RE: Are private labs offering fee for serological testing services?

From:

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To:

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Cc:

"Jarvis, Mark" <mark.jarvis@pco-bcp.gc.ca>, "Jarvis, Saskia" <saskia.jarvis@pco-bcp.gc.ca>

Date:

Mon, 22 Jun 2020 13:44:56 -0400

Hi Dom – Mark did some quick research and confirmed that All five sero tests that HC has approved thus far are lab-based tests meaning that blood is drawn via a syringe into a vial after which it is mixed with some kind of agent (which could even be another type of antibody) to determine the presence of the COVID antibody (or not). Depending on the test, it could be though a company specific, proprietary platform or more generic, common equipment.

Coming back to roles and responsibilities, HC approves the sero test itself for use in Canada, as well as the equipment for which to administer the test. HC does not oversee the testing process as this would fall under provincial jurisdiction.

Hope this makes sense. Thanks!

Chad

From: Hartnell, Chad
Sent: Monday, June 22, 2020 7:57 AM
To: Blanchard, Dominique <Dominique.Blanchard@pco-bcp.gc.ca>
Cc: Jarvis, Mark <Mark.Jarvis@pco-bcp.gc.ca>; Jarvis, Saskia <Saskia.Jarvis@pco-bcp.gc.ca>
Subject: Are private labs offering fee for serological testing services?

Hi Dom – per Thao's question last week re private serological testing, below is the response from HC. It is more complex and legalistic than expected, but here's my takeaway, if I understood correctly:

- While Health Canada must approve the diagnostic device for a serological test to be administered, the actual testing that is undertaken is not federally regulated.
- The assumption around all of this is that the diagnostic device must first be approved before it is used. Based on some media reports, that logical process may not be happening.
- Finally, with respect to Thao's question about which serological tests are being used in these clinics, I think we can assume that Health Canada does not know and likely views this as being out of their jurisdiction.

Please let me know if you have any questions. And thanks to Mark for his persistence on this.

It is possible that private labs are offering fee for serological testing services. However, such testing is not currently regulated by Health Canada thus we do not have oversight on this activity.

An in vitro diagnostic device for serological testing must be approved by Health Canada before it can be sold. The Food and Drugs Act and Medical Devices Regulations require the safety and effectiveness of such devices to be established for their recommended uses before they are approved for sale. However, testing per se that involves the use of such a device is not regulated by Health Canada. The Food and Drugs Act and the Medical Device Regulations only prohibit the

import, sale and advertising of an unlicensed medical device. They don't regulate testing involving the use of a device.

Laboratories can conduct tests using a device that they purchase (that Health Canada must approve before it can be sold) or a test developed "in house" by the laboratory. While an in vitro diagnostic device can't be sold without first being approved by Health Canada a Laboratory's use of device in testing is beyond the scope of the FDA. Much like the use of a drug or device by a doctor is provincially regulated as medical practice -- the accreditation of laboratories the testing conducted by them are regulated provincially.