ENGINEERED AND DESIGNED IN CANADA

Fact Sheet

COVID-19 Antigen Rapid Test Device

Rapid™ Response COVID-19 Antigen Rapid Test

HEALTH CANADA APPROVED | RESULTS AFTER 15 MINS | SAMPLE TYPE: NASAL SWAB | SPECIFICITY 100%

COV-19C25 CE IVD

Health Canada APPROVED

Background

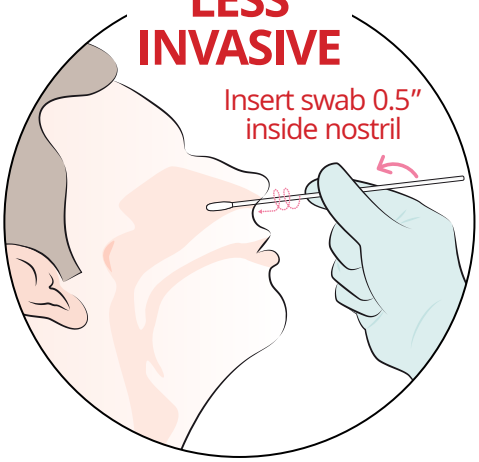
The Rapid ResponseTM COVID-19 Antigen Rapid Test Device is an in vitro immunochromatographic assay for the direct and qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from nasal and nasopharyngeal secretions from individuals suspected of COVID-19 within 6 days of symptom onset. This test is authorized for use at the Point of Care i.e., in patient care settings.

The Rapid ResponseTM COVID-19 Antigen Rapid Test Device is intended for use by trained laboratory personnel or health care professionals.

The Rapid Response™ COVID-19 Antigen Rapid Test Device detects SARS-CoV-2 viral antigens through visual interpretation of colour development. Anti-SARS-CoV-2 antibodies are immobilized on the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to coloured particles are immobilized on the conjugated pad. A sample is added to the extraction buffer which is optimized to release the SARS-CoV-2 antigens from specimen.

Target Customers

Essential Businesses: Production and manufacturing sites, logistics, customer facing employees, residential delivery, public transport employees, private hire companies, border control facilities.
Health Care: Physical and occupational health, therapists, GP practices, Residential care homes, visiting nurses.
Travel: International and domestic travel.
Education: Colleges, universities, private and public schools, boarding schools, school support staff.
Hospitality and Recreation: Service and bar staff, hotel staff and guests, airline and airport staff, sports teams.



Performance

Sensitivity:	90.2%
Specificity	100%
Estimated LOD:	$2x10^{2.4}$ $TCID_{50}$/mL
Storage:	2-30°C

What is inside the box?

- Individually packed test devices
- Extraction buffer
- Extraction tube
- Nozzle with filter
- Individually packed swabs
- Tube stand
- Package insert

For in vitro Diagnostic Use Only.

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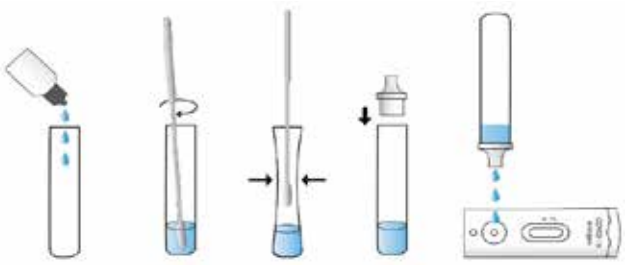
Test Procedure

Bring devices, reagents, and specimens and/or controls to room temperature (15~30°C) before use.

1. Label a clean extraction tube with patient or control identification and place it into the tube stand.
2. Gently mix extraction buffer. Without touching the buffer bottle to the extraction tube, add 10 drops into the extraction tube.
3. Insert the swab with the collected specimen into the extraction tube. Swirl the swab, mixing well. Squeeze the swab 10-15 times by compressing the walls of the tube against the swab.
4. Let the solution stand for 2 minutes.
5. Remove the swab while pressing the swab head firmly against the inner wall of the tube to release as much liquid as possible. Dispose of the used swab in accordance with the appropriate biohazard waste disposal protocol.



6. For each specimen, open the foil pouch just before testing and remove the test device and put it on a clean, level surface. For best results, the assay should be performed within one hour. Label the test device with patient or control identification.

Result Interpretation

Positive: Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

Negative: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).

Invalid: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

Note:

1. The colour intensity in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test region should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

For more information please refer to product insert

*NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

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