1% increase from FY20.

Turnaround Time

Our consultation service showed continuous improvement with regard to turnaround time, remaining excellent at 3.08 days on avergae per case. This represents a 4.3% improvement over last year and 21% quicker turnaround time compared to five years ago.

Technical-Only Histological Service

Our histology laboratory offers outside laboratories access to our test menu including immunohistochemical and *in situ* hybridization stains, which is handled by our highly skilled technologists. For a limited menu, we also perform both technical stains and pathologist interpretation.

Case Volume

Technical only cases were down 0.6% compared to FY20 but have increased by 10% from five years ago.

Turnaround Time

The turnaround time for Technical Only cases increased by 14% from FY20 to 1.96 days and demonstrated a 127% increase from FY17.

Personnel

In AP there are 55 faculty members that signout, including many world-renowned pathologists. This does not include pathologists who are part of leadership or other divisions, and it also does not include active emeritus faculty. The service also involves 8 fellows. Newly recruited faculty last year include Caroline E. Simon (pediatric pathology), Michael Caplan (autopsy/forensic pathology), Myra Kahn (forensic & breast pathology), and Darius Amjadi (VAAAHS).

Academic Activities

AP faculty excelled at fulfilling our research mission. AP pathologists collectively published 341 peer-reviewed articles in prestigious journals. Our faculty also collectively delivered 67 presentations at regional, national and international meetings and other institutions. Most of these were virtual talks due to the COVID-19 pandemic.

Education

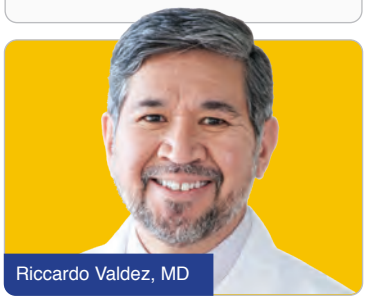
Medical School Teaching Graduate School Teaching

Under the organizational leadership of Dr. Madelyn Lew, nearly 40 AP faculty participated in medical school teaching (M1-M4 students) including lectures, labs, and experiential learning. Several AP faculty members also participated in teaching and mentoring 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.

Clinical Pathology



Director, Clinical Pathology

The Division of Clinical Pathology (CP) encompasses the medical laboratories within the Department of Pathology.These CLIA-certified and CAP-accredited laboratories, similar to the clinical laboratories within the Anatomic Pathology Division, support the diagnosis and management of human disease through automated and/or manual testing of blood, body fluids, bone marrow, and fresh or fixed tissue specimens.

The clinical laboratory disciplines and support services administered within 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; Morphology and Flow Cytometry (Hematopathology Service); Clinical Cytogenetics; Molecular Diagnostics; Histocompatibility; Point-of-Care Testing; Phlebotomy; Specimen Processing. The Michigan Medicine Genetics Laboratories shares infrastructure and CLIA resources with CP.

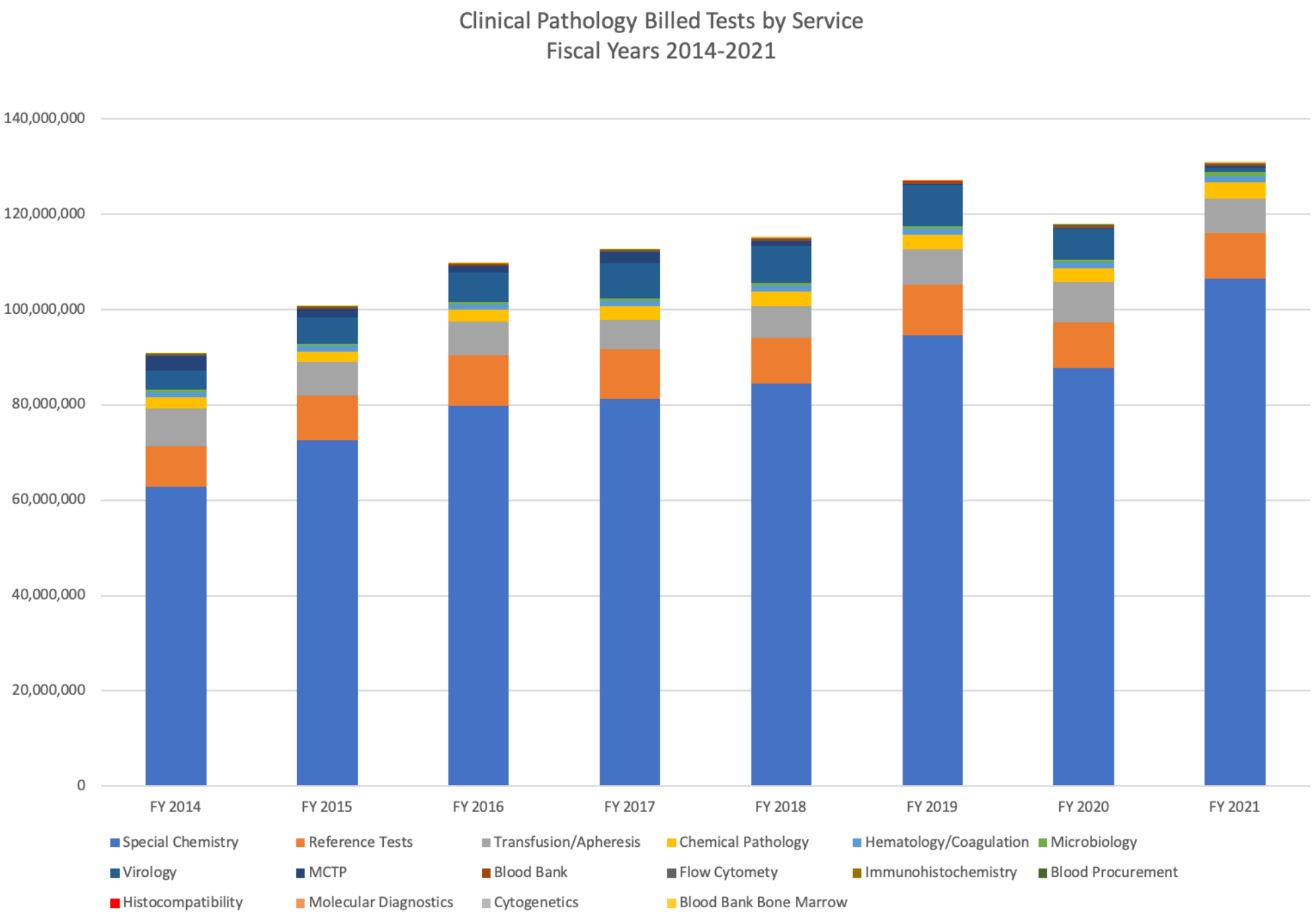
The CP Division has 27 active clinical faculty and approximately 662 staff. The clinical effort of the CP faculty member is equivalent to 12 FTE, and the RVU/FTE is essentially unchanged from last year.

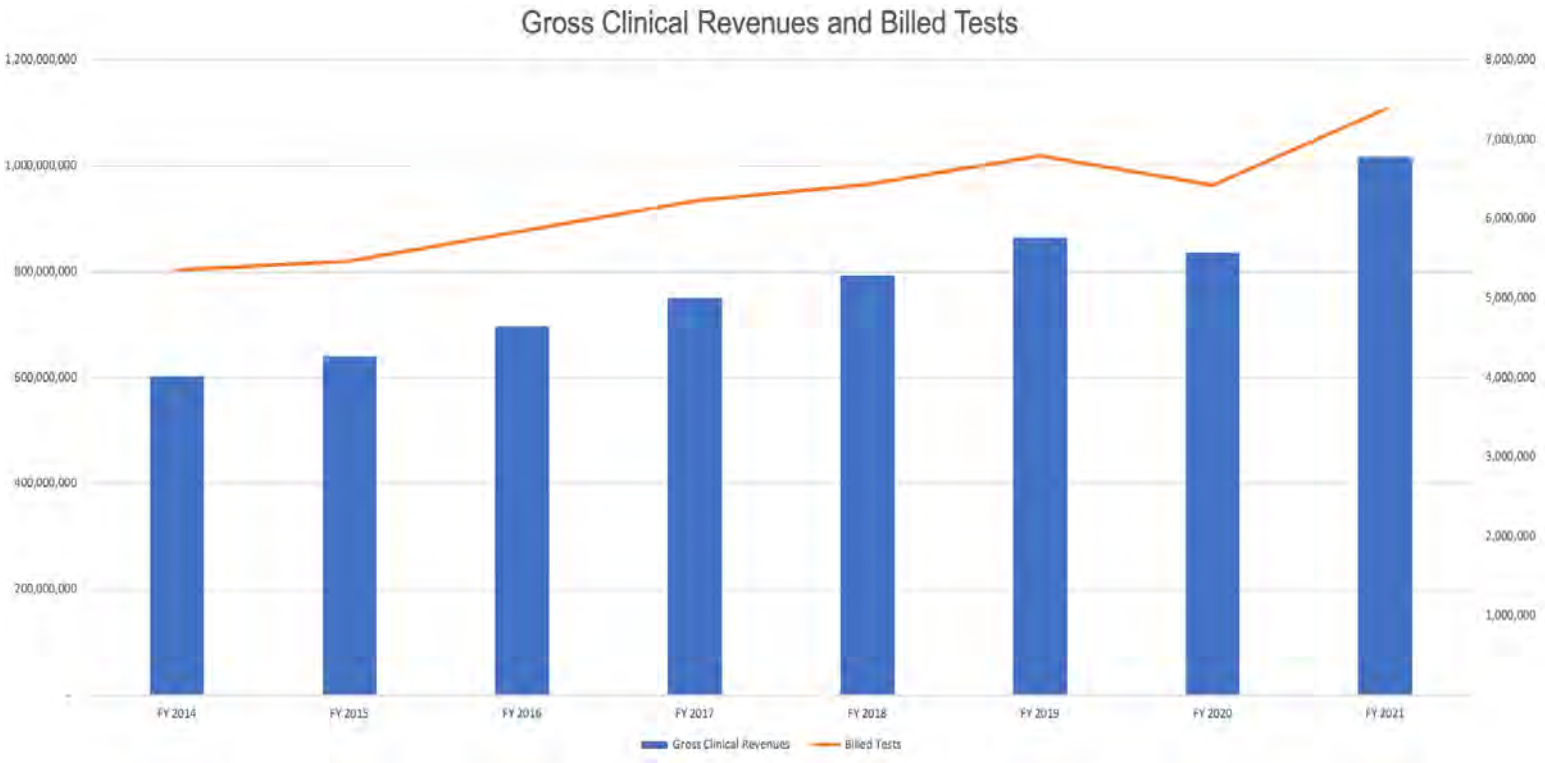
The medical laboratories in the Clinical Pathology Division achieved 7,067,834 billed tests and $937,095,571 gross revenues in FY21, representing increases of 15% and 22%, respectively, compared to FY20.

While the previous year was dominated by rapid and broad COVID clinical test implementation and capacity expansion, the major themes for FY21 were heterogeneous supply chain and laboratory staffing shortages. Nearly all the clinical laboratories, CP and AP, experienced unprecedented turnover and high numbers of open positions. The onsite and offsite phlebotomy services were notably challenged with staff vacancy rates of 35-45% throughout the year.

The UH clinical laboratory portion of the Pathology Relocation and Renovation Project (PRR) resumed in the Fall after a brief pause due to the COVID-19 pandemic. The Clinical Core Lab, Transfusion Medicine, and Specimen Processing Lab each dedicated significant effort and person hours to prepare, plan, and execute interim and permanent moves. This work included preparing and completing the numerous instrument and test validation studies required to maintain expected quality and patient safety.

The clinical laboratories within the CP and AP Divisions were inspected by the College of American Pathologists in FY21. This was a routine inspection in accordance with the CAP terms of accreditation, whereby clinical laboratories are surveyed on a biennial basis or at the discretion (non-routine) deemed necessary by the CAP. Due to COVID-19, the FY21 inspection was a hybrid consisting of one-week virtual document review followed by a traditional two-day onsite visit. Eight of our CLIA-certified and CAP-accredited sites were inspected by an 18-person inspection team (11 onsite) led by Dr. Katherine Robbins from St. Louis University. A total of 22 deficiencies (21 phase II) were identified among the eight lab sites with five of those defects corrected onsite. Five of the cited deficiencies were expunged by the CAP, and the remaining items were easily remedied. Each of the inspected labs received notice of full accreditation within several weeks of the inspection. For reference, the clinical laboratories received 55 deficiencies during the 2019 inspection and 35 during the 2017 inspection (when only six sites were inspected).


Clinical Pathology Billed Tests by Service
Fiscal Years 2014-2021
140,000,000
120,000,000
100,000,000
80,000,000
60,000,000
40,000,000
20,000,000
0
FY 2014
FY 2015
FY 2016
FY 2017
FY 2018
FY 2019
FY 2020
FY 2021
Special Chemistry
Reference Tests
Transfusion/Apheresis
Chemical Pathology
Hematology/Coagulation
Microbiology
Virology
MCTP
Blood Bank
Flow Cytomety
Immunohistochemistry
Blood Procurement
Histocompatibility
Molecular Diagnostics
Cytogenetics
Blood Bank Bone Marrow



Clinical Core Laboratory

Clinical Chemistry, Drug Analysis, and Toxicology

This section of the CCL includes STAT and routine testing in the areas of general chemistry, endocrinology, drug analysis, and toxicology. The testing menu includes routine chemistries (electrolytes, creatinine, liver function, glucose and proteins), lipids, vitamin testing, cardiac markers, tumor markers, reproductive hormones, hepatitis serology testing, metals testing (e.g. lead), therapeutic drug monitoring, drug of abuse testing, and intraoperative parathyroid hormone testing. These University Hospital based laboratories performed roughly 3.3 million billed tests in FY21. The clinical labs stationed in the Adult and Children's Emergency Services areas are administered by the chemistry section of the CCL.

In FY21, the CCL chemistry automation group implemented the following clinical tests: COVID Nucleocapsid and COVID Total antibody serology, Beta Cross Laps, and CA 27,29 tumor marker testing. New instruments were acquired to help manage increasing volumes of Hemoglobin A1c orders and to improve turnaround time. The automation section moved and validated 50 tests and 6 platforms into a newly renovated space as construction continued in the zone. Instrument and track installation of a new automation line capable of performing 51 million assays a year was started with a go-live date of November 2021.

The AES and CES labs began performing the Abbott ID NOW COVID diagnostic test during the past year, performing and resulting as many as 200 rapid COVID tests per day on a 24/7 basis. This improved patient wait times, medical decision making, and patient disposition (discharge, admission) in both emergency rooms.

The Toxicology area brought phosphatidylethanol (PETH) testing

in-house. This resulted in a turnaround time reduction from 7 -10 days (Mayo/Med tox) to 1 – 4 days, and the volume of orders also increased by 27%. A new ICP-MS system was validated and implemented to provide gold standard testing for metals and to pave the way for future assays.

Steroid assay orders also doubled during the last fiscal year, and the lab increased the number of days these tests are performed in response. This all occurred while the section completed moving into a newly renovated lab space requiring revalidation of their assays and instrument platforms.

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, providing lab techs to attend and assist these bedside clinical procedures. The hematology and coagulation labs performed 1,293,850 billed tests in FY21, essentially unchanged from last year. These lab areas have experienced a 6% increase in billed tests and 8.5% increase gross charges in the past five years.

The hematology and coagulation labs moved into newly constructed space during the past year, and in doing so, moved physically and administratively closer to the other labs comprising the Clinical Core Laboratory (chemistry, toxicology, and drug analysis). Substantial planning and work continued throughout the year with emphasis on finalizing automation line specifications and preparing for the implementation of new automated coagulation instruments in early FY22.

The hematology lab transitioned from the Work Area Manager (WAM) middleware to a new middleware product called Caresphere (CWS) in May 2021. The change was necessary for several reasons, but the need to decommission the WAM servers as part of the PRR project drove the decision to move forward with this complicated process during FY21. The electronic rules and triggers programmed into middleware support the automated hematology analyzers and enables the lab to optimize clinical practice, workflow, and throughput in the hematology lab.

Quantitative CD34 and T&B cell subset testing by flow cytometry was transferred to the hematology lab from cell therapy and NCRC hematopathology, respectively, in FY21.

Lauren Smith, MD
Service Director, Hematopathology

Clinical Immunology & Special Chemistry

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

The Clinical Immunology and Special Chemistry labs perform tests 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. The Clinical Immunology lab performed 134,300 billed tests in FY20 and 147,500 in FY21, representing a 9.8% increase. The Special Chemistry lab performed 108,538 billed tests in FY20 and 124,090 in FY21, an increase of 14.3%. Longitudinal year-over-year comparisons for these two areas is complicated by the historical organization of these labs within the clinical chemistry section. Notable highlights from this section include:

- Successful management realignment with Clinical Microbiology to create a more "NCRC-centric" management structure, facilitated by the recruitment of our new Laboratory Manager, Christina Bard.
- Improved efficiency of Quantiferon assay (Mycobacterium tuberculosis sensitization) through conversion from manual ELISA to automated chemiluminescence platform.
- Validation of Treponema pallidum particle agglutination assay (TPPA) in preparation for implementation of more efficient reverse syphilis testing algorithm.
- Implementation of a new renin-aldosterone decision support resource in collaboration with Endocrinology and Metabolism Division of Internal Medicine.
- Increased intra-laboratory platform redundancy for high volume Capillarys and Diasorin XL-based assays.

Jeffrey Warren, MD
Director, Clinical Immunology

Robertson Davenport, MD
Director, Blood Bank and Transfusion Service

Chisa Yamada, MD
Director, Apheresis Services

Laura Cooling, MD
Director, Cellular Therapy Laboratory

Transfusion Medicine

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

Overall blood product utilization increased slightly in FY21 (*See Appendix, **pg. 73***). Transition to all apheresis platelets as well as increased use of pathogen-reduced platelets occurred during the past year. Due to significantly decreased blood donations across the country, FY21 was noteworthy for more frequent blood product shortages compared to prior years. In addition to the typical careful management of the blood product supply performed by the lab staff and attending lab physicians, the FY21 shortages necessitated implementation of a tiered communication plan to ensure the clinical practice was informed of anticipated shortages in a timely manner such that mitigation planning could be performed as needed. The shortages also prompted evaluation of additional blood product suppliers to supplement the primary longstanding vendor, the American Red Cross.

Activity in the Immunohematology Reference Laboratory increased in FY21, reflecting increased complexity of the inpatient population. Similarly, activity also increased in the Cellular Therapies Laboratory because of increasing use of CAR-T therapies by the clinical practice. Overall activity in the Apheresis Procedure Unit increased, led mostly by a higher volume of stem cell collections. Other notable initiatives in FY21 included:

- Implementation of Revised Blood Transfusion Record Form
- Implementation of Confirmatory Blood Type process
- Establishment of workgroups to develop processes for communicating and mitigating blood product shortages
- Initiated QA project with BMT clinical team regarding chain of custody for products
- Initiated APU QA project regarding donor questionnaire to streamline the donation and collection process
- Introduced four new CART commercial products
- Activated participation in eleven new clinical trials

Hematopathology

Morphology & Flow Cytometry Laboratories

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 (morphology) and flow cytometry.

In FY21, 2,060 bone marrow and tissue biopsies collected from Michigan Medicine patients were diagnosed and signed out by eight hematopathology faculty, representing an 8.5% increase as compared to FY20. Bone marrow biopsies from MLabs sources showed a 145% increase compared to FY20 (31 versus 76 biopsies received). The diagnostic service also handled 1,304 cases from external healthcare systems associated with patients seeking care at Michigan Medicine (18% increase). Cases referred for expert consultation by external providers decreased by 10.2% in FY21. This decrease likely reflects lower patient volumes at other clinics and hospitals due to COVID-19. The diagnostic consult service has grown by 74.3% over the past five years.

The flow cytometry lab performed 101,981 billed tests in FY21, a 1% increase compared to FY20. This test volume includes 5,442 leukemia and lymphoma immunophenotyping panels (add chart). Over the past five years, flow cytometry lab test volume has increased by 27.3%. Notable FY21 achievements in the flow cytometry laboratory include:

- Creation of electronic order entry requisitions for clients
- Collaboration among several laboratories to improve bone marrow morphology review and scheduling
- Successful validation of new Becton Dickinson FACSLyric flow cytometers to replace the aged Beckman Coulter instruments
- Completion of four of thirteen lab developed panels (STML, CyAcute, Viability, COGBM, and Triage panels)
- Validation and implementation of the BD Duet system for a more hands off approach to leukemia and lymphoma specimen preparation

Clinical Microbiology and Virology

The Clinical Microbiology Laboratory consists of multiple subspecialty areas (bacteriology, mycology, parasitology, antimicrobial susceptibility, 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 FY21, the Clinical Microbiology Laboratory (including Virology) performed 963,936 total billed tests compared to a total of 566,888 the previous year, representing an 70% increase year-over-year. The significant increase in test volume reflects historical testing patterns re-emerging alongside diagnostic COVID test volume as clinical practice operations continued to ramp up and the pandemic evolved.

Like last year, FY21 was notable for continued supply chain issues affecting not only COVID testing, but also other testing platforms, such as the primary one used for sexually transmitted infection testing. The need for COVID testing in symptomatic individuals varied throughout the year with the ebb and flow of multiple surges; however, asymptomatic testing needs (largely pre-procedure testing) had significant impact on lab resources and testing capacity. To mitigate this, Clinical Microbiology partnered with Molecular Diagnostics, Point-of-Care, and the Core Lab Chemistry ED labs to provide COVID testing on additional platforms, enabling patient care to continue with excellent sensitivity and turnaround times.

Although the lab continued to be significantly impacted by the COVID pandemic in FY21, several notable advancements were achieved, including:

- Updating the design of the Influenza A/B and RSV multiplex test on Diasorin FABR 2.0
- Validating and implementing the Alinity high-throughput analyzer to help meet COVID testing needs
- Validation and implementation of the BioFire Respiratory Panel 2.1 (RP2.1) for the simultaneous detection of SARS-CoV-2 and 21 other respiratory viruses and bacteria in preparation for respiratory virus and influenza season
- Evaluation, validation, and implementation of COVID respiratory sample pooling for testing on the Alinity platform (used to increase capacity and maintain turnaround time of pre-procedure testing)
- Validation and implementation of saliva as an acceptable sample for Alinity COVID testing (to be used as alternative to nasopharyngeal or oropharyngeal swabs in special circumstances)
- Replacement and re-validation of a new Alinity instrument to replace the original instrument which was plagued by many mechanical and software problems
- Implementation of direct loading COVID specimen tubes, which eliminated the need to aliquot COVID specimens, reduced ergonomic stress for lab staff, and improved COVID test turnaround time
- Development of a workflow for biorepository and aliquot storage to enable more rapid and diverse test development going forward

Three major leadership changes occurred in the Clinical Microbiology Lab in FY21. First, Dr. Duane Newton, the laboratory section director and technical supervisor, left the Department of Pathology in September 2020 to pursue an opportunity as an industry consultant. Drs. Bachman and Lephart absorbed many of the duties fulfilled by Dr. Newton, with Dr. Bachman continuing to focus on new test development and serving as a clinical consultant, and Dr. Lephart transitioning to the role of technical supervisor and continuing in the clinical consultant role. A faculty search and selection process to fill the open position left by Dr. Newton's departure is expected to begin its work to find a new colleague for the complex and state-of-the -art clinical microbiology laboratory. Mr. Bill LeBar, the laboratory's administrative manager, retired in January after 14 years of service, and after a national search, Ms. Christina Bard was selected and began her tenure as the Administrative Manager for Clinical Microbiology/Clinical Immunology/Special Chemistry in May 2021.

Finally, because a portion of the Clinical Microbiology Laboratory is at the University Hospital, members of the team were also involved

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

Paul Lephart, PhD
Associate Director, Clinical Microbiology Laboratory

in the planning and preparing for the relocation of related lab services, including blood culture testing, to newly constructed space. Across both sites, the Clinical Microbiology Laboratory has applied lessons from the pandemic to improve its operational structure, and it is well-positioned to excel in the delivery of excellent microbiology testing to Michigan Medicine and MLabs clients in the future.

Molecular & Genomic Pathology

Molecular diagnostics is the science of analyzing biological markers in the genome and proteome, an individual's genetic code, to determine how cells express their genes as proteins. Several specialized laboratory techniques are utilized to diagnose and monitor disease, determine response to therapy, assess risk of relapse, and help determine 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.

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

Noah Brown, MD
Director, Molecular Diagnostics Laboratory

Molecular Diagnostics Laboratory

The Molecular Diagnostics Laboratory (MDL) performed 19,169 total billed tests in FY21, compared to 17,860 in FY20. This represents a 6.8% increase over last year's test volume.

The MDL again remained an active area of new test development, test maintenance, and continuous improvement, and the selected items below represent notable highlights from another productive year:

- Transitioned the solid tumor NGS platform from the Ion Torrent PGM to the Ion Chefs and S5 instrumentation. The workflow improvements allowed us to reduce staffing on the solid tumor NGS rotation to one staff from two and allowed for cost savings with higher throughput. Our cost savings for 1 year were $210,943.53. This was equal to savings of $4,056.61 per week running the new format.
- Factor V Leiden and Prothrombin 20210 mutation assays were changed from FDA kit assays to lab developed tests following a rigorous validation process. The transition led to cost savings of $148.95 per test, and an overall savings of $166,525 for a year of testing for both assays.
- A test platform change from 3130/3730 Genetic Analyzers to 3500 Genetic Analyzers for Fragment Analysis and Sanger Sequencing assays was completed in the past year. This transition resulted from ThermoFisher Scientific's intention to discontinue servicing of 3130 instruments in the near future.
- Molecular Diagnostics validated a COVID-19 test (TaqPath, ThermoFisher) which was put into use July 2020. We validated our COVID-19 testing with existing equipment and support Microbiology's COVID-19 testing when volumes are increased to assist with faster turnaround times. This specific COVID assay was especially useful for helping the University and local community combat the COVID UK variant outbreaks that occurred in January 2021.
- The MDL also began working on the following new test development initiatives during the past year. Each is aimed to improve service while increasing revenue and decreasing expenses:
- Development of common Fusion NGS Panels for a variety of cancer types, such as sarcoma, glioma, salivary, and gynecological tumors. Using a common panel validated and run for all applications conserves resources and reduces expenses, especially related to validation and implementation costs.
- Development of Methylation Array testing which will ultimately be standard of care. The expectation is that methylation array will be highly emphasized in the next WHO and we have an opportunity to be one of a limited number of centers performing the test at this time, supporting our NP consult service as well as oncology. There is also interest from the bone and soft tissue subspecialty, possibly others.

Clinical Cytogenetics

Cytogenetic testing involves analysis of bone marrow, blood, or fresh tissue specimens to look for changes in chromosomes, including rearrangements, additions, deletions, or insertions of genetic material. Changes in chromosome number or structure may be a sign of a genetic disease or condition and may help diagnose some types of cancer.

In FY21, the clinical cytogenetics lab performed 14,249 billed tests. This is an increase of 17.8% compared to FY20. The number of billed tests has increased by 72% over the past five years. The primary tests performed in the Clinical Cytogenetics lab are the karyotype, fluorescence *in-situ* hybridization (FISH; fresh and paraffin embedded tissue), and genomic microarray. Enhancements to increase the sensitivity are often performed including pre-analytical cell separation and mitogen stimulation of cultures.

The Clinical Cytogenetics lab continued to improve patient testing and workflow during the past year. These improvements included:

- The practice of routinely performing karyotyping and Myelodysplastic Syndrome (MDS) FISH panels when requested upfront on the same sample was discontinued. Several publications and our own experience have shown low utility of MDS FISH in patients whose karyotyping study was technically sufficient. A reflex MDS FISH panel was implemented in December 2020 whereby an MDS FISH is only performed in technically insufficient cases (fewer than 15 metaphases). MDS FISH testing was not performed in cases with technically valid karyotypes.
- The amount of reagent probe used for FISH assays was reduced. After careful validation, the lab switched to using 3 ul of probe instead of 7 ul for all oncology FISH cases with a consequent reduction in probe expenses.
- Two new CPT codes were implemented for supplemental analysis in the form of more cells analyzed, more cells counted, and/or additional karyotype analysis performed. The lab performed 394 additional karyotypes and 395 additional chromosome analysis procedures from December 2020 to August 2020.

Lastly, the Clinical Cytogenetics lab began performing the Oncoscan array test for neuropathology and dermatopathology tumors in late June 2021. Performance of these tests is a collaborative lab effort between the Cytogenetics and Molecular Diagnostics laboratories. The MDL performs the FFPE DNA extractions for this testing while the cytogenetics lab performs the testing itself. Faculty from the Clinical Pathology and Anatomic Pathology Division participate in the interpretation and sign out of this molecular genetic test.

Lina Shao, PhD
Director, Cytogenetics

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 Histocompatibility Laboratory performed 22,209 billable tests in FY21, an increase of 16.2% from FY20. In FY21, 1,477 high resolution typings were completed, as compared to 1,469 in FY20, a 0.56% increase. In FY21, 1,245 low resolution typings were completed, as compared to 1,335 in FY20, a 6.7% decrease. Antibody specificity testing increased 10.2% from 9,801 in FY20 to 10,801 in FY21. Antibody screening testing increased 1.9% from 3,618 to 3,687 in FY20. A total of 526 flow cytometric crossmatches were performed in FY21, representing 1% increase compared to FY20. Of note, disease association testing has been steadily increasing over the past several years with a 90% increase seen from FY20 to FY21 and 103% from FY18 to FY21. (*See Chart on* ***pg. 29***)

Validation of next generation sequencing for HLA typing was a major project completed by the HLA lab during the past year with an aim to transition high resolution typing to that method early FY22. Next generation sequencing for transplant compatibility applications has numerous advantages to the clinical laboratory and patient, including elimination of additional typing tests needed to resolve patient HLA type ambiguities. The latter improves workflow and conserves supply and personnel resources. Additional notable highlights for FY21 include:

Matthew Cusick, PhD
Service Director, Histocompatibility Laboratory

- Validation of new BD Lyric flow cytometers for living donor HLA crossmatches.
- Validation of new tray-based method for HLA flow crossmatches, which will eliminate many manual steps in the testing process.
- Continued work to improve antibody screening workflow for better throughput and turn-around time.
- Upgraded HLA specific lab information system, HistoTrac, for the first time in ten years.
- Collaborated and assisted with transition to Epic-Phoenix from Otis for transplant patient database to provide direct care and laboratory clinicians with centralized transplant-specific patient information.
- Streamlined molecular typing to decrease excess Sequence Specific Oligonucleotide typing, and in turn used the lab staff effort to focus on antibody testing and resulting.

Lastly, the HLA laboratory was successfully inspected and accredited by ASHI, as well as CAP, during the last year.

Lee F. Schroeder, MD, PhD
Director, Point of Care Testing

Point-of-Care Testing

The Point-of-Care Mission is to improve patient health by providing access to safe and efficient laboratory testing at the point of care, through service, technology, and education.

Point-of-Care testing (POCT) is laboratory testing performed at or near the patient bedside by thousands of operators throughout Michigan Medicine in both the inpatient and ambulatory settings. Examples include the simpler (waived) glucometer and urine pregnancy testing, as well as more complicated (non-waived) blood gas and viscoelastic testing. The Pathology POCT team supports clinical units with laboratory instruments and test systems, reagents, operator training, quality assurance and regulatory guidance.

Notable achievements for FY21 include the following selected items:

COVID Response
The initial response for point-of-care testing for SARS-CoV-2 was provided with our GeneXpert real-time PCR testing of asymptomatic and symptomatic patients. Throughout 2021, this was offered at several offsite health centers and main medical sites resulting in a total of 11 locations performing testing by non-pathology staff. This permitted aerosol-generating procedures to continue when patients were not able to obtain prior testing, and for symptomatic patients to be tested for COVID/Flu/RSV. To expand the options for SARS-CoV-2 assays, the point-of-care team undertook a set of validations and modeling exercises in order to identify assay/specimen solutions that would provide rapid results with the accuracy needed for our clinical applications. We modeled the diagnostic performance of real-time PCR, isothermic nucleic acid amplification, and antigen testing using both nasal and nasopharyngeal specimens. These efforts led to implementation of the Abbott ID NOW using nasopharyngeal specimens. POCT went live with the assay for Occupational Health Services and the Core lab implemented for Emergency Services.

Training/Quality Assurance

- Trained hundreds of operators to perform point-of-care testing. Includes supporting Nursing competency blitzes and other units such as Anesthesia, Radiology, Labor and Delivery, Survival Flight, ECMO, physician offices, ambulatory health centers, surgery and procedure centers, and Reginal Alliance of Healthy Schools program.
- Maintained glucometer program which includes over 600 glucometers, over 8000 operators, and about 525,000 patient tests in FY21.
- Managed about 20 different test systems and over 200 instruments for point-of-care testing.
- Performed about 500 quality assurance rounds and troubleshooting visits at the various supported sites.
- Integrated new clinical lab document control system into processes.

Laboratory Accreditation
The POCT team facilitated laboratory accreditation biennial inspections at main campus and 5 other CAP (College of American

Pathologists) accredited health centers, and at two other State of Michigan accredited health centers.

A sampling of test volumes for some tests performed at point-of-care is shown below.

Test Name	Number of Patient Tests Uploaded in FY2021
POC Glucose (Glucometer)	525,327
POC Hemoglobin A1C	21,855
POC Blood Gas/Electrolytes (GEM)	37,068
POC UA	48,838
POC COVID	3,955

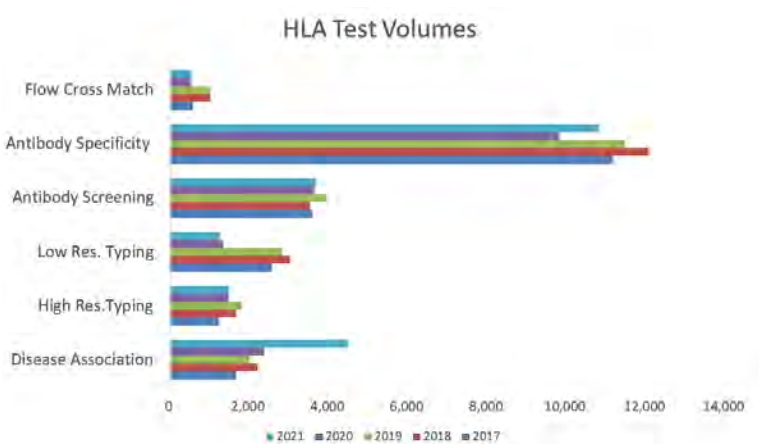


Table (Above): Disease association testing, mentioned on page 27.

Michigan Center for Translational Pathology

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 completed an extension of the earlier MET500 study, MET1000 that integrated the clinical outcomes of patients that had undergone clinical sequencing through MI-ONCOSEQ program. *(See Appendix, **pg. 76**)* Use of next-generation sequencing (NGS) to identify clinically actionable genomic targets has been incorporated into routine clinical practice in the management of advanced solid tumors; however, the clinical utility of this testing remains uncertain. To determine which patients derived the greatest degree of clinical benefit from NGS profiling, we enrolled patients with advanced cancers to undergo fresh tumor biopsy and blood sample collection for genomic profiling of paired tumor and normal DNA (whole-exome or targeted-exome capture with analysis of 1700 genes) and tumor transcriptome (RNA) sequencing. Somatic and germline genomic alterations were annotated and classified according to degree of clinical actionability and results were returned to treating oncologists. Patients' subsequent therapy and treatment response were extracted from the medical record to determine clinical benefit rate from NGS-directed therapy at 6 months and exceptional responses lasting 12 months or longer. During the study period, NGS was attempted on tumors from 1138 patients and was successful in 1015 (89.2%) (MET1000 cohort) (538 men [53.0%]; mean [SD] age, 57.7 [13.3] years). Potentially clinically actionable genomic alterations were discovered in 817 patients (80.5%). Pathogenic germline variants (PGVs) were identified in 160 patients (15.8% of cohort), including 49 PGVs (4.8% of cohort) with therapeutic relevance. For 55 patients with carcinoma of unknown primary origin, NGS identified the primary site in 28 (50.9%), and sequencing-directed therapy in 13 patients resulted in clinical benefit in 7 instances (53.8%), including 5 exceptional responses. The high rate of therapeutically relevant PGVs identified across diverse cancer types supports a recommendation for directed germline testing in all patients with advanced cancer. Additionally, the high frequency of therapeutically relevant somatic and germline findings in patients with carcinoma of unknown primary origin and other rare cancers supports the use of comprehensive NGS profiling as a component of standard of care for these disease entities. (*JAMA Oncol.* 2021 Apr 1;7(4):525-533).

Non-small cell lung cancer (NSCLC) accounts for 85% of cases and is frequently driven by activating mutations in the gene encoding the KRAS GTPase (e.g., KRASG12D). Our previous work demonstrated that Argonaute 2 (AGO2)-a component of the RNA-induced silencing complex (RISC)-physically interacts with RAS and promotes its downstream signaling. We therefore hypothesized that AGO2 could promote KRASG12D-dependent NSCLC *in vivo*. To test the hypothesis, the MCTP KRAS group evaluated the impact of Ago2 knockout in the KPC (LSL-Kras G12D/+ ;p53 f/f ;Cre) mouse model of NSCLC. In KPC mice, intratracheal delivery of adenoviral Cre drove lung-specific expression of a stop-floxed KRASG12D allele and biallelic ablation of p53. Simultaneous biallelic ablation of floxed Ago2 inhibited KPC lung nodule growth while reducing proliferative index and improving pathological grade. We next applied the KP Het C model, in which the Clara cell-specific CCSP-driven Cre activates KRASG12D and ablates a single p53 allele. In these mice, Ago2 ablation also reduced tumor size and grade. In both models, Ago2 knockout inhibited ERK phosphorylation (pERK) in tumor cells, indicating impaired KRAS signaling. RNA sequencing of KPC nodules

and nodule-derived organoids demonstrated impaired canonical KRAS signaling with Ago2 ablation. Strikingly, accumulation of pERK in KPC organoids depended on physical interaction of AGO2 and KRAS. Taken together, our data demonstrated a pathogenic role for AGO2 in KRAS-dependent NSCLC. Given the prevalence of this malignancy and current difficulties in therapeutically targeting KRAS signaling, our work may have future translational relevance. (*Proc Natl Acad Sci USA*. 2021 May 18;118(20):e2026104118).

Earlier, we developed a urine based panel, MyProstateScore, which combines urinary prostate cancer antigen 3 and the TMPRSS2:ERG gene fusion with serum PSA (MPS), which was previously validated to improve detection of GG ⩾2 cancer relative to PSA and clinical risk calculators combining PSA with digital rectal examination, family history and history of previous biopsy (ie Prostate Cancer Prevention Trial risk calculator). In this study, we sought to validate an optimal MyProstateScore threshold for clinical use in ruling out grade group ⩾2 cancer in men referred for biopsy. Biopsy naïve men provided post-digital rectal examination urine prior to biopsy. MyProstateScore was calculated using the validated, locked multivariable model including only serum prostate specific antigen, urinary prostate cancer antigen 3 and urinary TMPRSS2:ERG. The MyProstateScore threshold approximating 95% sensitivity for grade group ⩾2 cancer was identified in a training cohort, and performance was measured in 2 external validation cohorts. We assessed the 1) overall biopsy referral population and 2) population meeting guideline based testing criteria (ie, prostate specific antigen 3-10, or <3 with suspicious digital rectal examination). Validation cohorts were prospectively enrolled from academic (977 patients, median prostate specific antigen 4.5, IQR 3.1-6.0) and community (548, median prostate specific antigen 4.9, IQR 3.7-6.8) settings. In the overall validation population (1,525 patients), 338 men (22%) had grade group ⩾2 cancer on biopsy. The MyProstateScore threshold of 10 provided 97% sensitivity and 98% negative predictive value for grade group ⩾2 cancer. MyProstateScore testing would have prevented 387 unnecessary biopsies (33%), while missing only 10 grade group ⩾2 cancers (3.0%). In 1,242 patients meeting guideline based criteria, MyProstateScore ⩽10 provided 96% sensitivity and 97% negative predictive value, and would have prevented 32% of unnecessary biopsies, missing 3.7% of grade group ⩾2 cancers. In a large, clinically pertinent biopsy referral population, MyProstateScore ⩽10 provided exceptional sensitivity and negative predictive value for ruling out grade group ⩾2 cancer. This straightforward secondary testing approach would reduce the use of costlier and invasive procedures after screening with prostate specific antigen. (*J Urol.* 2021 Mar;205(3):732-739)

Diverse subtypes of renal cell carcinomas (RCCs) display a wide spectrum of histomorphologies, proteogenomic alterations, immune cell infiltration patterns, and clinical behavior. Delineating the cells of origin for different RCC subtypes will provide mechanistic insights into their diverse pathobiology. Here, we employed single-cell RNA sequencing (scRNA-seq) to develop benign and malignant renal cell atlases. Using a random forest model trained on this cell atlas, we predicted the putative cell of origin for more than 10 RCC subtypes. scRNA-seq also revealed several attributes of the tumor microenvironment in the most common subtype of kidney cancer, clear cell RCC (ccRCC). We elucidated an active role for tumor epithelia in promoting immune cell infiltration, potentially explaining why ccRCC responds to immune checkpoint inhibitors, despite having a low neoantigen burden. In addition, we characterized an association between high endothelial cell types and lack of response to immunotherapy in ccRCC. Taken together, these single-cell analyses of benign kidney and RCC provide insight into the putative cell of origin for RCC subtypes and highlight the important role of the tumor microenvironment in influencing ccRCC biology and response to therapy. (*Proc Natl Acad Sci USA*. 2021 Jun 15;118(24):e2103240118).

Covid Impact

Over the past few months, research activities have been allowed to resume to nearly normal at 100% following the initial COVID shutdown in March 2020. Nearly all laboratory research staff are working onsite and several staff members that are able to work remotely are doing so under remote work agreements. Early on we received funding to take advantage of our expertise in AR regulation and apply it towards SARS-CoV-2 related research, and have since published some of our findings (*Proc Natl Acad Sci USA*. 2020; *Communications Med.*, 2021). We are continuing our investigations and testing whether anti-androgen agents such as Proxalutamide or

Enzalutamide can block cytokine storm induced cell death and tissue damage during SARS-CoV-2 infection.

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 continue to develop novel approaches for clinical sequencing and broadening the application of sequence data towards predicting response to immunotherapy and determination of epigenetic status. Thus far we have sequences samples from over 5,000 adult and pediatric patients; a breakdown of the major cohorts for whom results are returned in the form of a 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.

Cohort	Total Patients Enrolled	Patients Enrolled FY21
MO- (MiOncoseq)	1,680	64
TP- (Tumor Profiling)	919	65
PO- (Peds Oncoseq)	751	106
MMRF- Molecular Profiling	715	-
MMRF- MyDrug	151	91
GL- (Germline for MMGL)	313	-
Total	**4,529**	**326**

MI-ONCOSEQ has been supporting several ongoing clinical trials/studies, listed in the Appendix *(pg. 76;* charges based on select cases chosen for sequencing).

In association with MLabs, MCTP's Molecular Testing Lab (MTL) receives orders for and carries out PCA3, Mi-Prostate Score (MPS), and to a smaller extent, Cell Search Circulating Tumor Cell (CTC) assays. Since 2010, MTL has processed 17,013 PCA3, 1,714 MPS and 1,669 CTC assays for clinical use. Additionally, 3,231 PCA3 and 3,231 MPS assays have been processed for research samples. In FY21, MTL processed 222 PCA3 and 86 MPS assays for clinical use.

Program	FY20 Revenue	FY21 Revenue	FY22 Projected Revenue
MMRF	$513,308	$258,781	$500,000
VA/PCF	NA	$185,032	$200,000

MTL also procures biological samples such as urine, blood, and tissue for ongoing clinical and research projects. Since 2010, MTL has procured 1,617 tissue, 5,279 Urine, 5,365 serum, 5,357 EDTA plasma and 5,152 DNA samples. MTL, working closely with the MI Prostate SPORE Biospecimen core, also 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
- **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).

- **HUM00148970** Clinical trial, EDRN Prostate MRI Biomarker Study and Reference set

- **HUM00086525** Biomarkers and clinical parameters associated with Gleason score upgrading

- **PC200234** Integrative molecular profiling of whole urine in African-American men with aggressive prostate cancer

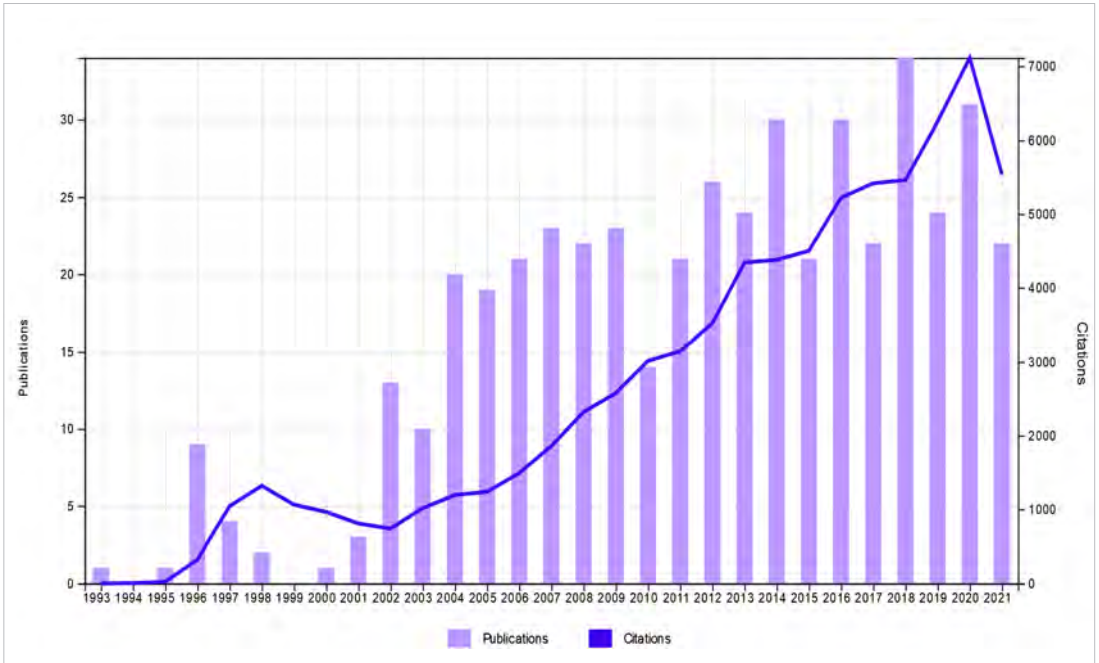
- Interstitial assessment of architectural heterogeneity in prostate cancer using a fine needle photoacoustic probe *ex vivo*. The ultimate goal of this research is to validate a fine needle photoacoustic (PA) probe methods for the diagnosis of prostate cancer (PCa).

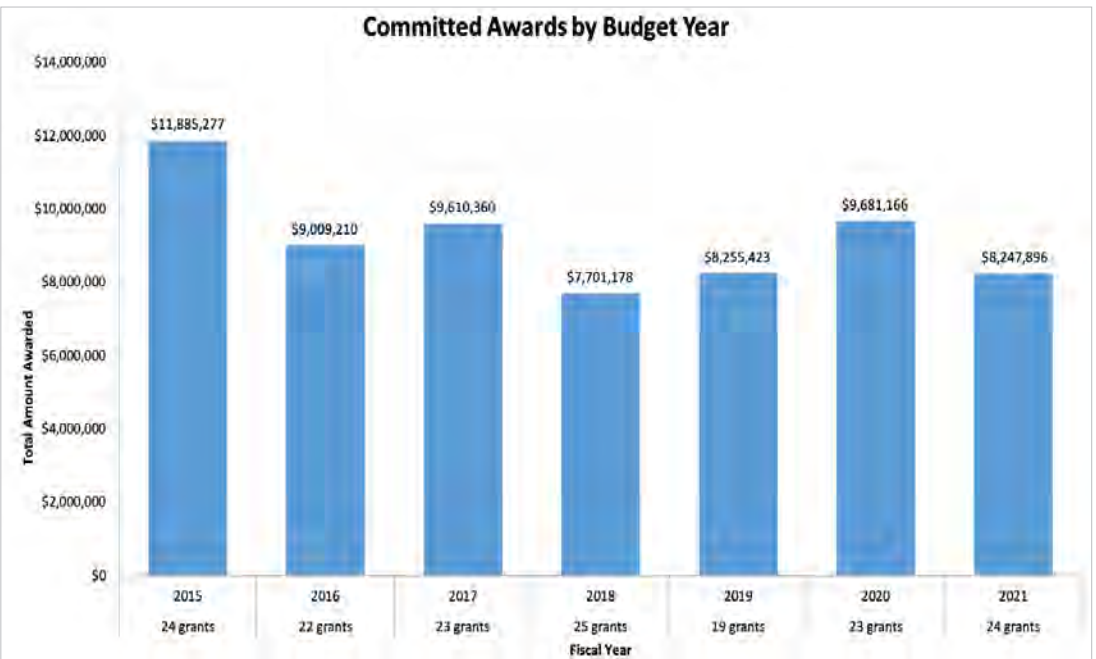
- Collaborative project with Dr. Dev Karan (Medical College of Wisconsin) on how MIC-1 could be used as a clinical diagnostic biomarker for aggressive prostate cancer, specifically for African American men.

Academic Activities

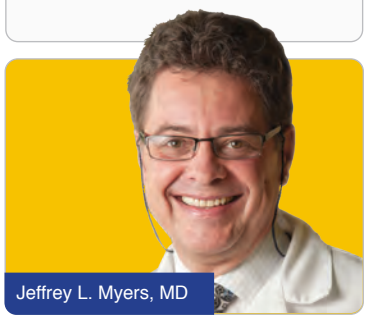
- Total number of publications in FY21:
  Overall, we published 40 papers from July, 2020 – June, 2021, several in high-impact journals (*Cell; Nature; European Urology*). Our publications are highly cited *(see graph top-right)* with an overall H-index of 127 for Dr. Chinnaiyan (Web of Science®).

- Total number of grants held and the total dollar value of the grants over the last 7 years. *(bottom-right)*





Michigan Medicine Laboratories (MLabs)



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 to Michigan Medicine expertise for patients around the world. 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."

FY21 was a busy year for MLabs. As the COVID-19 pandemic waxed and waned, MLabs facilitated COVID-19 tests for over 130,000 students, affiliate hospitals, members of our community, and others. Fast, accurate, easily accessible PCR testing provided collaboratively with faculty, staff, and laboratories throughout our department was a critically important public health measure for limiting spread of the virus. As part of that effort, we opened a pathology-managed drive-through collection site in September of 2020 to provide access to our community, including non-Michigan Medicine patients, to get people back to work, back to school, and traveling safely consistent with requirements of airlines and countries around the world. Creative solutions for unique problems and opportunities included a novel method developed by our team to facilitate observed remote self-collection of specimens linked to rapid transportation and results delivery in support of NYU faculty, staff, and dependents traveling to Shanghai, China.

Partnering with our clients in unique ways predated COVID and will remain a distinguishing feature of our brand. In August 2020, for example, we provided testing for St. Joseph Mercy Hospital in Ann Arbor during a 3-day down time of their laboratory information system. In the course of that project, we provided 3,927 individual test results for inpatients and outpatients cared for by Trinity Health providers.

During Patient Safety Awareness Week, MLabs collaborated with other divisions to initiate a departmental project to create standard work for notification of critical values and urgent unexpected diagnoses. As part of that initiative, MLabs completed a communication subproject comprising a comprehensive survey of our clients and modifications in Salesforce, our customer relationship management (CRM) software, to capture and verify client contact information. This project was submitted for presentation at Michigan Medicine's October 2021 Quality Month program.

Activity and Financials

Due in large part to COVID testing, total activity showed a year-over-year increase of 34% measured as total number of accessioned cases (457,461) (see Figure 1) and 28% measured as total billable tests (641,326).

Total gross charges grew just over 38% (see Figure 2) to a total of $125.8 million compared to $77.6 million in FY20. Gross charges do not reflect actual collections and are instead an imperfect surrogate for revenue. Getting to reliable and accurate measures of revenue and costs is one of the targets for our MSTAR project which is summarized elsewhere in this report.

The distribution of gross charges across the various categories ("market segments") in which we group our MLabs clients is illustrated in Figure 3. Growth was seen across all market segments

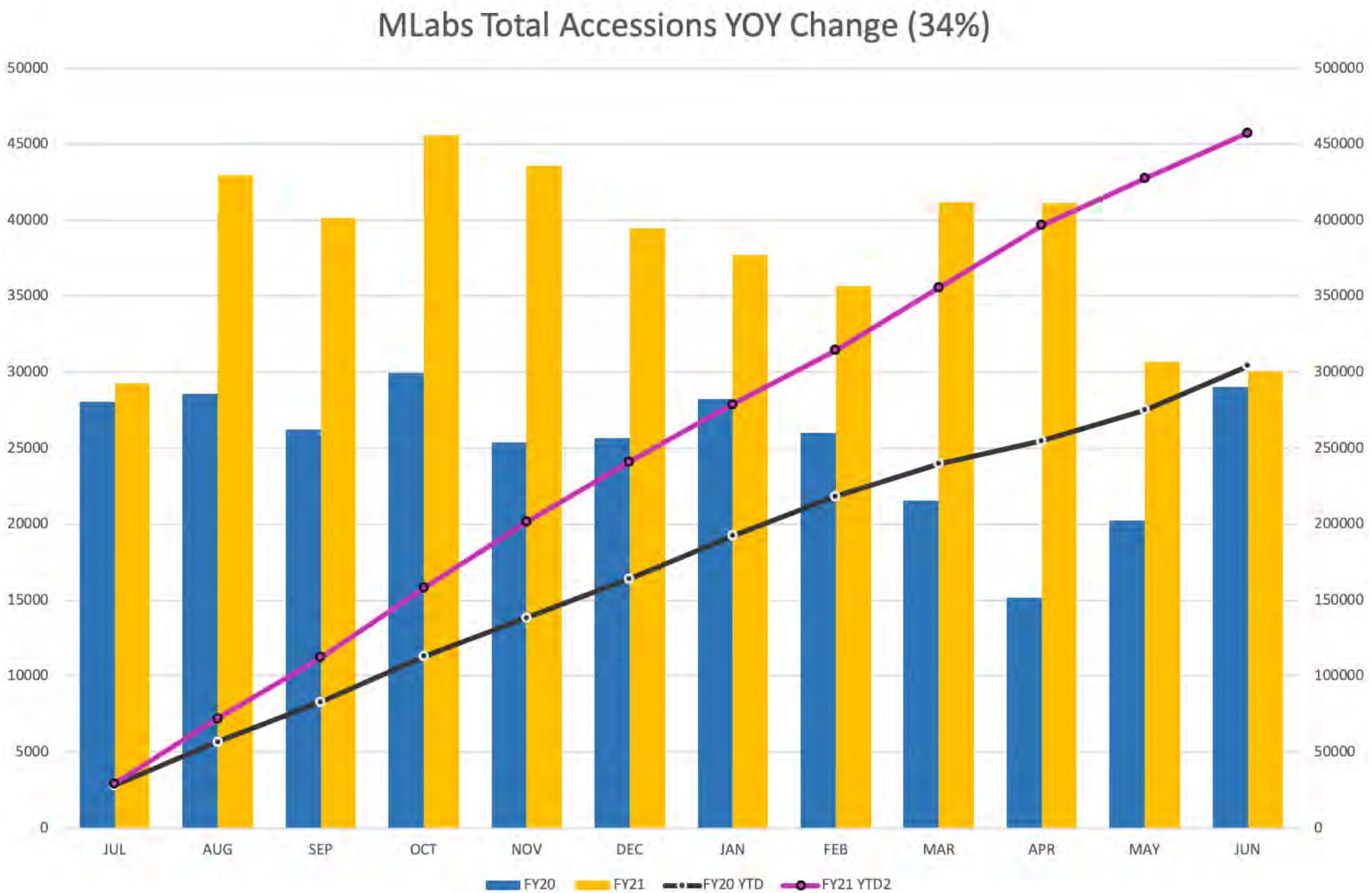


Figure 1. *FY2021 Total Accessions Showed 34% Year-Over-Year Increase*

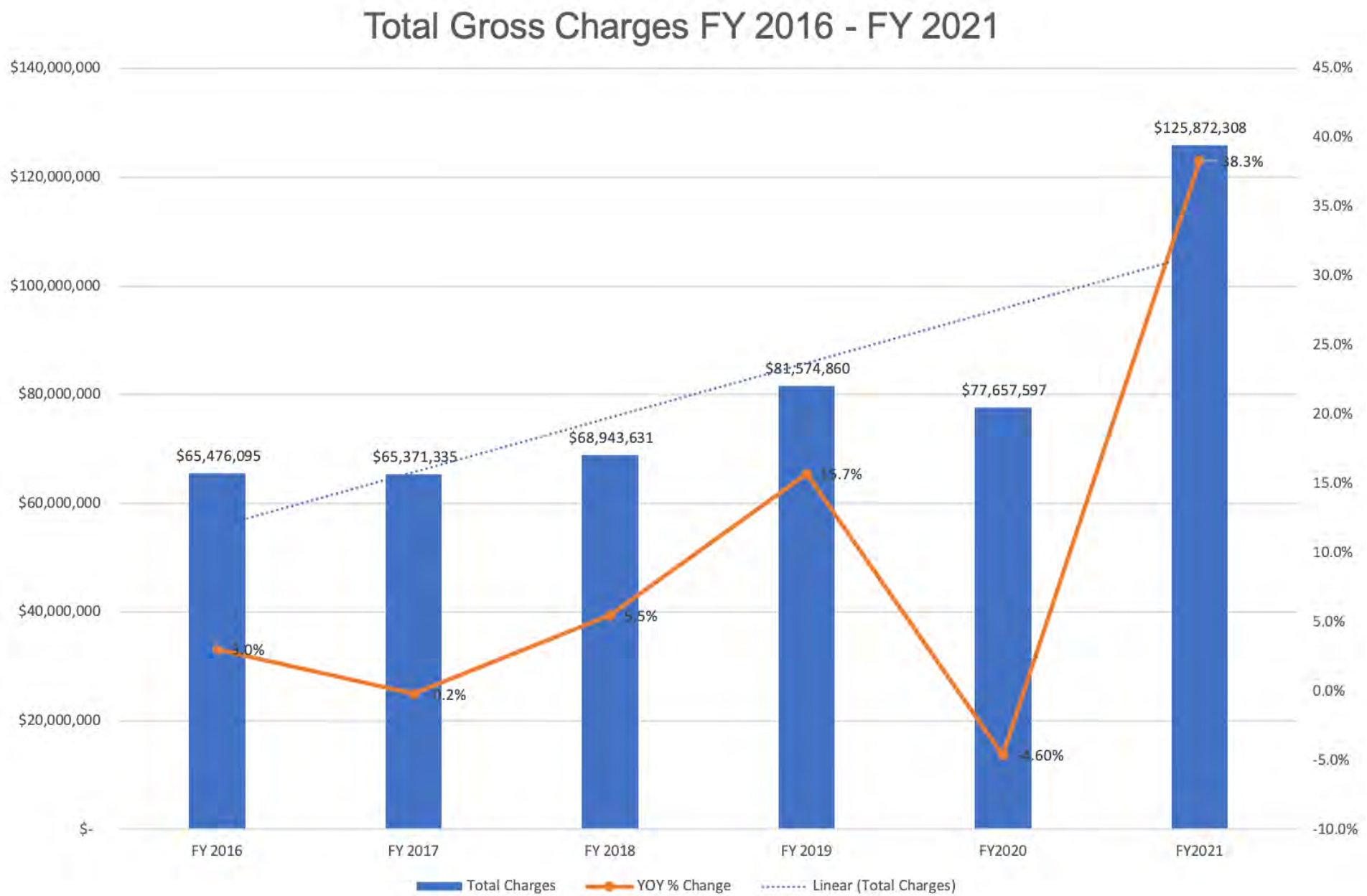


Figure 2. *Annual Gross Charges, FY16-FY21*

in FY21, with the largest year-over-year increases in hospital clients (↑ 101% to $63.2 million) and skilled nursing facilities (↑ 104% to $8.8 million) for whom gross charges doubled. All other sectors showed healthy growth ranging from a 23% year-over-year increase of $2.6 million in hospital pathology groups to a 32% increase in physician offices ($7.2 million) and a 34% increase ($0.9 million) in our reference laboratory/commercial sector.

MSTAR Reboot – MSTAR 2.0

MSTAR (Michigan Medicine Laboratories Strategy for Transformation and Rebirth), a project intended to position us for breakthrough improvement and expansion of the high-quality laboratory and pathology services that we deliver every day to Michigan Medicine patients and providers as well as over 1,000 external clients officially kicked off as MSTAR 2.0. MSTAR was conceived as a project to plan in FY19, then launched and throttled back in FY20, and was rebooted and put on a fast track in FY21. We are now collaborating with a team from the Office of Strategy and Business Development to develop a proposal for the UMH Board projected for institutional review and action by end of FY22.

In December 2020, a revised project plan was initiated in which a smaller, more nimble leadership sponsors group focused on a set of domains essential as foundational elements for success. The sponsors assembled small interdisciplinary exploration teams to do a deep dive into selected domains. Each domain exploration team was supported by our MSTAR consultants, Lester ("Les") Wold and Keith Laughman, who engaged the teams in a process of inquiry, data exploration, and ideation. A listing of currently active or completed domain exploration teams and their goals are listed below:

- **Test menu team** – Bryan Betz, Karla Bialk, Brigid Boggs (admin support), Carmen Gherasim, Janette Todd, Brian Tolle (PM/facilitator), Ric Valdez (lead), Jeff Warren

  Goal: To explore our current processes for test menu expansion with an eye toward developing a robust sustainable process for building and maintaining a dynamic forward-looking test menu to meet the needs of our patients and providers as a leading quaternary health system.

- **Courier management team** – Melina Adler (PM/facilitator), Gayle Carroll, Kathy Derkowski, Nichole Gabriel (admin support), Mike McVicker (lead)

  Goal: To understand our current model for courier services and identify short- and long-term opportunities for incremental and breakthrough improvements in the effectiveness and efficiency of specimen transportation and client resupply.

- **Client service and call center operations** – Christine Baker (PM/facilitator), Lisa Brown (admin support), Devon Fera, Deirdre Fidler (lead), Kristina Martin, Christine Meldrum, Janette Todd.

  Goal: To understand current state of our call center's operations and identify opportunities to extend call center functions that move us closer to a fully integrated (MM + MLabs) patient and client services center model.

- **CP accessioning and exception handling** – Lisa Brown (admin support), Jackie Goodman, Steve Gregg, Kristina Martin, Mary Tocco (lead), Brian Tolle (PM/facilitator)

  Goal: Evaluate the current state of work done within client sites that influences accessioning of clinical pathology specimens at our specimen collection sites, and specimen handling when received at NLNC or ULNC.

- **Clinical ordering patterns** – Lisa Brown (admin support), Scott Owens (co-lead), Lee Schroeder (co-lead), Ross Smith (data analyst), Brian Tolle (PM/facilitator), Riccardo Valdez.

  Goal: Explore the labs impact on the cost of care, and better

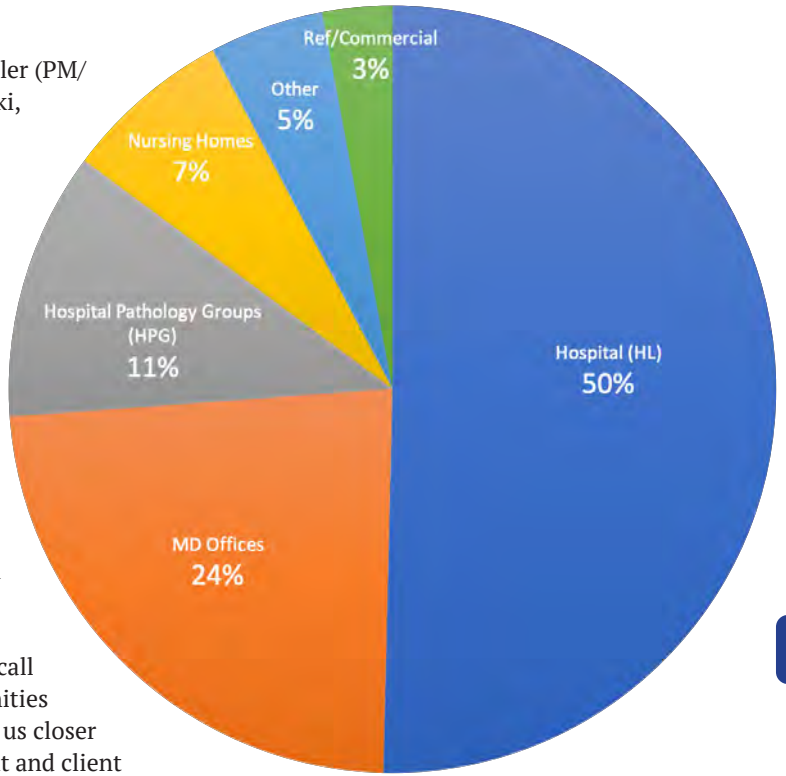


Figure 3. *FY2021 Total Gross Charges by Market Segment.*

communicate with MM the benefits of laboratory work.

- **Lab production costs** – Melina Adler (PM/facilitator), Julia Dahl (lead), Nichole Gabriel (admin support), David Golden, Mike McVicker, Christine Shaneyfelt.

  Goal: In combination with other MSTAR work group initiatives, develop a robust financial view of department clinical services (MLabs and Michigan Medicine) net revenue and margin to establish baseline KPIs for both. Provide a high-level view of resources required and processes involved in determining cost at both a laboratory and test level.

- **Middleware (Atlas)** – Michelle Adams, Melina Adler (PM/facilitator), Karla Bialk (lead), Deirdre Fidler, Nichole Gabriel (admin support), Jackie Goodman, Steve Gregg, Andrea Hawk, Eric Jedynak (ad hoc), Kristina Martin, Dave McClintock (ad hoc), Mary Tocco.

  Goal: Define the minimum viable product and services requirements (our minimum functional needs) for our middleware vendor considering each of your domains—functionality likely to result in an immediate improvement to your domain.

- **Phlebotomy services and workforce development** – Carol Farver (lead), Kristina Martin, Christine Rigney

  Goal: Develop a model to develop, nurture, and sustain the allied health staff and laboratory professionals essential for providing laboratory services at scale.

- **Market Opportunities Review and Proforma Development** - Karla Bialk, Shirley Hoffman (admin support), Kelly Labarge, Keith Laughman (lead), Christine Shaneyfelt

  Goal: Review and refresh previous market assessments [from MSTAR 1.0] and develop financial projections to forecast impact on margin contribution.

As a result of the tremendous amount of work the teams accomplished, several agile projects have been recommended to demonstrate the benefits and costs of closing gaps in our current portfolio of laboratory and pathology services and generate content for a business plan, providing context and compelling stories for whatever the ask(s) might be.

In the first quarter of FY22, Drs. Parkos, Dahl, and Myers together with our MSTAR consultants will meet with institutional leaders and staff from the Office of Strategic Planning and Business Development (SPBD) to explore ways in which we can work together to move MSTAR forward. The goal of this, the final leg of our MSTAR journey, is to craft a strategic business plan for institutional review, endorsement, and approval. As part of that process, members of SPBD, including Keith Dickey (Chief Strategy Officer), Scott Flanders (Chief Clinical Strategy Officer), Travis Souza (Director of Strategy), and Mayuri Guntupalli (Director of Strategic Planning) will meet with members of our faculty and staff as their team strives to understand the complex laboratory services that we provide. They will assess the strengths, weaknesses, opportunities, and threats that characterize our current state, while also assessing the financial impact of growth opportunities that are aligned with all our missions.

Summary

MLabs continues to thrive as a division that makes available to the region, the state, the country, and the world the expertise, skills, and experience that distinguish the students, trainees, staff, and faculty throughout our department of pathology. More than anything else it is our people – everyone, not just the staff and faculty administratively assigned to MLabs – who represent our market distinction in a highly competitive space. And never have they walked the talk with greater purpose than they did in FY21 as we continued the work of managing our response to an unprecedented and unpredictable global pandemic while simultaneously serving the needs of others who looked to us for help.

Veterans Affairs Pathology & Laboratory Medicine


Darius Amjadi, MD, JD

Chief of Pathology and Laboratory Services, 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. Darius Amjadi, MD, JD, joined the AAVAHS in May 2021 as the Chief of Pathology and Laboratory Services, filling the vacancy left by the retiring Chief, Dr. Stephen Chensue. Born and raised in Honolulu, Hawaii, Amjadi is a neuropathologist by training. After serving 8.5 years in the Army, including deployment to Iraq, and 9 years at the Portland, Oregon and Spokane, Washington VA Medical Centers, he relocated to Ann Arbor, Michigan with his wife, Leah Klass, and their two daughters. Amjadi is focused on expanding services to support other VA facilities both regionally and nationally, including working toward a national VA telepathology consortium. Toward this end, Shannon Bielauskas, DO, rejoined the AAVHS on September 1, 2020 as an Assistant Professor and Naumann Nisar, MBABS, joined the team on March 1, 2021 as a Clinical Instructor. Finally, Aaron Belknap, MD, Assistant Professor, joined the AAVHS Pathology and Laboratory Medicine unit on July 1, 2021.

The VA Ann Arbor is a designated cancer center providing regional full-service clinical laboratory testing. They support Anatomic Pathology services in Centers in Battle Creek, Saginaw, Detroit, and Northern Indiana. In addition, chemistry and hematology testing is offered at their Toledo, Ohio laboratory, and point-of-care testing is offered in Flint and Jackson, Michigan community outpatient clinics. Three new clinics are scheduled to open in Canton, Adrian and Howell in the next 6 months. Data presented below is for the year that ended December 31, 2020.

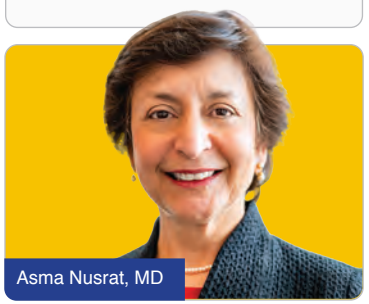
Clinical Pathology workload in the Ann Arbor laboratory has current average annual growth rate of 2% since 2009. Anatomic Pathology workload increased increase at an average rate of 6% per year in the prior decade but fell by almost 30% in 2020 due to COVID-related reduction in cases. The VHA establishes 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 88% 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 2020. Cytology reporting fell short for the second straight year, even with the addition of new staff in 2020, so this is a point of emphasis in 2021. When compared to similar VA medical centers, the VA Ann Arbor workload was the highest among those facilities in 2020, more than double the average RVUs of other 1b facility laboratories and greater than all but four 1a facilities. Pathologist productivity is likewise among the highest with the lowest pathologist labor expense per billable test.

In 2020-2021, the laboratory entered a new phase as a regional reference lab for COVID testing, including starting a molecular testing section. Our cytology section has begun using remote robotic microscopy to allow pathologists to perform rapid aspiration evaluations (ROSE) from their offices. In 2022, the VA Ann Arbor is scheduled to convert to a Cerner-based information system.

Service	Accessions	Target	%Meeting
Surgical Pathology	10,132	95% reported <2d	98.99%
Non-Gyn Cytology	2,370	95% reported <2d	89.66%
Gyn Cytology	834	95% reported <14d	98.07%
Frozen Section	108	95% reported <20min	99.50%
Autopsy	5	100% completed <30d	100%

Clockwise: *Darius Amjadi, MD, JD at scope, Nauman Nisar, MBBS, Aaron Belknap, MD, and Shannon Bieliauskas, DO.*

Research Mission



Director, Experimental Pathology

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 ~65,600 sq. ft. of research space in numerous building 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 $31,605,639 in grant funding the past academic year. At the National Level, we have the fifth highest number of R01 grants awarded to experimental pathology faculty. 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 thirteen NIH grants (R01 to R37 grants and subcontracts), four Department of Defense (DoD) grants and nineteen foundation/industry grants (Figure 2). EP faculty also continue to be outstanding mentors which is reflected in research fellowship and career development awards that were received by trainees in faculty laboratories. Members of our clinical divisions (AP/CP) participated on many of these extra-mural grant funded initiatives supporting our collaborative clinical and research environment in the department.

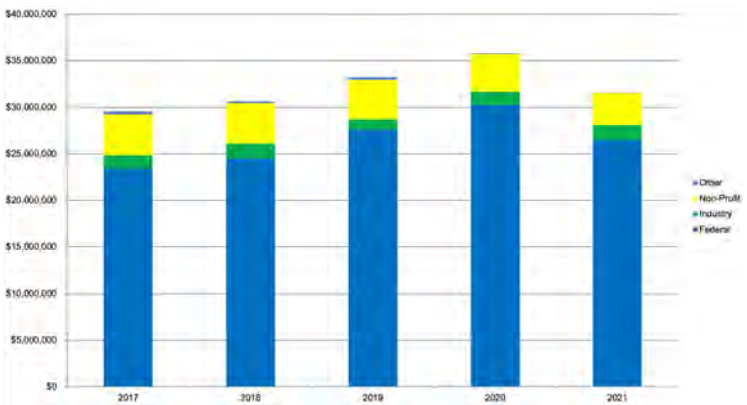


Figure 1: *Funds awarded from federal, non-profit, and industry.*

In addition to independent principal investigator grants, EP training awards have included career-development and fellowship grants from the NIH and private foundations. In keeping with these successful funding metrics, grant indirect costs excelled in the medical school and faculty continue to maintain high dollar density of research space that on the average is above $154/sq. ft.

Innovation and research success of EP faculty is further reflected in 31 patent applications and 15 issued patents,12 new invention reports and 6 new commercialization agreements. A summary of these faculty achievements is shown in Figure 3 (pg. 43).

Furthermore, high research productivity is supported by many new discoveries and high impact publications. Pathology faculty published 571 manuscripts in high-impact journals that include *Nature Methods*, *Nature Communications*, *Nature Chemical Biology*,

National Institute of Health (NIH)

Type of Grant	Faculty Name
R01 - Subcontract	Basrur, Venkatesha
R01 - Subcontract	DiFeo, Analisa
R01	Dressler, Gregory
R56	Ferguson, David
UH2 - Subcontract	Hodgin, Jeffrey
R03	Lieberman, Andrew
R21	Lombard, David
R37	Nunez, Gabriel
R01	Parkos, Charles
R01	Phan, Sem
R01 - Subcontract	Rajendiran, Thekkelnaycke
R01	Ryan, Russell

Other Governmental Granting Agencies

Sponsor	Faculty Name
DOD	Davenport, Robertson
DOD	Farkash, Evan
DOD	Hodgin, Jeffrey / Rao, Arvind
DOD	Lombard, David
Dept. of Veterans Affairs	Robinson, Dan

Figure 2: *Research Funding*

Industry & Nonprofits

Sponsor	Faculty Name
ASIP	Aslam, Muhammad
Prostate Cancer Foundation	Chinnaiyan, Arul / Cieslik, Marcin / Vaishampayan, Ulka / Xiao, Lanbo
King Abdullah University of Science and Technology (KAUST)	Cierpicki, Tomasz
Innovation in Cancer Informatics (ICI)	Cieslik, Marcin
BenevolentAI	DiFeo, Analisa
Tulane University	Harms, Paul
Arvinas, Inc.	Lieberman, Andrew
Dana's Angels Research Trust TO Support Of Accelerated Research for Niemann-Pick C	Lieberman, Andrew
Dana's Angels Research Trust TO Support Of Accelerated Research for Niemann-Pick C	Lieberman, Andrew
Genentech, Inc.	Nesvizhskii, Alexey
Circle Pharma	Nikolovska-Coleska, Zaneta
Bristol-Myers Squibb TO Prostate Cancer Foundation	Robinson, Dan / Alva, Ajjai
Bill and Melinda Gates Foundation TO Johns Hopkins University	Schroeder, Lee
Ara Parseghian Medical Research Foundation	Schultz, Mark
Niemann Pick Canada	Schultz, Mark
University of Sharjah	Soofi, Abdulsalam
Hyundai Hope on Wheels	Venneti, Sriram
Flamingo Therapeutics	Wang, Xiaoming “Mindy”
Edward P. Evans Foundation	Zhang, Xiaotian

Trainee and Career Development

Sponsor	Faculty Name
F31	Dang, Derek (Venneti, Sriram)
K01	Schultz, Mark / Lieberman, Andrew
Prostate Cancer Foundation	Tosoian, Jeffrey John/Chinnaiyan, Arul

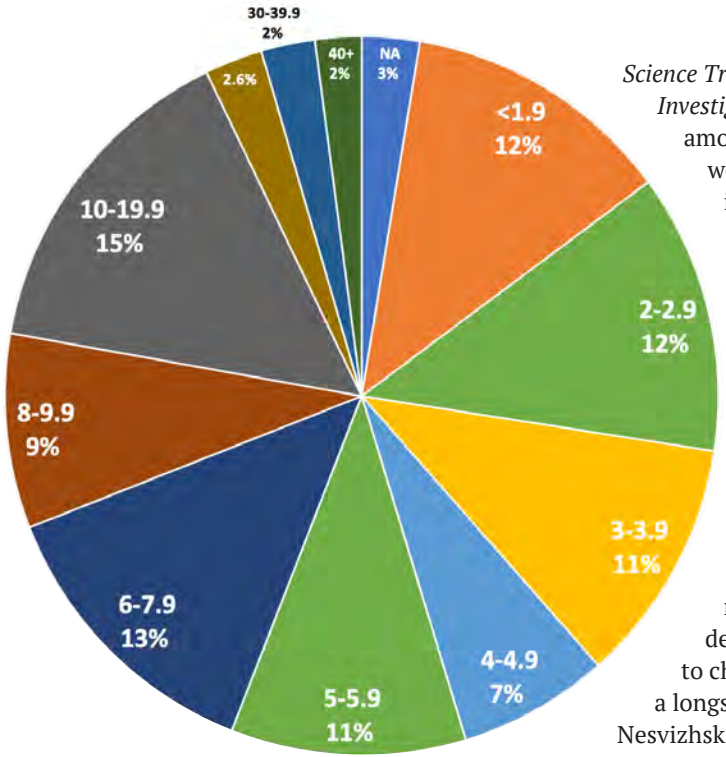


Chart: *Manuscripts published in FY21 by journal impact factor.*

Science Translational Medicine, *Journal of Clinical Investigation*, *Journal of Experimental Medicine*, among many others. 22% of manuscripts were published in journals with an impact factor of greater than 10 and an additional 22% were accepted in journals that have an impact factor of 6-10 (Adjoining figure). Among the many outstanding published manuscripts, a few highlights this year include the following:

- Dr. Alexey Nesvizhskii's high level of productivity includes senior-author mansucripts published in *Nature Methods*. Glycosylation is an important complex, post-translational modifications of proteins, making development of high-throughput methods to characterize protein glycosylation a longstanding goal of glycobiology. Dr. Nesvizhskii's group reported a novel algorithm for mass spectrometry (MS)-based glycoproteomics analysis, enabling a dramatic reduction in computation time compared to existing glycoproteomics tools. Because of how glycopeptides fragment in the mass spectrometer, the approach also greatly improves the sensitivity of detection of glycopeptides, ultimately identifying more glycopeptides and glycosylation sites. Together, these advances enable a more detailed understanding of protein glycosylation in large-scale analyses, helping to advance our understanding of the many roles of glycosylation in health and disease.

- In an article published in *Nature Chemical Biology*, Drs. Tomasz Cierpicki and Jolanta Grembecka report development of first-in-class small molecule inhibitors of PRC1 (polycomb repressive complex 1) E3 ligase module composed of RING1B-BMI1 heterodimer. They employed fragment-based drug discovery approaches combined with medicinal chemistry to develop a compound RB-3, which binds to RING1B-BMI1 in cancer cells and blocks its E3 ligase activity. Treatment of leukemia cell lines and AML patient samples with RB-3 resulted in loss of CD34 stem cell marker and cellular differentiation. Their team is currently developing a new generation of PRC1 inhibitors as a potential treatment to target leukemia initiating cells.

- Dr. Gabriel Nuñez continues to make important discoveries related to host defense. In an article published in *Cell Host Microbe*, his group reported that Staphylococcus aureus growth and invasion are differentially regulated by the Agr quorum-sensing system that limits intracellular killing within neutrophils to promote pathogen expansion in the dermis and subcutaneous tissue in the skin. Agr limited oxidative and non-oxidative killing in neutrophils by inhibiting pathogen late endosome localization and promoting phagosome escape.

- Dr. Thomas Wilson has continued to advance the field of DNA repair. Recent years have seen considerable interest in understanding the most important regulatory decision in DNA double-strand break repair – the transition to 5' resection – which commits a break to homologous recombination. This decision is critical to promoting accurate DNA repair and suppressing chromosomal translocations as seen in human diseases. In a recent paper that was published and highlighted in *Nucleic Acids Research*, Dr. Wilson's group addressed an experimental barrier to progress in this field by developing a novel method with low background for high-throughput sequencing of single DNA molecules undergoing resection in yeast. They tracked critical resection initiation events as they happened *in vivo*, leading to substantive new mechanistic insights into the resection process.

- Dr. Analisa DiFeo's studies have focused on pathogenesis of ovarian cancer. Her article published in *Nature Communications* identified a role of microRNA-181a in the initiation of ovarian cancer development through inducing genomic instability and simultaneously suppressing the intrinsic immune response. These studies introduced miR-181a as a putative biomarker for early detection of ovarian cancer and the miR-181a-STING axis as a promising target for therapeutic exploitation.

- Dr. Richard Miller's studies have continued to make significant advances in the field of aging. His laboratory is part of a three-site research consortium, the Intervention Testing Program, now in its 18th year, that evaluates drugs thought likely to slow aging and extend healthy lifespan in mice. Earlier ITP publications had shown that a non-feminizing steroid, 17-alpha-estradiol, could extend lifespan of males (without effect on female mice) when started early in adult life. In a recent study published in *Aging Cell*, his group reports that this agent extends lifespan, in males only, even when initiated late in middle age. In a separate paper, the Miller lab found that middle-aged mice treated with this agent show improved muscle strength, endurance, and glucose homeostasis.

- David B. Lombard's research group identified the contribution of a deacylase SIRT5 in melanoma pathogenesis. Results were published in the *Journal of Clinical Investigation*. SIRT5 promotes melanoma survival and growth by regulating chromatin, and expression of specific oncogenes such as Myc and the melanocytic transcription factor MITF. Since SIRT5 deficiency is well-tolerated in mice, these findings suggest that SIRT5 may represent an attractive novel therapeutic target in melanoma and certain other cancer types.

- Dr. Sriram Venneti has made novel discoveries in the field of childhood brain tumors. In two papers recently published in *Science Translational Medicine*, the Venneti group identified that childhood ependymomas are epigenetically driven diseases that bear global reduction of the repressive epigenetic marker H3K27me3. His studies demonstrated that posterior fossa ependymomas tumor cells epigenetically enhance key metabolic pathways including glycolysis and mitochondrial metabolism. Surprisingly, the anti-diabetic drug metformin inhibited these key metabolic pathways and increased H3K27me3 in tumor cells resulting in marked tumor suppression in pre-clinical animal models. Overall, this study raises the possibility of repurposing metformin as a potential treatment for these childhood brain cancers.

In a second paper also published in *Science Translational Medicine*, the Venneti group set out to identify therapeutic targets by performing comprehensive epigenetic analyses including mapping out aberrant histone and DNA methylation. They observed that the epigenetic changes led to increased secretion of LIF (leukemia inhibitory factor). LIF, in turn, activated STAT3 signaling, which has been implicated in a number of other types of cancer. In mouse models of H3.3G34R/V glioma, WP1066, which is a small-molecule inhibitor of STAT3 that can cross the blood-brain barrier, suppressed tumor growth and greatly improved length of mouse survival. WP1066 is currently being tested in clinical trials for adult glioblastomas and therefore offers promise to launch clinical trials for children with H3.3G34R/V mutant glioblastoma.

Our faculty have also continued to excel in many other important academic pursuits that include medical and graduate student teaching, participation in seminars and committees at the institutional, national and international levels. Dr. Nicholas Lukacs was elected and is serving as the President of the Society of Leukocyte Biology. Dr. Celina Kleer is a member of the Arthur Purdy Stout Society of Pathologists and was also invited to be the sole practicing pathologist on the organizing committee for the San Antonio Breast Cancer Symposium, the largest breast cancer meeting in the world. Dr. Kathy Cho serves as a Co-Leader in the Cancer Genetics Program, Rogel Cancer Center at our university. Furthermore, Dr. Jolanta Grembecka is a Co-Leader of the Developmental Therapeutics program at the Rogel Cancer Center. Dr. Andrew Lieberman serves as a Deputy Editor, JCI Insight. In the teaching arena, Dr. David Lombard serves as the Director of the Cancer Biology Graduate Training Program and Dr. Alexey Nesvizhskii successfully renewed the NIH T32 training grant for the Proteogenomics of Cancer Training program.

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 played an important role in advocating for the importance of scientific funding to senators and congress members in Washington, DC.

At the Institutional level, Dr. Thomas Wilson continues to serve in a senior position as the Co-PI of the Michigan Biosciences Initiative

All Issued Patents	
Patent Title	**Inventors**
Bridged Bicyclic Inhibitors of Menin-MLL and Methods of Use	Dmitry Borkin, Jolanta Grembecka, Jonathan Pollock, Szymon Klossowski, Tomasz Cierpicki
ERG Targeted Therapy	Arul Chinnaiyan, Xiaoju Wang
Substituted Inhibitors of Menin-MLL and Methods of Use	Dmitry Borkin, Jolanta Grembecka, Jonathan Pollock, Szymon Klossowski, Tomasz Cierpicki
Compositions and Methods for Treating Cancer	Arul Chinnaiyan, Yasuyuki Hosono
Non-Coding RNAs and Uses Thereof	Arul Chinnaiyan, Felix Feng, John Prensner, Matthew Iyer, Yashar Niknafs
Biomarkers for Predicting Responsiveness to Decitabine Therapy	Kristen Meldi, Maria Figueroa, Tingting Qin
RAF Gene Fusions	Arul Chinnaiyan, Nallasivam Palanisamy, Shanker Kalyana Sundaram
Compositions and Methods for Treating Cancer	Arul Chinnaiyan, Marcin Cieslik, Rohit Malik, Sethuramasundaram Pitchiaya, Yajia Zhang

Figure 3: *Patent Applications. Continued in Appendix on* ***pg. 76*** *for Invention Reports.*

(Single-Cell Spatial Analysis Program) in the medical school and has successfully implemented new cutting-edge technologies in this area.

Dr. Nick Lukacs serves as the scientific director for the Mary H. Weiser Food Allergy Center (MHWFAC). Four pathology faculty, Drs. Nick Lukacs, Simon Hogan, Chang Kim, and Catherine Ptaschinski, are members of the Food Allergy Center. 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, early life immune development, 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). 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. In addition, investigators in the MHWFAC have been successful in acquiring additional funding to support their research 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 Lukacs and Ptaschinski Labs have a recent manuscript in the *Journal of Experimental Medicine* that examines the maternal and post-natal effects of the microbiome on developing immune responses (*JEM* 2021 Vol. 218 No. 11). Dr. Chang Kim's laboratory published a seminal paper on innate lymphoid cells in *Science Immunology* (4:5(54)), while Dr. Simon Hogan's lab published an important study on the role of CFTR on gut epithelial cell barrier function that regulates the development of food allergy (*Mucosal Immunology* 14:135-143).

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 has continued to play an important 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 biorepository, 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 COVID19 pandemic.

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

Education Mission

Director, Division of Education Programs

In FY21, The University of Michigan Pathology Residency Program was the #1 ranked program in the Midwest and #6 in the United States. In addition, five of our six 2021 graduating residents stayed at Michigan Medicine to continue their training in a pathology subspecialty fellowship.

Program Type	Ranking by Reputation	Ranking by Research Output
All U.S. programs	6	22
Midwest programs	1	5

Michigan Medicine

For our incoming resident cohort, we received 494 applications to fill 6 open slots. The number of applications increased from 450 in the previous year. We had an exceptionally talented pool of applicants and this year, our AP/CP matched residents came mostly from the Midwest region including three from Michigan. Meet our class of 2025:

- **Ashley Brent, MD** / Wright State University Boonshoft School of Medicine
- **Ryan Cecchi, MD** / State University of New York Downstate (SUNY)
- **Elaina Daniels** / Oakland University
- **Elizabeth Higginson** / Michigan State University
- **Amber Holtz** / Wayne State University
- **Michael Olp** / Medical College of Wisconsin

Kristine Konopka, MD
Director, Residency Training Program

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 FY21, there were approximately 175 conferences, most offering CME credit. Following state and CDC guidelines, the majority were offered as a hybrid or modified in-person and virtual format.

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. 74*** *of the Appendix*).

Six residents completed residency training in FY21 with four remaining at Michigan Medicine to continue subspecialty training in pathology and one in fellowship in Virginia. 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, 2020, we welcomed:

- Bone and Soft Tissue Fellow
  Michella Whisman, MD
- Cytopathology Fellow
  Lin Zhang, MD, PhD
- Dermatopathology Fellows
  Tyler Menge, MD and Nicholas Zoumberos, MD
- Forensic Pathology Fellow
  Ariane Robison, MD
- Gastrointestinal Pathology Fellow
  Shula Schechter, MD
- Genitourinary Pathology Fellow
  Aaron Belknap, MD
- Gynecologic & Breast Pathology Fellow
  Emily McMullen, MD
- Hematopathology Fellows
  Ganna Shestakova, MD, PhD and Steven Van Norman, MD
- Molecular Genetic Pathology Fellows
  Jacob Abel, MD and Audrey Jajosky, MD, PhD
- Neuropathology Fellow
  Yelena Fudym, DO (year 2)
- Pathology Informatics Fellow
  Mustafa Yousif, MD
- Surgical Pathology Fellows
  Chae Hwa Kim, MD, Abid Rahman, MD, Chelsea Styles, MD, and Beena Ahsan, MD
- Thoracic Pathology Fellow
  Rachael Fels Elliott, MD, PhD

Medical Student Teaching

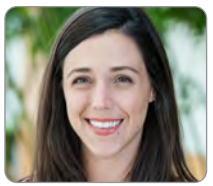
The Department of Pathology has a long history of playing an integral role in pre-clinical medical student education. In Foundations of Medicine 2, one of the first sequences encountered by medical students in the Scientific Trunk, we introduce the foundational principles of Pathology – Cell Injury & 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 Drs. 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, Sara Abbott, 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

Madelyn Lew, MD
Director, Medical School
Pathology Education Curriculum

Laura Griesinger, MD
Chief Resident

Ania Owczarczyk, MD, PhD
Assistant Chief Resident

Amanda Kitson, MD
HO IV



Ashley Bradt, DO
HO IV

Cisley Hines, MD
HO IV

Alex Taylor, MD
HO IV

Margaret Fang, MD
HO III

Efrain Gutierrez-Lanz, MD
HO III

Justin Kelley, MD, MPH
HO III

Lauren Kroll-Wheeler, MD
HO III

Tim Miller, MD
HO III

Catherine Perez, MD
HO III

William Perry, MD, MPH
HO III

Batoul Aoun, DP
HO II

Geoffrey Halling, MD
HO II

Ryan Landvater, MD
HO II

David Nai, MD
HO II

Emile Pinarbasi, MD, PhD
HO II

Jaclyn Plotzke, MD
HO II

Julianne Szczepanski, MD
HO II

Katelyn Zebrowski, MD
HO II

Haley Amoth, MD
HO I

Thomas Herb, MD
HO I

Vincent Laufer, MD, PhD
HO I

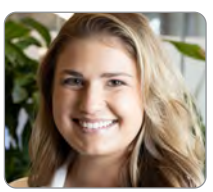
Nathan McCammon, MD
HO I

Corey Post, MD
HO I

Fysal Shennib, MD
HO I

Nicole Tomm, MD
HO I

Maxwell Wang, MD
HO I



Ashley Brent, MD
Incoming HO I

Ryan Cecchi, MD
Incoming HO I

Elaina Daniels, MD
Incoming HO I

Elizabeth Higginson, MD
Incoming HO I

Amber Holtz, MD
Incoming HO I

Michael Olp, MD
Incoming HO I

2020-2021 Pathology Residents

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

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. In January 2021, a revamped curriculum was launched which incorporated educational grossing and microscopic sessions directed specifically to medical students. Using these sessions along with case-based small group sessions 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.

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 & 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 38 Pathology research mentors/labs from which to choose and 22 students performing their PhD thesis research in Pathology Department laboratories during FY21.

The 2020-2021 academic year was a very challenging year. Due to the pandemic we had to modify many of the events that normally take place in person. Most of our events were conducted virtually including courses, preliminary exams, weekly seminar series, annual research symposium as well as the T32 TPTR workshops and retreat. We also started holding regular office hours through Zoom, providing a platform for our students to interact with the MCP leadership, ask questions, get information or just enjoy some conversation. To address the social needs of the MCP students, we organize multiple events throughout the year including happy hours, picnics, and ice cream socials. These activities give the students and faculty an opportunity to interact and strengthen their sense of community. This year, because of the pandemic and restrictions on gathering, we were not able to organize these regular events. Fortunately, following the CDC recommendations and social distancing guidelines, an ice cream social event was organized where the students walked to a nearby park to spend time with their peers. After several months of being at home the attendees enjoyed coming together again for some social interaction.

Another big shift in our program was holding our admissions and recruiting events online. While this may not have been the ideal experience for the students we were recruiting, we were able to facilitate outstanding conversations with the prospective students we interviewed while also showing them what the Molecular & Cellular Pathology program has to offer. Despite the challenges, we succeeded in recruiting four excellent students for our program. In August 2021, our new MCP and PIBS students participated in a half-day event to discuss the program and to learn about available research rotation projects.


Jacob Abel, MD


Beena Ahsan, MD

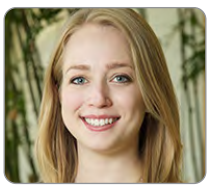

Aaron Belknap, MD


Rachael Fels Elliot, MD, PhD


Yelena Fudym, DO


Audrey Jajosky, MD, PhD


Chae Hwa Kim, MD


Emily McMullen, MD


Tyler Menge, MD


Abid Rhaman, MD


Ariane Robison, MD


Shula Schechter, MD


Ganna Shestakova, MD, PhD


Chelsea Styles, MD


Steven Van Norman, MD


Michella Whisman, MD


Mustafa Yousif, MBChB


Lin Zhang, MD, PhD


Nicholas Zoumberos, MD


Helen Worrell, MD

Fellow	New Position	Institution
Jacob Abel, MD	Physician, Molecular Pathology	Providence St. Joseph Health Molecular Genetic Laboratory, Portland, OR
Beena Ahsan, MD	Assistant Professor	University of Chicago
Aaron Belknap, MD	Assistant Professor	VA Ann Arbor
Rachael Fels Elliott, MD, PhD	Assistant professor	University of Kansas
Yelena Fudym, DO	Neuropathologist	Akron Children's Hospital
Audrey Jajosky, MD, PhD	Assistant Professor	University of Rochester, Henrietta, NY
Chae Hwa Kim, MD	Thoracic Fellow	Michigan Medicine
Emily McMullen, MD	Pathologist	Grand Traverse Pathology
Tyler Menge, MD	Pathologist	CTA Pathology, VA, Ann Arbor,
Abid Rhaman, MD	Taking time off	
Ariane Robison, MD	Deputy Chief Medical Examiner	Mississippi State ME Office
Shula Schechter, MD	Assistant Professor	University of Pittsburg
Ganna Shestakova, MD, PhD	Fellow – Molecular Genetic Pathology	University of Utah
Chelsea Styles, MD	Gastrointestinal Fellow	Michigan Medicine
Steven Van Norman, MD	Fellow – Molecular Genetic Pathology	University of New Mexico
Michella Whisman, MD	Assistant Professor	University of Arkansas
Mustafa Yousif, MBChB	Assistant Professor	Vanderbilt University
Lin Zhang, MD, PhD	Pathologist	Clin-Path Associates, Phoenix, AZ
Nicholas Zoumberos, MD	Assistant Professor	University of Arkansas
Helen Worrell	Pathologist	Beaumont Hospital, Troy, MI

2020-2021 Graduating Fellows

Each year, the Director of the MCP meets individually with the students to discuss their progress. In addition, students are invited to an annual MCP Student Council meeting to provide their feedback, opinions, and suggestions. These activities are organized 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 leadership and mentoring skills with younger students and undergraduates. In FY21, the students participated in many events led by a variety of organizations, including:

- Science Olympiad tutor
- Developing Future Biologists
- miLEAD Consulting
- Graduate Rackham International Advocacy Team (GRIN)
- Science Communication Fellow – UM Museum of Natural History
- Michigan DNA Day Ambassador
- Michigan Asylum Collaborative (UMAC)
- Chad Tough Pediatric Tumor Foundation
- Association of Multicultural Scientists (AMS)
- Bioinformatics Black Student Union (BBSU)
- Science Education and Engagement for Kids (SEEK)

Every year MCP students organize the Department Research Symposium. This year it was held virtually on November 6, 2020. The invited keynote speaker was Dr. Ana Maria Cuervo from Albert Einstein College of Medicine, presenting "Targeting selective autophagy in aging and age-related diseases".

During this fiscal year, five students joined the MCP graduate program. They and their mentors were encouraged to attend mentoring sessions offered by Rackham's Office of Student Success and prepare their mentoring plan. All five students successfully completed their preliminary exams in December 2020, and passed to candidacy status allowing them to focus on their research thesis work. By the end of the winter semester 2021, students had their first thesis committee meetings and presented their thesis research proposal. In this year two students graduated with their PhD degrees *(See Appendix, **pg. 77** for more details)*:

Graduate	Current Position
Samantha Kemp	Postdoctoral Fellow, University of Pennsylvania
Abhijit Parolia	Research Investigator, University of Michigan Medical School

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
Derek Dang	NIH F31 fellowship
Jessica McAnulty	Rogel Cancer Center PIBS Graduate Student Scholarship
Siva Kumar Natarajan	Mistletoe Research Fellowship
Sanjana Eyunni	Rackham Graduate Student Research Award
Kristen Lozada Soto	Training in Basic & Translational Digestive Sciences Award
Alexander Monovich	Proteogenomics of Cancer Training Program
Mohamed Mire	Society for Leukocyte Biology Abstract Award

The MCP students regularly published their research work in high-impact peer-reviewed journals. This year two first-author manuscripts were published by the following students: Brian Basinski and colleagues in *Trends in Molecular Medicine*, 2021; Jessica McAnulty and colleagues in *International Journal of Molecular Sciences*, 2020. Nine co-author manuscripts were published by the following students: Shih-Chun Chu et al. *Molecular Oncology*, 2021; Angela Guo et al. *Journal of Clinical Investigation*, 2021; David Hu et al. *Haematologica,* 2020; Kristen Lozada Soto et al. *Health Equity*, 2021; Sahiti Marella et al, *Cellular and Molecular Gastroenterology and Hepatology*, 2021; Mohamed Mire et al, *The Journal of Immunology*, 2021 and Viruses, 2021, Alexander Monovich et al in the *Journal of Clinical Investigation*, 2021 and Siva Kumar Natarajan et al. *Science Translational Medicine*, 2021.

Translational Pathology Training Grant

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

Trainee	Academic Program	Mentor	Year
Brian Basinski	Molecular & Cellular Pathology	Dr. Rajesh Rao	1st
Alec Chu	Molecular & Cellular Pathology	Drs. Marcin Cieslik & Arul Chinnaiyan	1st
Anthony Garcia	Pharmacology	Dr. Yoichi Osawa	1st
Jessica McAnulty	Molecular & Cellular Pathology	Dr. Analisa DiFeo	2nd
Anna Michmerhuizen	Cellular & Molecular Biology	Dr. Corey Speers	2nd

Collectively, thirteen students have been funded by the T32 TPTR program and five graduated. Importantly, all graduated trainees successfully continued their careers in the biomedical research workforce focusing on translational research: Lucas Huffman (Mentor: Dr. Roman Giger) is a Research Administration Fellow at the University of Michigan Medical School; Shawn Whitefield (Mentor: Dr. Evan Snitkin), after finishing clinical fellowship in Microbiology, started a new position in September 2021 as a Clinical Genomic Scientist in Infectious Disease and Metagenomics at Invitae; Andi Cani (Mentor: Dr. Scott Tomlins), recipient of the UM Precision Health Scholars Award in 2018, is a postdoctoral fellow at University of Michigan; Karson Kump (Mentor: Dr. Zaneta Nikolovska-Coleska), recipient of the American Association for Cancer Research Scholar-in-Training Award 2020, is a consultant at Health Advances; and Samantha Kemp (Mentor: Dr. Marina Pasca di Magliano) is a postdoctoral fellow at University of Pennsylvania.

In FY21, the first 5-years of the T32 TPTR were completed with great success. The TPTR team obtained an additional 5 years of funding from the NIH (2021-2026). We were fortunate to have the number of funded slots increase to six trainees proving that our program is achieving and exceeding its goals to improve the future of translational research.

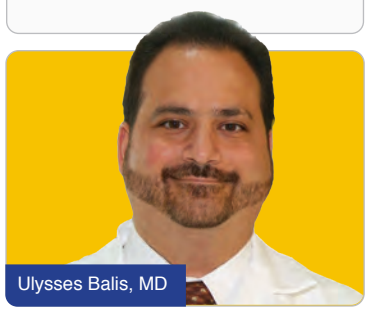
Conferences and Symposia

- 19th Annual Pathology Research Symposium, November 6, 2020. A symposium planned and led by graduate students. The symposium featured a keynote speaker, Dr. Ana Maria Cuervo, Robert and Renée Belfer Chair for the Study of Neurodegenerative Diseases, Professor, Department of Developmental & Molecular Biology, Department of Anatomy & Structural Biology and Department of Medicine (Hepatology), Albert Einstein College of Medicine, along with talks and posters by our students and faculty, as well as a career panel with experts from different career paths.
- 4th Annual T32 TPTR Retreat, December 9, 2020. At this event the trainees presented their translational research projects. The keynote speaker was Gary Hammer, MD, PhD, Millie Schembechler Professor of Adrenal Cancer, Director - Endocrine Oncology Program, University of Michigan.

The 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 we invited the following speakers: Lei Zheng, MD, PhD (Johns Hopkins), Jae Jung, PhD (Cleveland Clinic), Vera Gorbunova, PhD (University of Rochester), Nada Jabado, MD, PhD (McGill University), and Brian Liau, PhD (Harvard University).

The T32 TPTR holds monthly workshops covering topics of relevance to translational research and showcases the work being done by our trainees. This year we had presentations from Drs. Mark Cohen, Lauren Smith, and Gary Hammer. We also had presentations by trainees Jessica McAnulty (DeFeo lab), Brian Basinski (Rao lab), Anna Michmerhuizen (Speers lab), Anthony Garcia (Osawa lab), and Alec Chu (Cieslik lab).

Pathology Informatics



Ulysses Balis, MD

Director, Pathology Informatics

David McClintock, MD
Director, Digital Pathology

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 Whole Slide Imaging (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, the 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 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 Informatics 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

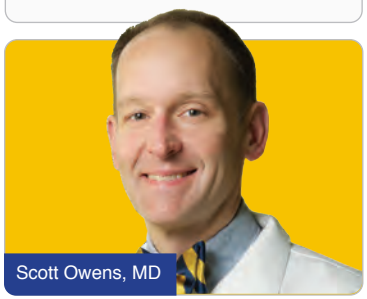
incremental desktop workstations intended for the new space at University Hospital. Additionally, the Informatics Desktop Team was an integral component of the ongoing instrumentation and workstation staging efforts at University Hospital, as PRR phase 2 commenced.

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



Director, Division of Quality and Health Improvement

Fiscal year 2021 was a time of significant change in the Division of Quality and Health Improvement (DQHI). The ongoing COVID pandemic saw continued changes in the way DQHI does business, although with little in the way of disruptions or slowdowns in progress due directly to the crisis. DQHI personnel continue to provide consultative expertise in quality improvement, high-reliability organizations, and project management for a variety of efforts and programs within the Department. The manager position was restored to 1.0 FTE during the year, as fiscal pressures in the institution stabilized.

While the division adapted to pandemic-related challenges, FY21 saw the departure of both occupants of the Project Manager positions in the division; Amy Harrison to a Project Senior Manager position in Michigan Medicine administration, and Jeff Lott to a Project Senior Manager position in the Michigan Medicine Quality Department. This significantly slowed progress on our main work streams (see below) for a time and, due to ongoing changes in the approval process for position replacements that have been in place since the early days of the pandemic, filling these positions was more challenging than in previous years. In addition, FY21 saw the permanent departure of Lukas Hager from our Data Scientist position, as he pursues a PhD in Economics from the University of Washington. Lukas had been helping with data gathering, analysis, and visualization on a part-time (0.2 FTE) basis but this position became untenable as the intensity of his studies increased. I am pleased to report that all three positions have now been filled, one in late FY21 and two in early FY22.

Education

Under the leadership of Brian Tolle, first- and second-year residents again undertook the annual Quality (QI) Curriculum, which was developed in partnership with the Education Division several years ago. After discussion with Dr. Kristine Konopka (former Residency Program Director), the decision was made to provide the FY20 cohort of residents with time to complete their projects, which were interrupted by the onset of the pandemic early in 2020. In addition, the first- and second-year residents began the scheduled FY21 curriculum roughly on schedule. Throughout these sessions, it became clear that the residents' attitudes about the value and priority of the curriculum had shifted over the course of the pandemic, giving an opportunity for additional P-D-C-A work to optimize the curriculum for FY22. Discussions with current program leadership are ongoing to this end.

MSTAR

Under the overall direction of Drs. Jeffrey Myers and Julia Dahl, several DQHI personnel played an increased role in the Michigan Medicine Laboratories/MLabs MSTAR project during late FY21. Project management, data science, quality improvement, and facilitation activities and expertise have all been utilized in several of the workstreams that have been sponsored as part of the MSTAR project, including work on a new test development approach, understanding and improving clinical test ordering patterns, and improvement of test/specimen accessioning. These efforts have significant commonality with many of the efforts that DQHI has been working on for several years, including laboratory stewardship/test utilization (clinical

test ordering patterns) and asset management (specimen accessioning, tracking and results reporting).

Patient Asset Management Initiative (PAMI)

Amy Harrison continued her leadership in early FY20 as overall program manager of this departmental initiative aimed at stewardship of patients' physical and digital assets while they are in our care. As in prior years, FY21'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 can interact with the laboratory information system (Soft) to accurately track the movement of assets throughout the Department. FY21 saw continued deployment throughout the enterprise, in work carried out by Amy, Jeff Lott and the Pathology Informatics team. After Amy's departure, work continued under Jeff Lott, albeit at a slowed pace. Additional work was largely on hold after Jeff's departure, and Keisha Beck is now becoming familiar with the project since her arrival in late FY21. Up- and downstream asset management activities (e.g., specimen ordering and collection practices, results reporting, and slide/block archiving and retrieval) are being evaluated for the next phase(s) of the project, which has significant areas of complementarity with work being done as part of the MSTAR project.

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; http://ihpi.umich.edu/our-work/strategic-initiatives/mprove), 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). The departures of Jeff Lott and Lukas Hager in the second half of FY21 led to a significant pause in the activity of the LSC, but also an appraisal of how the MSTAR initiative could be both served by these activities using DQHI personnel and could, itself, serve as a catalyst for additional and expanded laboratory stewardship work throughout the institution. Work has continued in the following areas:

- Evidence-based, best-practice reflex ordering systems/ordering

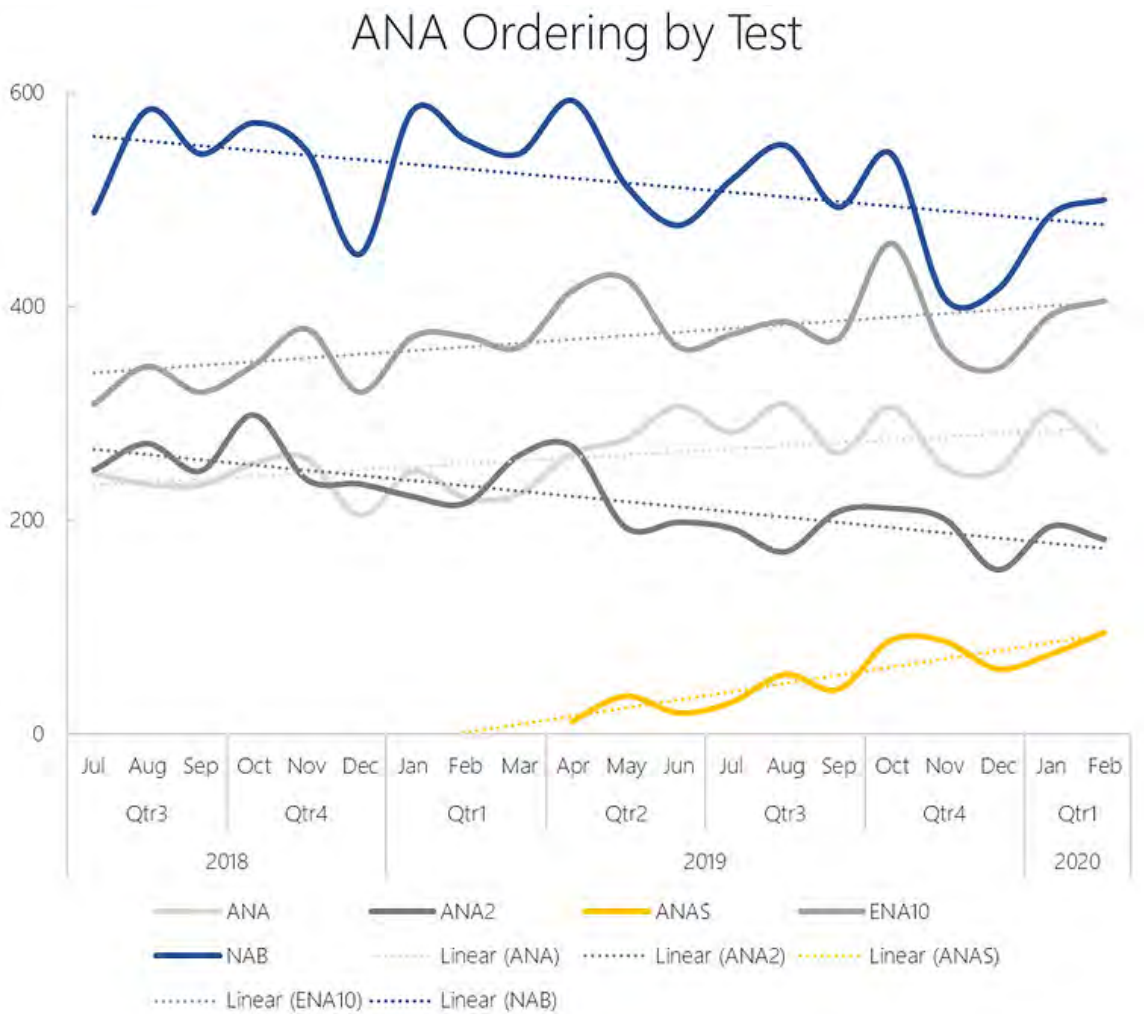


Figure 1. *Usage of the ANA diagnostic algorithm in clinical practice. This dashboard excerpt documents the use of the best-practice ANA diagnostic algorithm developed by the Laboratory Stewardship Committee (yellow line – "ANAS") relative to the individual tests, plotted by quarter (data through 2020 Q1). Note the increase in ANAS usage after introduction, but the relatively low "uptake rate" in comparison to the other individually ordered tests, an issue which has persisted since introduction and for which we are exploring additional measures to improve the use of this and other best-practice diagnostic approaches.*

algorithms for anti-nuclear antibody (ANA), celiac disease, and thyroid hormone testing have been deployed.

1. 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 (see Figure 1).

2. Discussions with Cybill Starr (HITS analyst) have identified opportunities to further push the utilization of these best-practice algorithms using a variety of MiChart-based changes and interventions.

- In collaboration with MSTAR consultants Lester (Les) Wold and Keith Laughman, preliminary work has been done on the possibility of optimizing hyponatremia testing for inpatients, with the potential to impact real-world and institutionally important metrics like length of stay and readmission rates.

- Optimization of C. difficile testing

  1. 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.

- 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 has been explored.

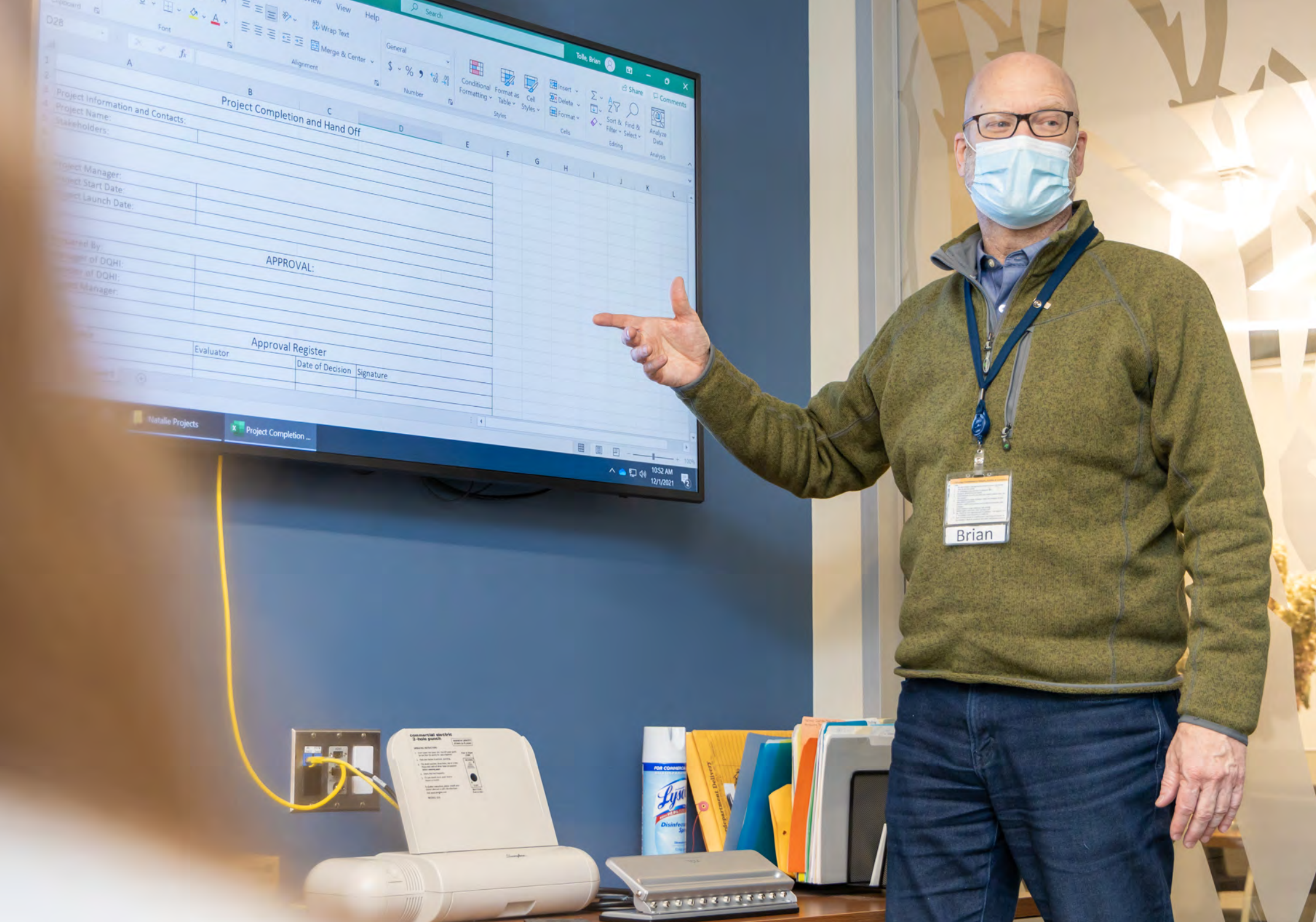
  1. Serum lipase alone is the preferred method for diagnosis, as outlined in national "Choosing Wisely" guidelines.

Data Science

With the significantly diminished data capacity linked to Lukas Hager's fractional effort and ultimate departure, the work of data science was significantly degraded during most of FY21. Lukas continued to perform with skill in a number of areas, including data display for COVID-related metrics and in support of data needs in connection with MSTAR. In addition, Lukas worked with Ross Smith, employed at that time through Pathology Informatics, in collaborations to support the same efforts. Over the course of late FY21 and early FY22, DQHI was able to post an open Data Scientist position, which was ultimately filled by Ross Smith in the first quarter of FY22.

Quality

In addition to involvement in a number of efforts described above, Eleanor (Ellie) Mills has worked to support multiple quality improvement projects, root cause analyses, and other quality-related efforts throughout the clinical divisions in the Department. These include work on the surgical pathology cancer reporting templates, a variety of specimen-related quality issues in surgical pathology, improvements in the use and leveraging of data generated by patient safety reporting, and exploring the potential for improved urine culture processing and reporting in Microbiology. In addition, Ellie has continued working on the departmental efforts centered on Michigan Medicine Quality Month activities.


Project Completion and Hand Off
Project Information and Contacts:
Project Name:
Stakeholders:
Project Manager:
Project Start Date:
Project Launch Date:
APPROVAL:
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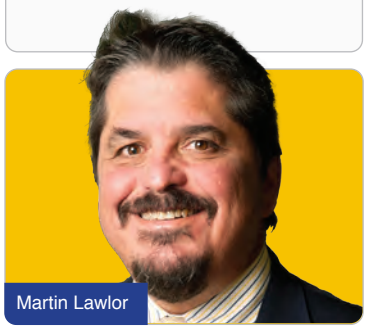
Finance & Administration



Director, Finance and Administration

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. 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 (Past Chair), and the Association of Pathology Chairs – Pathology Department Administrators Committee.
Some key divisional highlights for this academic year include:

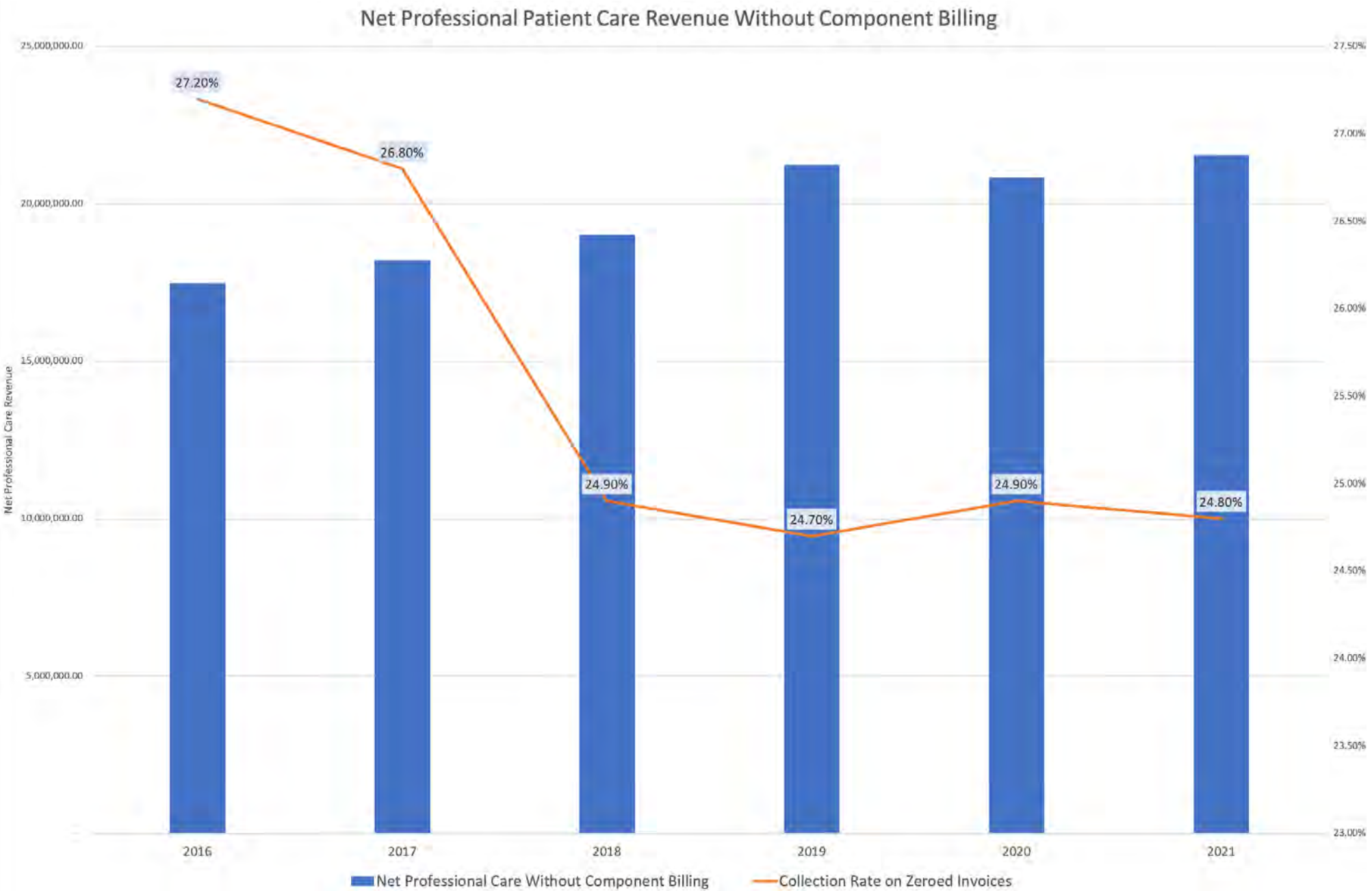
- Developed a plan for COVID-19 testing, including multiple testing platforms, and set up testing collection sites – including a tent site at NCRC.
- Developed safety protocols for COVID-19, including social distancing policies and mask compliance policies.
- Continued to make progress on the PRR project 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.

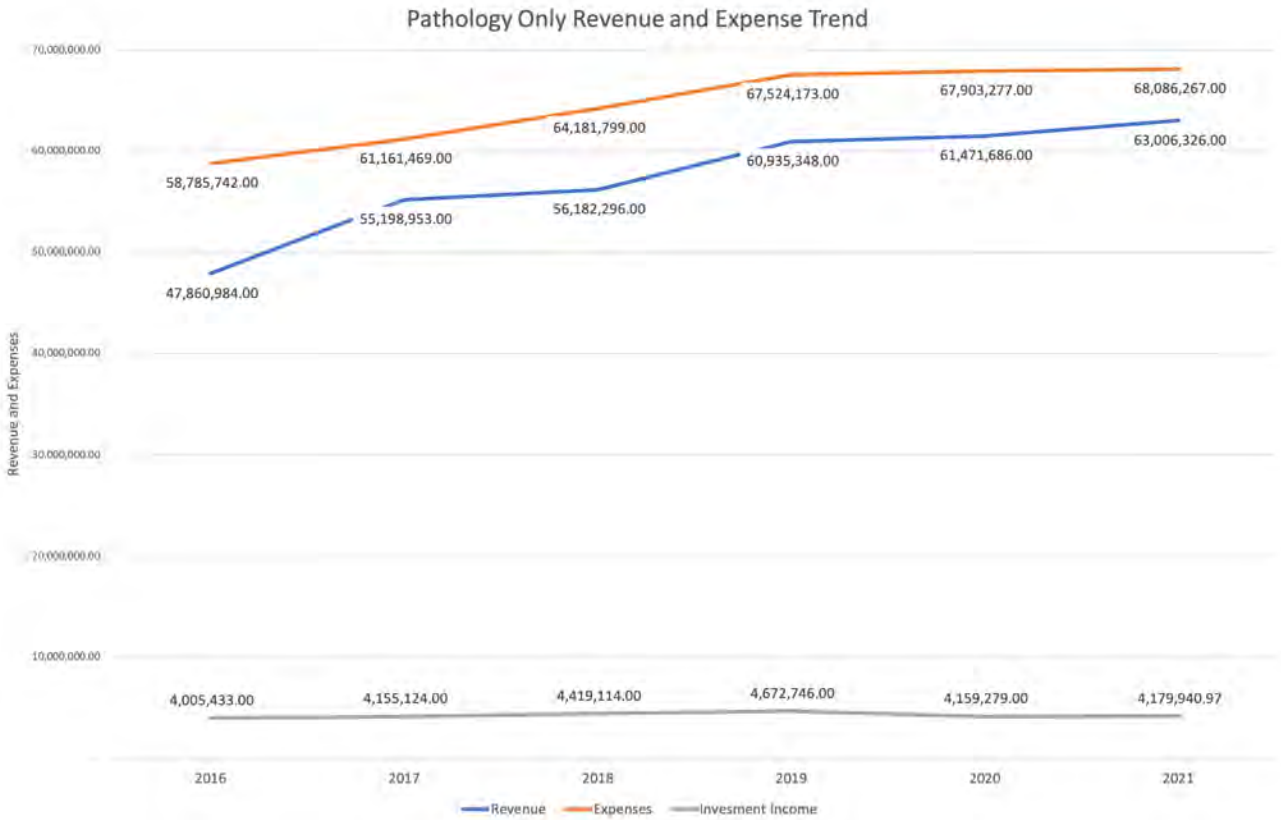
The Division of Finance and Administration is divided into support services for the pathology laboratories; academic and business affairs; and human resources, faculty affairs, and education.

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 $178 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 up 21.6% when compared to FY20 (and 17.5% increase over FY19) as we returned to more normal operations and ramped up additional COVID testing for our patients, students, faculty, staff, and community. 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 2020 to through June 30, 2021. Microbiology saw a 96.6% increase in gross revenue during the year and most of that increase occurred as a result of COVID testing. Overall expenses increased by 12.0% over FY20. Most of that increase was the result of added spending on reagents and supplies tied to COVID-19 testing (71.1% increase in COVID expenses over FY20).

The administrative support center team worked diligently in FY21 to prepare for and undertake the remodeling of the University Hospital clinical laboratories. The renovation of these spaces was 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 FY21, our facilities managers and the PRR team diligently addressed issues as they arose, especially with unanticipated issues surrounding


Net Professional Patient Care Revenue Without Component Billing
25,000,000.00
20,000,000.00
15,000,000.00
10,000,000.00
5,000,000.00
Net Professional Care Revenue
27.50%
27.00%
26.50%
26.00%
25.50%
25.00%
24.50%
24.00%
23.50%
23.00%
27.20%
26.80%
24.90%
24.70%
24.90%
24.80%
2016
2017
2018
2019
2020
2021
Net Professional Care Without Component Billing
Collection Rate on Zeroed Invoices



FY20 vs FY21 Pathology Income Statement

REVENUE	FY20	FY21
Patient Care Revenues	$19,785,095	$299,485
UMHS Service Payments	$10,916,413	$30,966,444
Net Total Research (Directs & Indirects)	$21,498,647	$22,278,142
Gifts and Other Income (Wayne/ Washtenaw ME, etc.)	$9,271,532	$9,462,255
Total Revenue	**$61,471,687**	**$63,006,326**
EXPENSES		
Total Salaries	$51,284,891	$50,520,050
Total Non-Payroll Expense	$16,618,387	$17,566,217
Total Operating Expenses	**$67,903,278**	**$68,086,267**
Operating Margin (Loss)	($6,431,591)	($5,079,941)
Non-Operating Income and Expense *(Includes Investment Income, UMHS Margin Sharing, Departmental Commitments, etc.)*	$8,998,765	$9,909,751
Total Margin	**$2,567,174**	**$4,829,810**

David Golden
Director, Finance

logistics of maintaining clinical laboratory operations during 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.

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 FY21 were $76.8 million and Hospital expenditures were $177.9 million.
- Hospital technical gross revenue for FY21 was $1.02 billion, compared to $836.2 million in FY20, an increase of 21.6%.
- Professional fee gross charges were $93.5 million in FY21 compared to $80.8 Million in FY20.
- Overall gross charges for Pathology's group practice were up 15.7% ($12.7 million).
- In FY21, our faculty received 53 awards from the NIH and ranked 9th in the nation in funding by the NIH, the same as FY20, and 7th in the nation when considering number of awards received. Total grants submitted in FY21 was $23.2 million, a slight decrease of approximately 1.1% over FY20. Our total sponsored research spending in FY21 was $33.4 million, up from $32.5 million in FY20.

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 interdepartmental, 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 $124.5 million. In FY21, we experienced a smaller gap between our revenues and expenses, with Revenues at $67.9 million, up 0.2% over FY20 and expenses at $76.8 million, down 1.3% over FY20, mostly due to decreased staffing needs associated with the pandemic. This resulted in an operating loss of $8.84 million. The loss was offset by non-operating income (investments, dean's contributions, and other institutional support payments). Including our non-operating income, FY21 ended with a net margin of $1.18 million. In contrast, in FY20 we experienced a loss of $699K, 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 at its lowest point in the past 15 years, at just 24.8% of charges. Pathology Faculty and staff paid FTEs have remained relatively flat at 1,196.7 in FY21 versus 1,221.2 in FY20. 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

Thomas Morrow
Administrative Manager, Clinical Operations

Kristina Martin
Manager, Clinical Operations

Christine Rigney
Assistant Administrator, Operations, Division of Anatomic Pathology

Christine Shaneyfelt
Financial Analyst Senior, Hospital

Mike McVicker
Financial Analyst Senior, Medical School

John Harris
Manager, Research Administration

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, FY21 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 825.05 FTEs) and Medical School support staff, including our research programs (approximately 232.2 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 164 active faculty and the 23 supplemental appointments in the Department. In FY21, nine new faculty joined the Department of Pathology while we bid farewell to twelve faculty members. Ten of our faculty successfully completed the promotion process *(Table on right)*.

Our faculty received numerous awards in recognition of their achievements in academics, research, and clinical service. *(See Appendix on **pg. 78**)*

The Education Office includes the Residency and Fellowship Training Programs (26 residents and 24 fellows in 9 ACGME and 8 non-ACGME 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 22 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 Lieberman, 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).

Faculty Promoted in FY21

Name	New Rank	Division
Boyer, Daniel F	Clinical Associate Professor	CP
Chan, May	Clinical Professor	AP
Farkash, Evan A	Clinical Associate Professor	AP
Konopka, Kristine	Clinical Associate Professor	AP
Lieberman, Richard W	Clinical Professor	AP
Nikolovska-Coleska, Zaneta	Professor	EP
Sciallis, Andrew P	Clinical Associate Professor	AP
Tien, Jean	Assistant Research Scientist	MCTP
Udager, Aaron M	Clinical Associate Professor	AP
Westerhoff, Maria	Clinical Professor	AP

Office of the Chair

The staff in the Office of the Chair coordinates the Advances in Forensic Medicine and Pathology conference, which was not held in FY21. 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 FY18.

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 FY21, 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 78.***) 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 78.***)

Sarah Dudley-Short
Manager, Faculty Affairs

Pathology Relocation & Renovation Project

Project Manager, PRR

The Pathology Relocation and Renovation (PRR) Project is a multi-year, multi-phase project embracing the opportunities to relocate a large sector of the department into new 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 seven years and leads this large 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 with activation 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 very complicated and unique challenge—all current labs at University Hospital must remain fully operational while the new laboratories are 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, each followed by a period of activation. A few temporary spaces were constructed in early FY20 to allow for the beginning of Phase 2. Phase 2.1 construction was briefly disrupted by the beginning of the COVID pandemic but completed in September 2020. This included new laboratory space for Hematology and sections of the Chemistry lab. It also included a new automation line for the Hematology laboratory, replacing their current line. Despite numerous challenges presented by construction phasing and the pandemic, the faculty and staff at University Hospital completed the activation and formally turned over the recently vacated spaces for phase 2.2 of construction at UH.

Phase 2.2 will complete in July 2021, and includes a new automation line for Chemistry, as well as new space for Specimen Processing, Anatomic Pathology, and Microbiology stat-functions. Later phases include the remaining portions of the Core lab, a Transfusion Medicine neighborhood with new- and updated space for the Blood Bank, Cellular Therapy, and Apheresis. Finally, space for the Phlebotomy team, the Education Program, administration functions and other support areas will be updated in the final phases of the project.


BUILDING
DETOX

Anatomic Pathology Case Volumes

Cytopathology Case Volumes	FY17	FY18	FY19	FY20	FY21	1-YR	5-YR
FNA by Pathologist w/ ROSE[1]	169	164	183	142	134	−5.63%	−20.71%
FNA, No ROSE[1]	659	687	842	767	871	13.56%	32.17%
FNA, w/ ROSE[1]	2,171	2,101	2,102	1,788	2,048	14.54%	−5.67%
Gyn Case[1]	23,295	23,003	23,580	18,608	24,384	31.04%	4.67%
Non-Gyn Case	6,660	7,392	8,128	7,432	7,868	5.87%	18.14%
Total	**32,954**	**33,347**	**34,835**	**28,737**	**35,305**	**22.86%**	**7.13%**
Dermatopathlogy Case Volumes							
Derm In-House	15,774	16,327	15,979	13,470	15,733	16.80%	−0.26%
Derm Outside	7,687	7,170	7,400	6,518	6,382	−2.09%	−16.98%
MLabs Derm	12,238	10,398	9,748	7,549	7,979	5.70%	−34.80%
Total	**35,699**	**33,895**	**33,127**	**27,537**	**30,094**	**9.29%**	**−15.70%**
Hematopathology Case Volumes							
Hemepath In-House	1,856	1,939	2,301	2,657	3,669	38.09%	97.68%
Hemepath Outside	2,434	2,604	2,707	2,347	2,400	2.26%	−1.40%
Total	**4,290**	**4,543**	**5,008**	**5,004**	**6,069**	**21.28%**	**41.47%**
Neuropathology Case Volumes							
Muscle In-House	156	139	86	78	98	25.64%	−37.18%
Muscle Outside	179	203	266	218	189	−13.30%	5.59%
Neuro In-House	846	773	834	741	786	6.07%	−7.09%
Neuro Outside	450	496	522	597	879	47.24%	95.33%
Total	**1,631**	**1,611**	**1,708**	**1,634**	**1,952**	**19.46%**	**19.68%**
Ophthalmic Case Volumes							
Ophthalmic In-House	1,248	1,311	1,455	1,367	1,397	2.19%	11.94%
Ophthalmic Outside	61	56	52	73	75	2.74%	22.95%
Total	**1,309**	**1,367**	**1,507**	**1,440**	**1,472**	**2.22%**	**12.45%**
Pediatric and Perinatal Pathology Case Volumes							
Fetal Exams	178	215	230	215	256	19.07%	43.82%
Peds Autopsy	33	37	27	24	24	0.00%	−27.27%
Peds In-House	3,514	3,564	3,747	3,307	3,677	11.19%	4.64%
Peds Outside	351	432	477	407	408	0.25%	16.24%

(continued)

Placentas	1,834	2,071	2,148	1,894	1,825	−3.64%	−0.49%
Total	**5,910**	**6,319**	**6,629**	**5,847**	**6,190**	**5.87%**	**4.74%**
Renal Case Volumes							
Renal In-House	1,099	1,294	1,413	943	811	−14.00%	−26.21%
Renal Outside	49	56	59	43	34	−20.93%	−30.61%
Total	**1,148**	**1,350**	**1,472**	**986**	**845**	**−14.30%**	**−26.39%**
Technical Only Case Volumes							
Technical Only	1,923	2,062	2,005	1,673	1,722	2.93%	−10.45%
Technical w/ Interpretation			160	460	399	−13.26%	
Total	**1,923**	**2,062**	**2,165**	**2,133**	**2,121**	**−0.56%**	**10.30%**
Outside Case Volume							
Breast	1,602	1,765	1,737	1,541	1,509	−2.08%	−5.81%
Cardiac	9	13	20	21	24	14.29%	166.67%
Cytology	1,353	1,372	1,196	1,192	1,076	−9.73%	−20.47%
Dermatopathology	7,687	7,170	7,400	6,518	6,382	−2.09%	−16.98%
Endocrinology	600	598	613	551	539	−2.18%	−10.17%
Gastrointestinal	4,963	5,088	5,220	5,043	5,107	1.27%	2.90%
Genitourinary	1,872	2,038	2,148	1,959	1,845	−5.82%	−1.44%
Gynecologic	1,443	1,480	1,696	1,571	1,520	−3.25%	5.34%
Head & Neck	1,192	1,300	1,366	1,255	1,303	3.82%	9.31%
Hematopathology	2,434	2,604	2,707	2,347	2,400	2.26%	−1.40%
InterDepartmental Consult		370	635	356	608	70.79%	
Misc. Outside Case	8	31	22	9	6	−33.33%	−25.00%
Muscle	1	14	33	29	22	−24.14%	2,100.00%
Neuropathology	450	496	522	597	879	47.24%	95.33%
Ophthalmic	61	56	52	73	75	2.74%	22.95%
Pediatric	351	432	477	407	408	0.25%	16.24%
Pulmonary	2,811	2,971	3,184	2,712	2,564	−5.46%	−8.79%
Renal	49	56	59	43	34	−20.93%	−30.61%
Soft Tissue	1,343	1,507	1,630	1,481	1,696	14.52%	26.28%
Total	**28,229**	**29,361**	**30,717**	**27,705**	**27,997**	**1.05%**	**−0.82%**

Table 1 : *Anatomic Pathology Case Volumes 2017-2021 (From pg. 8)*

Clinical Pathology Billed Test Volumes								
	FY16	FY17	FY18	FY19	FY20	FY21	1-Yr	5-Yr
Clinical Chemistry and Toxicology								
Chemical Pathology	2,545,505	2,861,047	2,990,055	3,165,847	2,985,204	3,277,102	9.8%	28.7%
Special Chemistry	659,007	642,556	650,105	714,738	649,436	771,761	18.8%	17.1%
Clinical Chemistry and Toxicology	3,204,512	3,503,603	3,640,160	3,880,585	3,634,640	4,048,863	11.4%	26.3%
Transfusion Medicine								
Blood Bank Bone Marrow	1,127	1,155	1,118	1,034	1,490	1,353	-9.2%	20.1%
MM Pathology Blood Bank	285,079	307,395	315,601	327,245	326,459	335,100	2.6%	17.5%
Blood Procurement	67,765	61,994	64,254	66,414	59,056	66,279	12.2%	-2.2%
Transfusion/Apheresis	2,165	1,804	1,965	2,008	2,132	1,238	-41.9%	-42.8%
Total	**356,136**	**372,348**	**382,938**	**396,701**	**389,137**	**403,970**	**3.8%**	**13.4%**
Other Clinical Laboratories								
Path Hemo/Coag Unit Uh	1,186,694	1,220,890	1,236,698	1,268,568	1,227,916	1,293,850	5.4%	9.0%
Flow Cytometry Lab	78,958	78,390	87,062	105,598	99,902	101,981	2.1%	29.2%
Cytogenetics Lab	8,283	8,399	9,296	12,313	11,709	14,249	21.7%	72.0%
Histocompatibility	24,152	21,085	23,801	23,480	19,157	22,209	15.9%	-8.0%
Microbiology & Virology	488,490	520,905	549,418	571,808	566,888	963,936	70.0%	97.3%
Molecular Diagnostics	20,736	15,899	17,026	20,106	17,860	19,169	7.3%	-7.6%
Path Reference Tests	141,648	129,294	126,650	151,392	141,665	145,234	2.5%	2.5%
MCTP	2,084	2,487	1,355	393	248	283	14.1%	-86.4%
Total	**2,439,535**	**2,518,254**	**2,600,724**	**2,725,466**	**2,652,233**	**3,524,847**	**32.9%**	**44.5%**

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	**FY16**	**FY17**	**FY18**	**FY19**	**FY20**	**FY21**	**Change**
Red Blood Cells	26,515	30,905	32,004	33,065	31,040	34,340	10%
Random/Pooled Platelets	20,959	6,009	6,080	5,880	51	--	--
Apheresis Platelets	6,394	10,120	10,648	11,000	13,640	16,193	16%
Plasma	6,642	6,997	7,267	7,073	6,676	8,144	18%
Cryoprecipitate	6,011	6,437	7,404	7,840	6,676	7,504	11%
Total Components Transfused	**66,521**	**60,462**	**63,403**	**64,858**	**58,475**	**66,181**	**12%**
Immunohematology Reference Lab							
Antibody Identifications	1,081	1,376	1,240	1,153	1,516	1,685	10%
ABO Resolution	156	111	187	233	312	258	-21%
BMT	247	203	320	319	284	298	5%
Eulates	176	227	215	255	265	326	19%
Adsorptions	317	464	319	402	547	318	-72%
Titers	303	324	295	477	484	616	21%
Special Antigen Typing		6,314	5,896	6,137	6,384	7,097	10%
Total Activity*	**2,801**	**9,861**	**9,097**	**10,624**	**11,402**	**12,619**	**10%**
**Includes procedures not listed above*							
Cellular Therapies Laboratory							
Collections Processed	415	452	427	452	454	485	6%
Bags Frozen	542	718	619	608	703	809	13%
Transplants, Autologous	116	122	136	130	113	130	13%
Transplants, Allogeneic	45	36	32	54	43	51	16%
Transplants, Unrelated	61	44	67	75	64	58	-10%
CAR-T Products		4	12	54	24	26	8%
Total Transplants	**222**	**202**	**235**	**259**	**220**	**239**	**8%**
Apheresis Service							
Therapeutic Plasmapheresis	1,389	1,207	1,220	1,310	1,416	1,334	-6%
HPC Collections	416	370	345	308	346	347	0%
Donor Pre-Evaluations	243	219	255	308	236	202	-17%
LDL Apheresis	124	89	106	94	95	62	-53%
RBC Exchange	120	103	112	170	175	199	12%
CART-T Collections		4	12	33	20	40	50%
Total Procedures	**2,407**	**2,024**	**2,074**	**2,206**	**2,288**	**2,184**	**-5%**

Faculty Awards 2020-2021

Faculty	Award Name	Organization
Henry Appelman, MD	Arthur Purdy Stout Lecture	Arthur Purdy Stout Society
Ul Balis, MD	Inaugural Donald Connelly Lectureship in Pathology Informatics	Institute for Health Informatics
Arul Chinnaiyan, MD, PhD	Science of Oncology Award 2021	American Society for Clinical Oncology
Laura Cooling, MD	Top Poster	American Association of Blood Banks 2020 Annual Meeting
Sean Ferris, MD, PhD	Faculty Poster Award	Beyond Amyloid Research Symposium
Carmen Gherasim, PhD	Residents Teaching Award 2020-2021	UM Pathology
Joel Greenson, MD	Rodger Haggitt Memorial Lecture Award	Gastrointestinal Pathology Society
Amer Heider, MD	Best Case Report Award	Society for Pediatric Pathology
Alexandra Hristov, MD	2022 Mentorship Award	American Society of Dermatopathology
David Keren, MD	Distinguished Service Award	Rotary Club of Ann Arbor
Madelyn Lew, MD	Elizabeth Crosby Award for Most Outstanding Teacher of Medical Students in Basic Sciences	Galens Medical Society
Sethu Pitchiaya, PhD	RNA Society Conference Award	National Science Foundation
Carl Schmidt, MD	Gift of Life 2021 Champion Award	Gift of Life
Sriram Venneti, MD, PhD	Named the Al and Robert Glick Family Research Professor of Pediatrics	Hyundai Hope on Wheels Foundation
Tom Wilson, PhD	Breakthrough Article	Nucleic Acids Research Editorial Board
Peter Ward, MD	Named “World Expert in Sepsis”	Expertscape

Table 5-8 *(Above)*: *List of Faculty Awards received 2020-2021. (From pg. 62) Followed by New National Leadership Positions and Leadership Appointment from pg. 62.*

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

New National Leadership Positions- 2021

Faculty	Role	Organization
Aleodor Andea, MD	House of Delegates	American Soc of Dermatopathology
Lakshmi Kunju, MD	Council Member	Association of Directors of Anatomic and Surgical Pathology
Laura Lamps, MD	President	United States and Canadian Association of Pathologists
Zaneta Nikolovska-Coleska, PhD	Chair	NIH/NCI Mechanisms of Cancer Therapeutics Study Section
Chisa Yamada, MD	• Chair • Director/Organizer/Moderator	• International Affairs Committee, American Society for Apheresis • American Society for Apheresis/ International Society for Apheresis 2021 Virtual Annual Meeting

New Department Leadership Appointments

Faculty	Role	Area/Specialty
Sara Abbott, MD	Resident Education Coordinator	Anatomic Pathology
Bryan Betz, PhD	Ombudsman	UM Pathology Ombuds Program
Daniel Boyer, MD, PhD	Morphology Laboratory Technical Supervisor	UM Pathology
Stephanie Skala, MD	Director	Gynecology Pathology Fellowship
Analisa DiFeo, PhD	Medical Affairs Advisory Committee	University of Michigan
Evan Farkash, MD, PhD	Director	Medical Renal Pathology Service
Thomas Glover, PhD, FACMG	Medical School Program Admissions Committee	Department of Human Genetics
Myra Khan, DO	Forensic Fellowship Director Liaison	UM Pathology
Liron Pantanowitz, MD, MHA	Director	Anatomic Pathology
David Manthei, MD, PhD	Director	Michigan Diabetes Research Center Chemistry Laboratory
Jonathan McHugh, MD	Co-Director	Biospecimen/Population Core, Head & Neck SPORE
Aaron Udager, MD, PhD	Emerging Leaders Council	UM Rogel Cancer Center
Thomas Wilson, PhD	• Associate Director • Faculty Director	• Molecular Diagnostics Laboratory • Advanced Genomics Core

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	

Invention Reports

Title	Inventors
Ordered Klebsiella Pneumoniae Transposon Library	Harry Mobley, Michael Bachman, Sara Smith, Laura Mike, Jay Vornhagen, Valerie Forsyth
Autophagy Inhibition via Targeting of PIKfyve Potentiates Immune Checkpoint Blockade in Prostate Cancer Therapy	Arul Chinnaiyan, Yuanyuan Qiao
The Method to Give Bacteria Probiotic Features by Genetic Engineering	Naohiro Inohara, Gabriel Nunez, Masashi Ono
Novel Small Molecules and Their Use as MALT1 Inhibitors	Zaneta Nikolovska-Coleska
IgA Induce Mucosal Immune Tolerance	Nicholas Lukacs, Srikanth Elesela
BRAVO-DX Signature for Triple Negative Breast Cancer	Marcin Cieslik, Arul Chinnaiyan, Yuping Zhang
Detection and Reporting of Precision Oncology Genomic Alterations in Cancer Patients using Circulating Tumor Cell Genomic Profiling	Scott Tomlins, Daniel Hayes, Andi Cani
Exosomes (and their contents) as Therapeutic Targets/Sentinals in Bipolar Disorder	Melvin McInnis, Katherine Campbell, Kathy O'Shea, Anastasia Yocum, Daniel Schill, Cynthia DeLong, Durga Attili, Guihua Jiang
ScribeMonkey	Ulysses Balis
B6(Cg)-Dot1l/SyjoJ: Requirement for Dot1l in Murine Postnatal Hematopoiesis and Leukemogenesis by MLL Translocation	Jay Hess, Ivan Maillard, Stephanie Jo
Synthetic Super Resolution Microscopy using High Dimensional Generative Adversarial Networks (GANs)	Ulysses Balis
huPTM-001 Promotes cMet Independent Epithelial Wound Repair	Jennifer Brazil

Table 10-11 *(Above)*: *Inventions Report continued from pg. 46. Then the Ongoing Clinical Trails/Studies Supported by MI-ONCOSEQ from pg. 30.*

Table 12 (right): *Graduate Thesis Defenses 2020-2021 mentioned on pg. 54.*

Ongoing ClinicalTrials/Studies Supported by MI-ONCOSEQ

NCT ID	Clinical Trial	PI	Patients	Sites
NCT00261456	UMCC 2018.050	Alva	44	University of Michigan, Memorial Sloan Kettering, Johns Hopkins, Washington University St Louis, UCSF
NCT03456804	UMCC 2019.031	Heath	10	Karmanos
NCT03287050	UMCC 2017.069	Alva	6	University of Michigan
NCT03242915	UMCC 2017.057	Gadgeel	33	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	168	Ann Arbor VA, Bay Pines VA, Jesse Brown VA, James Haley VA
NCT03639935	UMCC 2018.044	Sahai	26	University of Michigan, Vanderbilt University
NCT04194554	UMCC 2019.117	Jackson	19	University of Michigan
NCT04748042	UMCC 2020.080	Reichert	3	University of Michigan
NCT03300505	UMCC 2017.055	Alva	7	University of Michigan
NCT04497038	UMCC 2020.007	Sahai	1	University of Michigan
NCT03785873	UMCC 2018.101	Sahai	34	University of Michigan Rogel Cancer Center Cancer and Hematology Centers of Western Michigan University of Utah Virginia Mason University of Wisconsin
NCT04203160	UMCC 2019.116	Sahai	24	University of Arizona Cancer Center Northwestern University, Lurie Comprehensive Cancer Center University of Michigan Rogel Cancer Center Atlantic Health System University Hospitals - Seidman Cancer Center Vanderbilt-Ingram Cancer Center UT Southwestern -- Simmons Comprehensive Cancer Center Fred Hutch/University of Washington Cancer Consortium University of Wisconsin - Carbone Cancer Center

Graduate StudentThesis Defense and Current Positions					
Name	**Defense Date**	**Thesis Title**	**Mentor(s)**	**Current position**	**Current Company**
Samantha Kemp	*February 10, 2021*	*Elucidating mechanisms of immune suppression in mouse and human pancreatic cancer*	Marina Pasca di Magliano, Howard Crawford and Celina Kleer	Postdoctoral Fellow	University of Pennsylvania, Perelman School of Medicine
Abhijit Parolia	*February 17, 2021*	*Characterizing and targeting the chromatin determinants of cancer cell identity*	Arul Chinnaiyan	Research Investigator	Michigan Medicine, Center for Translational Pathology

Years of Service Recognition- 2021

10 Years		
Kierstin Abbott	Scott Howard	Pamela Moyer
Kristine Acker	Saba Kassab-Matti	Andrea Parkinson
David Best	Charnbir Kaur	Nancy Raynal
Joanna Bixby	Iwona Kopania	Ivie Snowdon
Jin Chen	Shirley Li	Dana Strobel
Yunhui Cheng	Jennifer Mattison	Leann Vance
Kelli Farhat	Scott McClellan	Heng Zheng
Andrea Hartlerode	Christine Meldrum	
Casey Hollier	Laverne Miner	

20 Years		
Katherine Eichbauer	Jim Sedayao	Rui Wang
Peter Kuffa	Joyce Seleska	Dana Wells
Donna Renner-Chuey	Leesa Stanislovaitis	Zhigang Yu
Nicole Robinson	Tasha Thurman	

30 Years		40 Years
Alganesh Abraham	Christine Shaneyfelt	J Michael Meade
Marisol Lafontaine	Leisa Stempek	
Lori Roberts	Sylvia Zelenka-Wang	

Table 13-14 *(Above):* *Years of Recognition and Above and Beyond Award Recipients (From pg 67.)*
Table 15 *(Right)*: *Retired Faculty and Staff 2020-2021 (From pg. 67).*

Above and Beyond Award Recipients

Anatomic Pathology		
Muntajib Alhaq	Amanda Howard	Levon Sargsyan
Samantha Bialy	Lana Jajko	Misty Sayar
Marie Brady	Sharon Kerr	Sally Smith
Abigail Conley	Eric LaPres	Tracie Sobchik
David De La Espriella	Karen Marusza	Jamie Southard
Allison Geagan	Kimberly Meekins	Tammi Toth
Kyra Harvey	Kara Meldrum	
Casey Hollier	Threase Nickerson	
Team Awards		
Consult Accessioning	Slide Librarian	

Clinical Pathology		
Janette Brown	Pamela Hensley	Michelle Merkel
Kathleen Chandler	Melanie Herbert	Pamela Moyer
Mary Conniff	Ashley Hoffmeyer	Brandon Newell
Jason Dobreff	Megan Jordan	Scott Parker
Amy Drouillard	Lindsay Kochan	Yusuf Peaks
Coretta Ealy	Christine Kwierant	Cory Peitsch
Nell Field	Beth Lawless	Ashley Roman
Samantha Fogel	Emily Manion	Tony Sinay
Jonathan Grant	Elizabeth McCloud	Helmut Weigelin
Sarah Guenther	Colleen McDermott	Brittany Williams
Team Awards		
William LeBar / Microbiology	Specimen Processing	Molecular Microbiology

Pathology Informatics		
David Austin	Beth Gibson	Stephen Marshall
Oliver Bichakjian	Eric Jedynak	Brent Temple
Christine Gaunt	Ryan MacFadden	
Finance & Administration		
Camren Clouthier	Tim Kimmel	Christine Rigney
Tanya Coyle	Tamara Kutter	Jason Schwartzenberger
Brooke Dougherty-Reyes	Kristina Martin	Carrie Scott
Regina Ferguson	Lynn McCain	
Experimental Pathology	**MLabs**	**DQHI**
Katherine Toy	Rafael Baran	Lisa Brown
	Devon Fera	
	Christine Meldrum	

Retired 2020-2021

Name	Job Title	Date	Years
Jeffrey M. Jentzen	Clinical Professor, Forensic Pathology	*July 2020*	12
Donald A. Giacherio	Clinical Associate Professor, Chemical Pathology	*August 2020*	38
Randy K. Dishman	Word Processing Operator Inter, Anatomic Pathology	*August 2020*	16
Gui-Ying Yin	Clinical Technologist Senior, Histocompatibility	*August 2020*	27
Pamela Lincoln	Research Lab Specialist Intermediate	*August 2020*	36
Binh H. Ho	Medical Technologist, Chemical Pathology	*August 2020*	16
Becky J. Ott	Medical Technologist Spec, Microbiology	*September 2020*	15
Paul E. McKeever	Professor, Neuropathology	*September 2020*	37
Usha Rani Kota	Administrative Manager, Flow Cytometry Lab	*October 2020*	32
Mary T. Deis	Allied Health Associate Supervisor, Specimen Processing	*December 2020*	14
Kathryn E. Daavettila	Allied Health Senior Supervisor, Histocompatibility	*December 2020*	28
Elizabeth Minors	Executive Assistant, Anatomic Pathology	*December 2020*	16
Chuck Jasman	Laboratory Technician, Microbiology	*December 2020*	13
Weslier M. Moorhouse	Training Specialist Lead, In-Patient Phlebotomy	*December 2020*	36
Ronald Allen	Research Lab Specialist Senior	*December 2020*	12
Karen A. Schairer	Patient Care Tech Associate, Blood Bank	*December 2020*	18
Cathy M. Angelocci	Registered Nurse - Level C	*January 2021*	23
Linda J. O'Brien	Administrative Assistant Senior, Anatomic Pathology	*March 2021*	30
Stephen W. Chensue	Professor, AAVHS	*April 2021*	34
Pamela Howard	GME Program Administrator Intermediate	*May 2021*	12
Sharon K. Henderson	Histotechnologist, Surgical Pathology	*June 2021*	20
Robert C. Jones	Medical Technologist Spec, Heme/Coag Unit	*June 2021*	32