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Diagnostic devices for use against coronavirus (COVID-19): List of applications received

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List of applications received

❑ Important!

Only diagnostic tests authorized by Health Canada can be imported or sold in Canada. Unauthorized tests may not produce accurate results, leading to potential misdiagnosis. Health Canada has confirmed that authorized COVID-19 tests are well supported by evidence indicating they will provide accurate and reliable results.

❑ This page is updated daily Monday to Friday. Last updated on April 9, 2020

Health care professionals can request access to COVID-19 medical devices not yet approved for sale in Canada through the [Medical Devices Special Access Program](#).

The diagnostic devices below have been submitted to Health Canada seeking approval for sale or import in Canada under the [interim order](#):

Please note:

- Diagnostic devices on this list **have not been authorized** by Health Canada. The sale or import of these devices in Canada is prohibited under the *Food and Drugs Act* until an authorization or licence has been issued.
- Being on the list of applications **does not guarantee** that a product will be authorized by Health Canada.
- Nucleic acid amplification testing is the diagnostic technology used by public health laboratories across Canada and around the world for diagnosing COVID-19. As such, **diagnostic tests using nucleic acid technology are being prioritized for review** to increase the number of tests available in Canada. For more information see [expedited access](#).
- Health Canada will not discuss details of any applications other than with an authorized representative of the applicant.

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entries

COVID-19 Diagnostic Device Applications Received by Health Canada

Device Name, Manufacturer and National Affiliation <input type="checkbox"/>	Device Type ¹ and Indications for Use <input type="checkbox"/>	Status in Canada <input type="checkbox"/>
(COVID-19)IGM/IGG test kit, LM1100 Dry Fluorescence Immunoassay Analyzer (Portable) Lansion Biotechnology Co., Ltd. (China)	Type of test TBC Serological technology	Received - 2020-03-26 Additional information requested 2020-03-27 and 2020-04-03 Additional information received 2020-04-02

¹ Lab-based means the technology must be used in a laboratory. Point of Care means the technology can be used in doctors offices, for example.

Device Name, Manufacturer and National Affiliation <input type="checkbox"/> <input type="checkbox"/>	Device Type ¹ and Indications for Use <input type="checkbox"/> <input type="checkbox"/>	Status in Canada <input type="checkbox"/> <input type="checkbox"/>
2019-NCOV AB Test (colloidal gold) Innovita Biological Technology Co. Ltd. (China)	Point of care test Nucleic acid technology	Received - 2020-03-21 Additional Information Requested - 2020-03-23 and 26 Additional information received - 2020-04-05
2019-NCOV Direct QPCR Kit Healgen Scientific Limited Liability Company (United States)	Type of test TBC Nucleic acid technology	Received - 2020-03-25 Additional information requested 2020-04-07 Additional information received 2020-04-05
2019-NCOV IGG & IGM Antibody Determination Kit, IGG/IGM Anitbody Rapid Test Kit (Colloidal Gold Assay) Beijing Diagreat Biotechnologies Co., Ltd. (China)	Type of test TBC Serological Technology	Received - 2020-03-30

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Device Name, Manufacturer and National Affiliation <input type="checkbox"/> <input type="checkbox"/>	Device Type ¹ and Indications for Use <input type="checkbox"/> <input type="checkbox"/>	Status in Canada <input type="checkbox"/> <input type="checkbox"/>
2019-NCOV IGG/IGM Diagnostic Kit Colloidal Gold Nanjing Vazyme Medical Technology Co. Ltd (China)	Type of test TBC Serological technology	Received - 2020-03-23 Additional information requested - 2020-03-27 and 31 Additional information received 2020-03-30
2019-nCoV IgG/IgM Rapid Test Cassette Hangzhou Alltest Biotech Co., Ltd. (China)	Lab-based test Serological technology	Received - 2020-03-17 Additional information requested - 2020-03-26 Additional information received - 2020-03-27 and 2020-03-30 Under evaluation
2019-NCOV IGM/IGG Antibody Test Kit (Colloidal Gold) Shijiazhuang Hipro Biotechnology Co., Ltd (China)	Type of test TBC Serological Technology	Received - 2020-03-30

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Device Name, Manufacturer and National Affiliation <input type="checkbox"/> <input type="checkbox"/>	Device Type ¹ and Indications for Use <input type="checkbox"/> <input type="checkbox"/>	Status in Canada <input type="checkbox"/> <input type="checkbox"/>
2019-Novel Coronavirus (2019-NCOV) Triplex RT-QPCR Detection Kit Nanjing Vazyme Medical Technology Co. Ltd (China)	Type of test TBC Nucleic acid technology	Received - 2020-03-27 Additional information requested 2020-04-01 Additional information received 2020-04-02
2019-Novel Coronavirus (2019-NCOV) Triplex RT-QPCR Detection Kit Reagent Genie Ireland Ltd (Ireland)	Type of test TBC Nucleic acid technology	Received - 2020-03-26
3D Med 2019-NCOV RT-QPCR Detection Kit 3D Biomedicine Science & Technology Co., Limited (TBC)	Type of test TBC Nucleic acid technology	Received - 2020-03-24 Additional information requested 2020-03-27

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Date modified:

2020-04-10