LAB JUNE 2022 ISSUE 178 Connections





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Published July 2022

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Impacts on patient care through high complexity testing of cancer biomarkers

In this time of rapid and ongoing technological evolution, Pathologists continue to make significant impacts on patient care through high complexity testing of cancer biomarkers. Over the past year, Cancer Care Ontario has significantly increased funding for biomarker testing in Pathology and Genetics. Prior to this change, biomarker testing consisted of single gene tests or limited panels for major cancer types. Testing has become more comprehensive with the use of panel-based genetic testing in addition to expanded use of immunohistochemistry in the setting of diagnostic, predictive and prognostic biomarker testing and overlapping with hereditary cancer risk assessment.

In the first quarter of 2022, HRLMP performed and reported on over 4,000 biomarker tests and this number is expected to increase. Biomarker testing is provided to patients of the Hamilton/Niagara/Haldimand/Brant LHIN and Wellington/Waterloo LHIN.

Highlights of recommended testing introduced in recent years are summarized in Figure 1 and represent a significant collaboration between the immunohistochemistry and genetics laboratories (Figure 1).

| Disease site | NGS testing | IHC / ISH testing |
|-----------------|------------------|-------------------|
| Adrenal | - | MMR |
| Breast | PIK3CA | ER, PR, Her2 |
| Bladder | FGFR2/3 | |
| Cervix | - | HPV |
| Endometrial | POLE, KRAS, | p53, ER, PR, |
| | PIK3CA, PTEN | Her2, MMR |
| GI | BRAF, KRAS, | MMR, EBV |
| | NRAS, PIK3CA, | (gastric), Her2 |
| | PTEN (CRC, SB | (gastric, GEJ, |
| | only) | esophagus) |
| GIST | KIT,PDGFRA | - |
| Head and Neck | - | PD-L1, HPV |
| Lung | ALK, EGFR, | PD-L1 |
| | ROS1, BRAF, | |
| | MET, RET, | |
| | FGFR1, HER2, | |
| | KRAS, PIK3CA, | |
| | SMARCA4, | |
| | NTRK | |
| Melanoma of | BRAF, KIT, | |
| skin | NRAS | |
| Nasopharyngeal | - | EBV |
| Ovary | - | MMR, p53, WT1 |
| Penile | - | HPV |
| Prostate | BRCA1/2, ATM, | AR |
| | PALB2 | |
| Sebaceous | - | MMR |
| carcinoma | | |
| Thyroid | BRAF, HRAS, | - |
| | NRAS, NTRK3, | |
| | PPARG, RET, | |
| | KRAS | |
| | 111015 | |
| Ureter | - | MMR |
| Ureter Uveal | - GNAQ, GNA11 | MMR |

Figure 1. Highlights of recommended testing introduced in recent years are summarized below and represent a significant collaboration between the immunohistochemistry and genetics laboratories.

Immunohistochemistry for mismatch repair (MMR) proteins.

In many cancer types, deficient mismatch repair (dMMR) is strongly associated with genomic and microsatellite instability (MSI), a high tumor mutational burden (TMB) and potential

responsiveness to immune checkpoint inhibitor "immunotherapy". Additionally, dMMR may help identify cancers with a hereditary basis such as those associated with Lynch Syndrome. MMR testing is now funded for multiple cancer types of GI tract, adrenocortical and gynecologic origin, sebaceous carcinoma and involves assessing the expression of mismatch repair proteins MLH1, MSH2, MSH6 and PMS2 by immunohistochemistry. **PD-L1 testing**. Another test that is predictive of response to immunotherapy is immunohistochemistry for programmed death ligand 1 (PD-L1), currently funded for lung and head and neck disease sites. Analysis is performed using an FDA-approved kit with visual scoring performed by a pathologist specifically trained and proficient in test interpretation. It is anticipated that PD-L1 testing will be expanded to additional disease sites such as breast, cervix and esophagus in the coming year.

Comprehensive next-generation sequencing (NGS) panel for lung cancer.

Reflexive lung cancer biomarker testing was first adopted over ten years ago and has progressed from relatively expensive single-gene tests to more streamlined panel testing. DNA and RNA sequence analysis is performed by NGS to identify mutations and fusion transcripts of targetable or clinically important genes such as EGFR, ALK, ROS-1. More recently identified genes important in targeted therapy selection include NTRK, RET and KRAS. In general, pathologists order the lung cancer NGS panel reflexively in all newly-diagnosed cases of non-small cell carcinoma (any stage).

Biomarker testing of endometrial cancer.

Molecular profiling of endometrial cancer is now central to patient risk stratification and management. The testing algorithm is based on mutational analysis of key genes (POLE, KRAS, PIK3CA, PTEN) and immunohistochemistry for p53 and MMR proteins.

Expanded mutational testing for multiple cancer types.

NGS panel testing is often indicated for advanced and/or metastatic carcinomas as well as melanoma.

Gene coverage is tailored to each disease site according to clinical needs. It is hoped that expanded testing for CNS neoplasms will be taken on by HRLMP in the near future.

In situ hybridization (ISH) techniques.

Both fluorescent and brightfield ISH are offered at HRLMP for various applications. For example, assessment of Her2 gene copy number by fluorescent-ISH (FISH) is used to determine eligibility for anti-Her2 therapy in breast, endometrial, esophageal, gastroesophageal and gastric adenocarcinomas showing uninformative results by Her2 IHC. Testing to confirm an EBVassociated malignancy (lymphoma, gastric and nasopharyngeal carcinoma) is achieved through detection of Epstein-Barr virus-encoded RNAs (EBER) in tissue sections.

Rising to the challenge of increased biomarker testing.

With all the excitement that comes with expanded and funded testing, the increased demands placed on the lab's clerical, technical and professional staff cannot be overlooked. For clerical staff, the number of incoming biomarker specimens requiring accessioning, transcription, tracking and logistics has risen at least twofold and continues to increase. The immunohistochemistry lab at St Joseph's Hospital has been faced with a large, sustained surge in the number of tissue blocks requiring cutting for NGS testing in addition to increased immunohistochemical staining of tissue sections for MMR and PD-L1, among others. Pathologist Disease Site Teams (DST's) now handle dozens of cases daily that require assessment of specimen adequacy for downstream testing, interpretation of biomarker tests by IHC and ISH and reporting / integration of complex test results into surgical pathology, cytology and consultation reports. It is anticipated that revision of staffing levels will be critical to meeting turnaround time and quality benchmarks set by Cancer Care Ontario and laboratory regulatory bodies.

Biomarker test requisitioning and reporting in the Epic Beaker era.

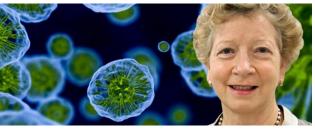
Transition from Meditech to Epic represents an advancement of around 30 years-worth in software

technology. HRLMP endeavors to remove dependency on paper-based forms and develop real-time tracking of pathology specimens, including all processes involved in biomarker testing. Biomarker test requests are created within a live system with ongoing efforts made to facilitate multi-platform and parallel testing by means of premade panel-type orders and their associated laboratory technical tasks. Biomarker tests are reported in a standardized and consistent synoptic format as mandated by Cancer Care Ontario. In conclusion, the past year has been exceptionally challenging and exciting for HRLMP to be given the opportunity to offer a more comprehensive approach and contribution to cancer care.

Submitted by:

Dr. J.-C. Cutz MD FRCP(C) Pathologist, St. Joseph's Healthcare, HRLMP

News from Administration



Dr. Fiona Smaill

Dr. Fiona Smaill, Medical Microbiologist with HRLMP, Infectious Diseases physician at McMaster Children's Hospital and Hamilton Health Sciences, Professor of Pathology and Molecular Medicine, and former departmental Chair, is **retiring in July 2022** after 34 years of exemplary and inspiring service.

Fiona obtained her medical degree from Otago University in New Zealand in 1978, followed by training in Internal Medicine, Infectious Diseases and Medical Microbiology, which she completed in 1988 at McMaster University. She went on to a truly remarkable career in

Microbiology and Infectious Diseases based at the McMaster site, serving both children and adults, with a keen interest in women's health. She helped found and lead our regional HIV program, and had a profound impact on the development of clinical care for HIV patients through clinical service, teaching, and extensive collaborative clinical research.

She helped train almost all of the current Medical Microbiologists, and supported us through training and our faculty development. She served as Microbiology residency program co-director, Microbiology discipline director, and then 11 years as Chair of the Department of Pathology and Molecular Medicine. Her vision of academic laboratory physicians providing impactful clinical service, of driving clinically relevant diagnostic testing and research, of constantly learning and teaching, and of collaborating broadly, have been admirable hallmarks of Fiona's career.

Earlier this year, Fiona was awarded a welldeserved Lifetime Achievement Award by the Association of Medical Microbiology and Infectious Diseases of Canada (AMMI-Canada). She received this honour in April 2022 in Vancouver, in the first in-person meeting since the pandemic started.

After many years as a clinical researcher, Fiona accelerated her translational research work. Working closely with Dr. Zhou Xing on an inhaled adenovirus-vector vaccine for tuberculosis, and now for COVID-19, she has brought together disparate specialists to work together on exciting and breathtaking research (pun intended!).

It has been an honour and an absolute pleasure to work with Fiona for over 30 years. We cannot think of a kinder, more collaborative, and more enthusiastic physician and teacher.

We thank you personally for years of mentoring us all to be better physicians, teachers, leaders, researchers, and human beings. Thank you for all of the advice, for the late night and weekend phone calls, and for always being there. We trust that you will continue to be involved with McMaster University, and wish you a wonderful and well-earned retirement!

Submitted by:

Dr. Marek Smieja & Dr. Deb Yamamura, **HRLMP Microbiologists**

Education News





Thursday, October 20, 2022

Click on the link below for further information: https://chse.mcmaster.ca/events/event-details/2022/10/20/defaultcalendar/quality-improvement-and-patient-safety-symposium-2022gips?utm_source=BenchmarkEmail&utm_campaign=Quality_Improvem ent and Patient Safety Symposium 2022 QIPS -MYC x 1&utm medium=email

News from Chemistry



Discipline Director / Head of Service, Clinical Chemistry / Immunology, HRLMP

I am very pleased to announce the appointment of **Dr. Joe Macri** to the position of **Discipline Director and Head of Service** for the Hamilton Regional Laboratory Medicine Program's Division of Clinical Chemistry/Immunology.

This appointment was effective June 1, 2022, pending approval by the Medical Advisory Committees at both Hamilton Health Sciences and St. Joseph's Healthcare, Hamilton. Dr. Macri has been employed as a Clinical Biochemist with the HRLMP since 2000, and has been an Associate Professor in the Department of Pathology and Molecular Medicine at McMaster University since 2005. He is based at the Hamilton General Site.

Dr. Macri has shown strong leadership in his oversight of the HRLMP's Laboratory Reference Centre; he has a true passion for investigating and implementing new assays, supporting research, and providing professional support to clients. Dr. Macri's commitment to collaboration and integration is clear in all that he does.

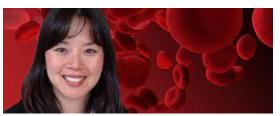
I would also like to thank **Dr. Tony Chetty** for his significant contributions as Discipline Director of CC/I, a role he has held since 2010. Dr. Chetty has successfully led his Discipline through challenge after challenge, including two core laboratory analyzer implementations, and rapid expansion of clinical services at all sites. He has balanced his laboratory and administrative roles with an active clinical practice in metabolic disease, and teaching of undergraduate and postgraduate learners. At the heart of Dr. Chetty's leadership lie his professionalism, his collegiality, and his deep respect and support of CC/I staff and faculty.

Please join me in welcoming Dr. Macri to his role as HRLMP's Discipline Director / Head of Service of Clinical Chemistry/Immunology. I wish him much happiness and success in this new position.

Submitted by:

Dr. Menaka Pai, Chief of Laboratory Medicine, Hamilton Health Sciences and St. Joseph's Healthcare Hamilton

Hematology News



Dr. Patricia Liaw

Effective July 1, 2022, the Jack Hirsh Professorship will convert to the fully endowed **Jack Hirsh and Clive Kearon Chair in Thromboembolism Research**. This change is the result of a very successful fundraising campaign to which many in our Division generously donated.

Dr. Patricia Liaw, the current holder of the Jack Hirsh Professorship, will be the inaugural holder of this prestigious endowed Chair, which celebrates two of McMaster University's most influential researchers.

I cannot think of a more worthy inaugural Chair and I am sure you will all join me in congratulating Patricia.

Submitted by:

Dr. Shannon Bates, Discipline Director, Hematology and Thromboembolism

A message shared with our laboratory staff ...

"Dear TM Staff

We would like to recognize with thanks and admiration your hard work leading up to EPIC Go Live, and especially since Go Live. It has been an exhausting and challenging time. You have gone beyond with your tremendous hard work, dedication, resilience and perseverance. Your efforts directly impact and improve patients' lives every day. We appreciate all the extra work - phone calls, over-time shifts, problem-shooting, ticket-logging, meetings, down-times and so much more. We are so grateful that you are part of this team.

Please continue to learn, log tickets, report challenges, share what you have learned and support your colleagues. AND take a few moments every day to breathe.

Thank you for being extraordinary,

Mickey, Ted, Shuoie and Menaka"

Microbiology News



So much to celebrate from the **Association of Medical Microbiology and Infectious Disease (AMMI) Canada** Conference 2022

Dr. Deb Yamamura started her term as **President** of the AMMI Canada. AMMI is a national specialty association that represents over 725 members which include adult and pediatric infectious diseases physicians, medical microbiologists, clinical

microbiologists, residents, and other health care workers.

Dr. Fiona Smaill was awarded the prestigious **AMMI Lifetime Achievement award**.

This award recognizes a member who has made outstanding national or international contributions in clinical, research or advocacy in infectious diseases or medical microbiology. Dr. Smaill is amongst a prestigious group of medical microbiologists and infectious diseases physicians.



Dr. Fiona Smaill



HRLMP and McMaster University was well represented at the AMMI conference

A few highlights include:

Mark Gaskin, Technical Specialist
 Microbiology, was the primary author of four
 posters on a NICU outbreak with MDR
 Enterobacter, evaluation of chromogenic media
 to detect Serratia for neonatal surveillance,

evaluation of a method to detect carbapenemases, and the evaluation of the Vitek MS Prime for the detection of bacterial pathogens

- **Dr. Padman Jayaratne** presented on using his lab-developed LAMP test for Ureaplasma in neonates
- **Dr. Deb. Yamamura** presented on the VitekMS Prime identification of fungal pathogens
- The microbiology residents were also well represented with a number of posters:
 - 1. **Dr. Adam Komorowski** on quality score for wound swab specimens
 - 2. **Dr. Charlotte Fuller** on urinary colony count cut-offs and urinary tract infection
 - 3. **Dr. Xena Li** with a case report of *C*. septicum endocarditis
 - 4. **Dr. Brody Duncan**, had his case report on eculizumab and serogroup B meningococcemia selected for the oral case report symposium

These accomplishments represent the contributions of many microbiologists and technologists in the division. Congratulations!!!

Submitted by:

Dr. D. Yamamura, Microbiology Division, HRLMP

Quality News



Congratulations to the 2021/2022 MLT and MLA students who have completed their placement at HRLMP. HRLMP welcomed most of the students that came through as staff members. Thank you to all the HRLMP staff members who were involved as teaching techs and those who contributed to a positive student experience.

We look forward to welcoming our next group of students in September 2022 from The Michener Institute, St. Clair College and Ontario Tech University.

HRLMP will continue to create a meaningful, positive learning environment for our students.

2022 Rapid Fire Showcase: Call for speakers!

The 2022 HRLMP Rapid Fire Showcase will take place in October this year (date to be determined) to accommodate the Accreditation Canada Diagnostics Surveillance Visit in November 2022.

This is a great opportunity for education and showcasing our program.

If you or your department would like to present an interesting case this year please email HRLMPQuality@hhsc.ca to secure your spot. More information to come.

Submitted by:

HRLMP Quality Team

Research News

MMRI supports research and innovation within the HRLMP

The HRLMP is excited to be collaborating with the McMaster Manufacturing Research Institute (MMRI) on a variety of laboratory improvement projects.



Alison and Juliana (pictured) are in their 5th year of Mechanical and Biomedical Engineering at McMaster University. This summer they are working for the McMaster Manufacturing Research Institute as Research Assistants.

Alison and Juliana have been collaborating with the HRLMP to find solutions for common problems experienced in the Core Laboratories. Some of their projects include a redesign of the blood gas mixer and alternatives to specimen transport foam holders.

Submitted by:

Mackensey Bacon, HRLMP Research Coordinator



From left to right: Amanda Cocca, Linda Tweedle, Mackensey Bacon, Tracy Carrier, Meredith Hanna, Lorraine Phillip, Sandra Fazari, Amanda Hurdowar

On May 14th, the **HRLMP team** was excited to be supporting women's mental health programs at St. Joseph's Healthcare Hamilton Foundation by participating in the **LOVE YOU by Shoppers Drug Mart™ Run for Women**.

The past two years have been incredibly tough on everyone. Our mental health has suffered due to the pandemic, and the mental health of women has been disproportionately affected, too.

We do the best we can everyday.

Sometimes our hearts are on our sleeves, sometimes our hearts are on the ground. But when we put our hearts together, when we're there for each other, we're amazing!

Please join us next year!

Submitted by:

Sandra Fazari, Interim Executive Director, HRLMP



Join us for an evening walk and fall-themed festival at *Illuminight*!

Now in its fifth year, this <u>special event to</u> "Shine a Light on Cancer" is back in person and will be held at a brand new venue.

When: Saturday, October 1, 2022 Where: F.H. Sherman Recreation and

Learning Centre, Hamilton

Click on the link for details and registration link: http://events.hamiltonhealth.ca/site/TR/Events/TeamraisersTheme1?fr_id=2613&pg=entry&utm_source=05_11_22&utm_medium=email&utm_campaign=illuminight_2022

Join Us on September 17 for Strides 2022 at Bayfront Park

Registration and fundraising are in full swing for **Strides** in support of **Hamilton General Hospital Foundation and St. Peter's Hospital Foundation!**

At Strides, you can take part in a 5km walk or timed 5km run. The event also features:

- a vendor village with breakfast and lunch options
- health and wellness activities like yoga
- live entertainment
- much more!

Click on the link below for more information and registration details:

http://events.hamiltonhealth.ca/site/TR?fr id=2573&pg=entry &utm_source=06_08_22&utm_medium=dd&utm_campaign=St rides 2022

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https://choosingwiselycanada.org/hospitals/using-labs-wisely/