New investments in the Toronto High Containment Facility will help train the health-care workforce of tomorrow, enhance the life sciences ecosystem in Ontario and protect the health care of all.
# TRANSFORMING ONTARIO’S CRITICAL RESEARCH INFRASTRUCTURE

## SUMMARY OF TORONTO HIGH CONTAINMENT FACILITY UPGRADES

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<th>Aims</th>
<th>Existing Toronto High Containment Facility</th>
<th>Revitalized Toronto High Containment Facility</th>
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| **Enhance Capacity + Collaboration** | • Separated spaces for CL3 work  
• Multiple areas/systems to maintain  
• Designed for specific pathogen program  
• Capacity limitations; no collaboration space | • Consolidated infrastructure  
• Designed for pathogen flexibility  
• Expanded capacity  
• Designed for collaborative ecosystem  
• Provision of CL3 capacity for wide span of Canadian institutions |
| **Accelerate Research (Diversify Pathogen types + Establish Novel Research Platforms)** | • Effluent decontamination system (EDS) only for in vivo CL3  
• No Security Sensitive Biological Agents (SSBA) capacity  
• No in vivo imaging  
• Dated analytical equipment  
• Limited pre-clinical assessment | • EDS supporting all CL3  
• Dedicated SSBA area  
• Multiple in vivo imaging modalities  
• Dedicated modules for systems approach to interrogate cell and tissue level mechanisms  
• Creation of physiological monitoring suite |
| **Upgrade Safety + Security** | • Aging/end of life components  
• Potential incompatibilities with update to Canadian Biosafety Standard (CBS) | • Modern design, new primary containment devices and systems  
• Designed to accommodate increased testing requirements in updated CBS |

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Canada’s next pandemic is likely to start in one of its cities, arriving in a major airport on the wings of global human, business, and knowledge networks. Indeed, SARS-CoV-2 and the original SARS-CoV-1 were first identified in Canada by researchers at Toronto hospitals. Fortunately, Toronto is also equipped with the advanced health infrastructure and cutting-edge talent that transform acute challenges into better health and new, globally-leading therapeutics and treatments.

The GTA contains the country’s most dynamic life-sciences ecosystem, including the Toronto High Containment Facility (THCF), a physical and human capital resource at the forefront of pandemic preparedness.

$7.3 billion
amount of revenue the pharmaceutical sector in Ontario generates

55%
Percentage of Canada’s pharmaceutical companies in the GTA

65%
Percentage of Canada’s pharmaceutical jobs in the GTA

73%
Percentage of Canadian pharmaceutical exports that originate in Ontario

Research at the facility is increasing the capacity of the health-care system to adopt the most effective therapeutics and vaccines, manufacture novel compounds, develop more efficient research platforms, and expand the number of pathogens being studied. Its renewal will accelerate the impact of the Emerging and Pandemic Infectious Disease Consortium (EPIC), a program anchored by the THCF. EPIC joins science, engineering and public policy to address the impact of existing and emerging pathogens and harnesses the full inter-disciplinary potential of the comprehensive ecosystem of U of T and its hospital partners.

The proposed $85-million revitalization and expansion of the THCF infrastructure is expected to be cost-shared by federal and provincial governments, the University, and the internationally-renowned partner hospitals and hospital network that have supported the facility. Added capacity will enhance access by Ontario universities, including York University, Ryerson University, the University of Guelph’s Ontario Veterinary College and Queen’s University. Once completed, the modernized facility will become the largest and most advanced high-containment research centre in Canada.

Now is the time to make transformational investments in a facility that will advance the resilience of Ontario’s health-care system and enhance the health security and prosperity of Canadians.
A strong network of collaborators has been centred at the THCF over the almost two decades it has been in continuous operations. Significant advances have been made at the facility against tuberculosis and HIV, two of the world’s most devastating pathogens, as well as against rabies, Zika, West Nile and SARS-CoV-1 and SARS-CoV-2.

HIV continues to affect 37 million people worldwide and is estimated to cost $687-million in health-care spending in Canada annually. TB is the leading infectious disease killer in the world and exerts an unequal burden on Canada’s most vulnerable populations.

As national and global regulatory standards for the handling of pathogens and toxins have evolved, the THCF has consistently met and exceeded new regulations, setting a standard of regulatory excellence for in vitro and in vivo studies. Indeed, the facility was among the first in the world to isolate and sequence the SARS-CoV-2 virus in 2020 because the Public Health Agency of Canada was confident in the THCF’s ability to perform risk assessments and develop new procedures to manage the virus securely.

The isolation of the virus was the first milestone in a fast-paced trajectory of discovery and impact. Research conducted at the CL3 facility has been the foundation for better protection for frontline health-care workers, the development and testing of safe and effective processing of test samples, and new therapeutics to address SARS-CoV-2. The lab supported industrial research efforts that are yielding significant commercialization potential, including new vaccine options currently undergoing trials from Providence Therapeutics, Eyam Vaccines and Immunotherapeutics, and the British Columbia Centre for Disease Control, as well as treatments for acute respiratory distress syndrome from Edesa Biotech.

In late 2021, researchers within the TAHSN network leveraged the facility to rapidly sequence and understand the Omicron virus. Specific research conducted at the THCF has included:

- Novel HIV therapeutic and treatment approaches
- Technical validations to support Public Health Ontario’s sample processing
- Developing optimal tuberculosis-vaccination strategies
  - The discovery of mechanisms underlying the impact of SARS-CoV-2 infection on cardiac cells
  - New targets for SARS-CoV-2 drug development
  - Research for the Public Health Agency of Canada, the Bank of Canada, the Royal Canadian Mint, and the Ontario Human Milk Bank.
The Toronto High Containment Facility is at the centre of research efforts to understand pathogens and mitigate their impact on health care systems and individuals. Work at the THCF is also building the talented life sciences workforce whose research and innovation will prevent future pandemics and address persistent pathogens and the costs they impose.

WHAT IS A CL3 LAB?
CL3 or Containment Level 3 labs are critical research infrastructure for working with infectious biological agents posing elevated risks – such as deadly viruses – that require high security and safety procedures. While CL2 labs are more common in biomedical research settings, CL3 labs require additional operational controls and infrastructure, such as specialized ventilation, full-body personal protective equipment, and special handling of waste and water. This equipment and infrastructure allow researchers to safely study high-impact infectious diseases.

RESEARCH FOCUS I: MADE-IN-CANADA THERAPEUTICS
The U of T and its hospital partners are a powerhouse of entrepreneurship in the life sciences sector. Together, they have created over 200 company startups over the past decade, while members of the Toronto Academic Health Sciences Network, who use and support the facility, are engaged in industrial partnerships valued at over $100M annually.

In April 2022, Moderna signed a partnership with the University of Toronto to prevent and treat infectious diseases, during which Moderna Canada CEO Patricia Gauthier, above, right, and Andrea Carfi, Chief Scientific Officer for Moderna received a tour of the CL3 facility from EPIC Director of Strategy and Operations, Natasha Christie-Holmes.

(Photo by Johnny Guatto).

The facility has been instrumental in the research to commercialization journey, including:

• Moderna will collaborate with U of T researchers, including in molecular genetics, biomedical engineering, and biochemistry, to prevent and treat infectious diseases. Moderna is also launching their “mRNA Access” program at U of T to propel research in the areas of emerging and neglected diseases, many of which require the CL3.

• Providence Therapeutics used the CL3 lab to adapt a messenger RNA vaccine that was in development for HIV to prevent SARS-CoV-2 infections. This made-in-Canada vaccine is currently in phase 2 clinical trials.

• I3 BioMedical Inc. used the CL3 lab to validate their antimicrobial coating, which deactivates 99% of the SARS-CoV-2 virus on medical masks. The technology enables mask and ventilator re-use and is sold globally.

• Edesa Biotech is using the CL3 lab to study the efficacy of a drug with the potential to limit the inflammatory immune response that leads to acute respiratory distress syndrome – the main cause of death in COVID-19 patients. The THCF made it possible for Edesa to complete its product development in Canada.
The facility supported the ability of public health authorities, including Public Health Ontario, to respond. Research from THCF director Scott Gray-Owen on techniques to disinfect N95 respirators informed healthcare policies on reuse of PPE and validated the ability of novel respirator materials developed by I3 Biosciences to create safer PPE. In another example, and working with Public Health Ontario, the THCF established six methods of SARS-CoV-2 inactivation to facilitate safe handling of diagnostic samples.

RESEARCH FOCUS III: VIRUS SURVEILLANCE

Preventing the next pandemic depends on surveillance of existing and emerging pathogens, whether viral, fungal, or bacterial, as well as guarding against a resurgence of SARS-CoV-2, and rapidly detecting and understanding new emerging pathogens.

Since 2016, Dr. Samira Mubareka, a clinical scientist at Sunnybrook Research Institute and Professor in U of T’s Faculty of Medicine, has been conducting zoonotic pathogens surveillance with several government partners. Recently, she co-authored a study that examined the spread of COVID-19 from humans to deer in Canada. Dr. Mubareka is part of a national team of researchers who are actively monitoring animal reservoirs of the virus.

RESEARCH FOR INNOVATION: BUILDING TOMORROW’S TALENT PIPELINE

An analysis by BioTalent Canada predicts that by 2029, Ontario’s biomanufacturing sector will face a labour shortage of 5,820 workers. Only 25% of those positions are projected to be filled if steps are not taken to train more skilled workers.

The THCF will train an expert and inclusive workforce and empower them to take their skills and experience to industry as well as academia. Indeed, training in operations and regulatory requirements at the facility mirror the GMP requirements for biopharmaceuticals and biomanufacturing, providing broad opportunities for CL3 trainees. The THCF will also provide space to research teams from Guelph, York, Ryerson and Queen’s universities, and host trainees and staff to advance the growth of talent Ontario-wide.

As the pandemic has revealed, the burden of disease is not felt equally within Ontario, Canada and globally, and the perspective of affected communities must be integrated into the development of clinical trials, vaccine and therapeutic development, and physical mitigation measures. That is why the Epidemic and Pandemic Infections Consortium (EPIC, epic.utoronto.ca) has committed to train under-represented investigators in Canada, and to facilitate access and exchange with research institutions in the Global South.

Additional support will encourage our best and brightest to build careers in Ontario, create new companies, make new investments, and pursue new discoveries. It will enhance opportunities to commercialize made-in-Canada therapeutics, vaccines and treatments and unleash the full potential of Toronto’s Bioinnovation Ecosystem.
The pandemic has underlined the necessity of developing next-generation vaccines and therapeutics for existing and emerging pathogens and developing diversified supply chains, including made-in-Canada biomanufacturing facilities. As the federal government recognized through its investments in the country’s biomanufacturing capacity, supporting a resurgent domestic biomanufacturing industry has the potential to accelerate the innovation to commercialization pipeline and to improve the prosperity and health of Ontarians.

However, this renewed domestic and global investment in the future of Canada’s bioinnovation sector is expected to further challenge the capacity of the current facility to meet the demand.

Key updates are planned to leverage the economic and research potential of the Toronto High Containment Facility:

- Modernizing the lab with state-of-the-art molecular, imaging, and clinical equipment to expand research and training capacity and allow therapeutic and clinical interventions to be developed and validated.
- Expanding the usable space to create one single contiguous plan which will increase lab space for industry users and other private and public entities that require integrated CL-2+ and CL3 facilities and expertise.
- Enhancing biosecurity infrastructure for pathogenic samples that require a high level of containment.
- Additional biocontainment capabilities to meet emerging regulatory standards, study a wider variety of pathogens and operate a biobank, also increasing researchers’ ability to participate in national and global surveillance projects.
- Increasing our pathogen program to including emerging threats, such as avian influenza, allowing researchers to understand pathogens before they arrive in Canada and growing Ontario’s pandemic preparedness.

Renewed and modernized CL3 facilities will spur and support a new era of bioinnovation in Ontario, train, recruit and retain leaders in research, medicine and biotech, and develop the early warning and pathogen response systems that Canada and Ontario need to respond to the next pandemic.

With the assistance of other levels of government, the THCF will support research that is creating new therapies and treatments, accelerate the commercialization of discoveries into globally competitive products and processes, and support a homegrown bioinnovation ecosystem.

U of T has the global talent, networks, research, innovation, and expertise necessary to repair critical gaps in Canada’s health security, grow the country’s health-sector economy to new heights, and catalyze world-changing medical treatments and therapies that can create better health for all.