

Abbott ID Now COVID-19 Expanded Use – Shelf Life

Abbott and the regulatory approval of ID Now COVID-19 test

- Abbott is an American company that holds 365 medical device licenses in Canada under 19 separate legal manufacturers. The test is manufactured in the USA.
- In the context of the pandemic, Abbott has 6 authorizations under the Interim Order for the following tests:
 - Abbott Realtime SARS-CoV-2 PCR COVID test (March 25, 2020)
 - Abbott Architect (May 14, 2020)
 - Abbott Alinity (June 11, 2020)
 - Abbott Panbio COVID-19 Ag Rapid Test Device (NP) (October 5, 2020)
 - Abbott Alinity M SARS-CoV-2 Assay (October 6, 2020)
 - Abbott Panbio COVID-19 Ag Rapid Test Device (nasal) (December 31, 2020)
- Health Canada has previously licensed the Abbott ID Now instrument (the platform).
- **On September 30, 2020, Health Canada issued an authorization under the Interim Order for the Abbott ID Now COVID-19 test.**
- **On May 26, 2021, Health Canada issued an amendment authorization under the Interim Order for the Abbott ID Now COVID-19 test to extend the shelf life from 6 to 9 months.**
- **On August 04, 2021, Health Canada issued an Expansion of Use to the authorization under the Interim Order for the Abbott ID Now COVID-19 test to extend the shelf life from 9 to 12 months.**
- **On November 10, 2021, Health Canada issued a subsequent Expansion of Use to the authorization under the Interim Order for the Abbott ID Now COVID-19 test to extend the shelf life from 12 to 18 months.**
 - An accelerated stability study performed by the National Microbiology Laboratory was leveraged to support this expanded use.
 - As this was not requested by the manufacturer, the instructions for use and packaging will not be updated to reflect this change.
 - The 18 month shelf life will apply to both newly purchased Abbott ID Now COVID-19 testing devices, as well as previously purchased devices that have yet to be utilized.
 - The expanded uses of the Abbott ID Now COVID-19 device can be found on: [The list of medical devices for expanded use.](#)
 - This expanded use authorization requires that the manufacturer continue to fulfil all conditions previously set out
- The **IO authorization includes conditions** the manufacturer must fulfil to ensure a minimum standard of safety and reliability.
- The Abbott ID Now has received an Emergency Use Authorization (EUA) in the US.

The ID Now COVID-19 test

- The Abbott ID Now COVID-19 test is a rapid molecular test that uses isothermal nucleic acid amplification technology to detect SARS-CoV-2 viral RNA.
- The test is authorized for use by trained operators who are proficient in performing the test using the ID now instrument in laboratory or point-of-care settings.
- The test identifies the presence of SARS-CoV-2 viral RdRp gene RNA in nasal, nasopharyngeal or throat swabs samples collected from individuals suspected of COVID-19 by their health care provider, within the first seven days of symptom onset.

- The assay kit consists of:
 - Test base, containing reagents and an internal control
 - Sample receiver, containing elution buffer
 - Transfer cartridge
 - Proprietary nasal swab
 - Positive control swab
- Materials required but sold separately from the test kit include:
 - ID NOW Instrument
 - Nasopharyngeal swabs
 - Non-proprietary nasal swabs
- The workflow includes turning on the ID NOW instrument, inputting user ID and patient ID into the device, inserting the test base, inserting the sample receiver, inserting and mixing the sample in the sample receiver, transferring the sample to the test base using the transfer cartridge, running the test and reading the results.
- The time to result is 13 min.
- Clinical trials provided by the manufacturer indicate a sensitivity of 92.9% and a specificity of 98.2% on the proprietary nasal swab.
- The approved shelf life is 18 months at 2-30°C.



Intended use

- The ID Now COVID-19 assay performed on the ID Now Instrument is a rapid molecular in-vitro diagnostic test intended for use by medical professionals or trained operators who are proficient in performing tests using the ID NOW Instrument in laboratory or point-of-care settings.
- The qualitative test is intended to aid in the identification of SARS-CoV-2 nucleic acids in nasal, nasopharyngeal or throat swabs samples.
- The test is intended for use in symptomatic individuals, within seven days of symptom onset.

Next steps

- [The list of medical devices for expanded use](#) was updated on November 10, 2021.
- Federal partners will be informed.

Approved by

David Boudreau
Director General
Medical Devices Directorate

ID NOW COVID-19 Test Kits lots with extended expiry

Lot Number	Original Expiry	Health Canada Expiry
1007354	4/12/2021	4/12/2022
1007428	4/13/2021	4/13/2022
1009987	5/4/2021	5/4/2022
1010958	5/11/2021	5/11/2022
1010970	5/11/2021	5/11/2022
M134782	5/30/2021	5/30/2022
M135511	6/3/2021	6/3/2022
M135565	6/4/2021	6/4/2022
M135779	6/4/2021	6/4/2022
M135869	6/5/2021	6/5/2022
M136079	6/6/2021	6/6/2022
M136233	6/9/2021	6/9/2022
M136233	6/9/2021	6/9/2022
M136503	6/10/2021	6/10/2022
M136973	6/13/2021	6/13/2022
M137286	6/15/2021	6/15/2022
M137286	6/15/2021	6/15/2022
M140094	6/30/2021	6/30/2022
M140844	7/6/2021	7/6/2022
M140852	7/6/2021	7/6/2022
M140983	7/7/2021	7/7/2022
M140991	7/8/2021	7/8/2022
M141087	7/9/2021	7/9/2022
M141232	7/9/2021	7/9/2022
M145116	7/31/2021	7/31/2022
M145127	8/1/2021	8/1/2022
M145309	8/2/2021	8/2/2022
M145167	8/3/2021	8/3/2022
M145316	8/3/2021	8/3/2022
M145340	8/4/2021	8/4/2022
M145606	8/4/2021	8/4/2022
M145627	8/4/2021	8/4/2022
M145643	8/5/2021	8/5/2022
M147190	8/11/2021	8/11/2022
M147273	8/11/2021	8/11/2022
147269	8/12/2021	8/12/2022
M147264	8/12/2021	8/12/2022

M147370	8/12/2021	8/12/2022
147344	8/13/2021	8/13/2022
M147344	8/13/2021	8/13/2022
M147517	8/13/2021	8/13/2022
M147551	8/13/2021	8/13/2022
M147399	8/14/2021	8/14/2022
M147927	8/14/2021	8/14/2022
M147926	8/15/2021	8/15/2022
M147962	8/15/2021	8/15/2022
M147988	8/15/2021	8/15/2022
M148145	8/16/2021	8/16/2022
M148318	8/16/2021	8/16/2022
M148327	8/16/2021	8/16/2022
M148336	8/17/2021	8/17/2022
M148662	8/17/2021	8/17/2022
M150137	8/26/2021	8/26/2022
M150455	8/26/2021	8/26/2022
M149877	8/27/2021	8/27/2022
M150365	8/27/2021	8/27/2022
M150472	8/27/2021	8/27/2022
M150514	8/27/2021	8/27/2022
M150453	8/28/2021	8/28/2022
M150589	8/28/2021	8/28/2022
M150761	8/28/2021	8/28/2022
M150719	9/1/2021	9/1/2022
M150778	9/1/2021	9/1/2022
M150785	9/2/2021	9/2/2022
M150796	9/2/2021	9/2/2022
M150888	9/3/2021	9/3/2022
M150978	9/3/2021	9/3/2022
M150991	9/4/2021	9/4/2022
M151010	9/4/2021	9/4/2022
M151020	9/4/2021	9/4/2022
M151288	9/5/2021	9/5/2022
M151614	9/5/2021	9/5/2022
M152778	9/5/2021	9/5/2022
M151320	9/6/2021	9/6/2022
M151625	9/6/2021	9/6/2022
1026501	9/7/2021	9/7/2022
M151423	9/7/2021	9/7/2022
M151855	9/7/2021	9/7/2022

M151905	9/7/2021	9/7/2022
1026570	9/8/2021	9/8/2022
1026573	9/8/2021	9/8/2022
1026601	9/8/2021	9/8/2022
1026619	9/8/2021	9/8/2022
M151445	9/8/2021	9/8/2022
M151956	9/8/2021	9/8/2022
M151985	9/8/2021	9/8/2022
1026669	9/9/2021	9/9/2022
1026672	9/9/2021	9/9/2022
1026684	9/9/2021	9/9/2022
1026687	9/9/2021	9/9/2022
1026708	9/9/2021	9/9/2022
1026711	9/9/2021	9/9/2022
M151601	9/9/2021	9/9/2022
M151915	9/9/2021	9/9/2022
1026876	9/10/2021	9/10/2022
1026928	9/10/2021	9/10/2022
1026931	9/10/2021	9/10/2022
M152183	9/10/2021	9/10/2022
1027011	9/11/2021	9/11/2022
1027088	9/11/2021	9/11/2022
1027091	9/11/2021	9/11/2022
1027094	9/11/2021	9/11/2022
1027097	9/11/2021	9/11/2022
1027100	9/11/2021	9/11/2022
1027103	9/11/2021	9/11/2022
1027106	9/12/2021	9/12/2022
1027181	9/12/2021	9/12/2022
1027222	9/12/2021	9/12/2022
1027227	9/12/2021	9/12/2022
1027262	9/12/2021	9/12/2022
1027343	9/13/2021	9/13/2022
1027369	9/13/2021	9/13/2022
1027387	9/13/2021	9/13/2022
1027404	9/13/2021	9/13/2022
1027408	9/13/2021	9/13/2022
M136930	6/11/2021	6/11/2022
M136930	6/11/2021	6/11/2022
M1007357	4/13/2021	4/13/2022
M138457	6/21/2021	6/21/2022

M136209	6/7/2021	6/7/2022
M136218	6/21/2021	6/21/2022
M140923	7/7/2021	7/7/2022
M147980	8/15/2021	8/15/2022