Appendix 2 (as supplied by the authors): Reforms to statutory regulation LDTs across four jurisdictions

	US	EU	Australia	Canada
Effort to create statutory regulation for market access for LDTs	The US FDA has attempted to assert regulatory authority over this field since 1992. A current congressional bill attempts some regulation.	The EU recently introduced a new regulation for in vitro diagnostics in 2017, covering many LDTs. To take full effect by 2022.	Australia's Therapeutic Goods Administration (TGA) began developing a system to track and regulate these technologies in the 2000s, relying heavily on laboratory accreditation.	None
Effort to track LDTs	The FDA has written warning letters but there is no comprehensive effort to track tests and publicly identify them.	Currently unclear whether the EU will publish a registry of the LDT tests covered by the new regulation.	Track all LDTs in a non-public registry and track high-risk LDTs in a public registry.	None

Appendix to: Holloway K, Miller FA, Rousseau F, et al. Mind the gap: Health Canada needs to act on laboratory-developed diagnostics. *CMAJ* 2019. doi: 10.1503/cmaj.190550