

# Regulatory framework of laboratory developed tests: Canada vs U.S.

July 09, 2024

Lab-developed tests (LDTs) are diagnostic tests developed and used within a single laboratory. These tests are regularly used in healthcare to detect pathogens or to diagnose disease in patients. In Canada, LDTs are not regulated under the [Medical Device Regulations](#) and instead rely on provincial and territorial regulation of laboratories. Until very recently, the United States Food and Drug Administration (FDA) took a similar approach to LDTs. As of April 29, 2024, all LDTs used in the United States are subject to FDA oversight as medical devices. While there has yet to be any indication that Health Canada intends to mirror the FDA approach, for now, the LDT industry will want to monitor developments closely.

## Background

Canadian health care professionals and facilities regularly use LDTs to detect **conditions, diseases, and infections in patients**. LDTs are a type of “in vitro diagnostic test” (IVD), which means that the test occurs in a vessel outside of a living organism (such as a test tube). While some IVDs are created in a lab and sold commercially, LDTs are generally designed, manufactured, and performed within the same laboratory.

## LDTs in Canada

Health Canada does not currently regulate LDTs. While all commercially sold IVDs are medical devices and [require appropriate licensing](#) under the Medical Device Regulations, LDTs are not medical devices. LDTs are viewed as a “[health care service](#)” provided by a licensed laboratory. The Medical Device Regulations do not regulate the provision of services or the use of medical devices in Canada.

LDTs are instead primarily regulated through provincial and territorial laboratory regulation and accreditation, but these requirements can vary by province/territory. While the Standards Council of Canada released [standards](#) in April 2018 for the design, development, and validation of LDTs, these standards are voluntary. Some accreditation bodies have [incorporated these standards](#) (for example, the Institute for Quality Management in Healthcare which affects Ontario, New Brunswick, and Newfoundland and Labrador).

## LDTs in the U.S.

Until recently, the United States took a similar approach to LDTs. LDTs did not require FDA approval if they were developed and used within a single laboratory. In response to an increase in the complexity of the types of LDTs that labs are capable of developing and a perceived increased risk to patients, the FDA [decided](#) to regulate LDTs. For example, the FDA identified concerns over some LDTs that lead patients to being over- or under-treated for heart disease, patients with cancer being exposed to inappropriate therapies, and incorrect diagnoses of some rare diseases.

As of [April 29, 2024](#), all in vitro diagnostic products, whether they are LDTs or not, are deemed to be medical devices under the Federal Food, Drug and Cosmetic Act. The FDA's [five stage "phaseout" plan](#) will gradually introduce oversight of IVDs offered as LDTs over the next four years. Although the FDA intends to exercise [some discretion](#) when enforcing applicable requirements for some LTDs (e.g. forensic tests), LDTs will generally be expected to meet applicable requirements following the four-year period. The phaseout policy will begin on May 6, 2025.

## The future of LDTs in Canada

There have been some calls by physicians and researchers for Health Canada to increase oversight of LDTs. Historical regulatory trends suggest that Health Canada could move in a similar direction as the FDA but there is yet no indication of such a change. The industry is encouraged to remain proactive to best prepare for what may lie ahead and to ensure compliance.

By

[Edona C. Vila](#), [Benjamin Fuhrmann](#)

Expertise

[Health Law](#), [Health Care & Life Sciences](#)

---

## **BLG | Canada's Law Firm**

As the largest, truly full-service Canadian law firm, Borden Ladner Gervais LLP (BLG) delivers practical legal advice for domestic and international clients across more practices and industries than any Canadian firm. With over 725 lawyers, intellectual property agents and other professionals, BLG serves the legal needs of businesses and institutions across Canada and beyond – from M&A and capital markets, to disputes, financing, and trademark & patent registration.

[\*\*blg.com\*\*](http://blg.com)

### **BLG Offices**

#### **Calgary**

Centennial Place, East Tower  
520 3rd Avenue S.W.  
Calgary, AB, Canada  
T2P 0R3

T 403.232.9500  
F 403.266.1395

#### **Ottawa**

World Exchange Plaza  
100 Queen Street  
Ottawa, ON, Canada  
K1P 1J9

T 613.237.5160  
F 613.230.8842

#### **Vancouver**

1200 Waterfront Centre  
200 Burrard Street  
Vancouver, BC, Canada  
V7X 1T2

T 604.687.5744  
F 604.687.1415

#### **Montréal**

1000 De La Gauchetière Street West  
Suite 900  
Montréal, QC, Canada  
H3B 5H4

T 514.954.2555  
F 514.879.9015

#### **Toronto**

Bay Adelaide Centre, East Tower  
22 Adelaide Street West  
Toronto, ON, Canada  
M5H 4E3

T 416.367.6000  
F 416.367.6749

The information contained herein is of a general nature and is not intended to constitute legal advice, a complete statement of the law, or an opinion on any subject. No one should act upon it or refrain from acting without a thorough examination of the law after the facts of a specific situation are considered. You are urged to consult your legal adviser in cases of specific questions or concerns. BLG does not warrant or guarantee the accuracy, currency or completeness of this publication. No part of this publication may be reproduced without prior written permission of Borden Ladner Gervais LLP. If this publication was sent to you by BLG and you do not wish to receive further publications from BLG, you may ask to remove your contact information from our mailing lists by emailing [unsubscribe@blg.com](mailto:unsubscribe@blg.com) or manage your subscription preferences at [blg.com/MyPreferences](http://blg.com/MyPreferences). If you feel you have received this message in error please contact [communications@blg.com](mailto:communications@blg.com). BLG's privacy policy for publications may be found at [blg.com/en/privacy](http://blg.com/en/privacy).

© 2025 Borden Ladner Gervais LLP. Borden Ladner Gervais LLP is an Ontario Limited Liability Partnership.