Responses to "Health Canada needs to act on laboratory-developed diagnostics"

We appreciate the responses[1,2] to our article published in *CMAJ* entitled, "Health Canada needs to act on laboratory-developed diagnostics."[3]

Michele D'Elia from Roche Diagnostics offered an update, indicating that the company's noninvasive prenatal test was approved by Health Canada while our article was under review.[1] Roche submitted an application for their test after it had been on the Canadian market for several years, demonstrating our point that Health Canada does not require premarket approval for laboratory-developed tests. We agree that the voluntary standard Roche helped to develop through the Standards Council of Canada could be a useful first step to set minimal requirements for these tests. We reiterate that this voluntary standard does not require any manufacturer to submit their test for an external evaluation for safety and efficacy.

We also acknowledge the position advanced by Berry and colleagues[2] that, in some cases, it may be necessary to balance the need for regulatory guidelines and oversight with the importance of access to novel tests for patients who have no other options. Our paper touches on the European Union's approach to regulation, where a health institution exemption would require reduced but still substantial oversight for tests that are used within individual hospital laboratories. Health Canada should look to this type of international leadership on medical devices to improve the regulation of laboratory-developed diagnostics in Canada.

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References

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2. Berry DM, Parekh RS, Irwin MS. Regulatory oversight for research tests and laboratory-developed diagnostics should be more nimble [letter]. *CMAJ* 2019;191:E1388.
3. Holloway K, Miller FA, Rousseau F, et al. Health Canada needs to act on laboratory-developed diagnostics. *CMAJ* 2019;191:E1067-9.

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