

Hage-Moussa, Vanessa

From: Martel, Camille
Sent: Tuesday, October 6, 2020 7:05 PM
To: Belliveau, Sébastien; Gagnon, Chantal; Hage-Moussa, Vanessa; Hughes, Vincent; Khalil, Samantha; Kim, Sabrina; Lemkay, Kevin; MacKendrick, Andrew; Sewani, Shehzad; Stickney, Matt; Thalmann, Brett; Theis, Rick; Tran, Thi; Vaillancourt, Ann-Clara; Wellstead, Alex; DPMO Comms-Issues-Parl / Comm-Enjeux-Parl CVPM
Cc: MacKillop, Ken; Tessier, Jean; Butara, Frank; Mondou, Isabelle; Soni, Shannon-Marie; Baril, Sonia; Curtner, Anna; Paxton, Taylor; Laghi, Brian; McLaren, Steven; Mitchell, Heloise
Subject: RE: Flagging: HC authorizes Abbott Alinity Kit

Hi again,

Health Canada has shared a few additional details following this authorization. I was advised that they don't usually update their media lines for every new authorization, however I thought this short brief would be useful.

- On October 6, Health Canada issued an authorization under the Interim Order for the Abbott Alinity m SARS-CoV-2 test.
- The Abbott Alinity m is a molecular PCR test for use in laboratory settings, using nasopharyngeal and oropharyngeal swabs collected by a healthcare provider. Clinical evidence from the manufacturer indicates **100% sensitivity and 96.5% specificity**.
- The test is intended for use in patients who are suspected of COVID-19 infection.
- In the context of the pandemic, Health Canada has already issued authorizations under the Interim Order for the following tests:
 - Abbott Realtime SARS-COV-2 PCR COVID test (March 25)
 - Abbott Architect (May 14)
 - Abbott Alinity (June 11)
 - Abbott ID Now (Sept 30)
 - Abbott PanBio (October 5)

Please let me know if you have any questions.

Merci,

Camille

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From: Martel, Camille

Sent: Tuesday, October 6, 2020 5:54 PM

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Subject: Flagging: HC authorizes Abbott Alinity Kit

Hi everyone,

Please note that Health Canada regulators have authorized the Alinity M Sars-Cov-2 Amp Kit, Alinity M Sars-Cov-2 Ctrl Kit, and has now been posted live in the authorized list on the web pages below.

I've pressed for any new media lines and will share these as soon as possible.

COVID-19 Testing Device Applications Authorized by Health Canada

<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html>

<https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/covid19-industrie/instruments-medicaux/autorises/liste.html>

Thanks,
Camille

Camille Martel

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