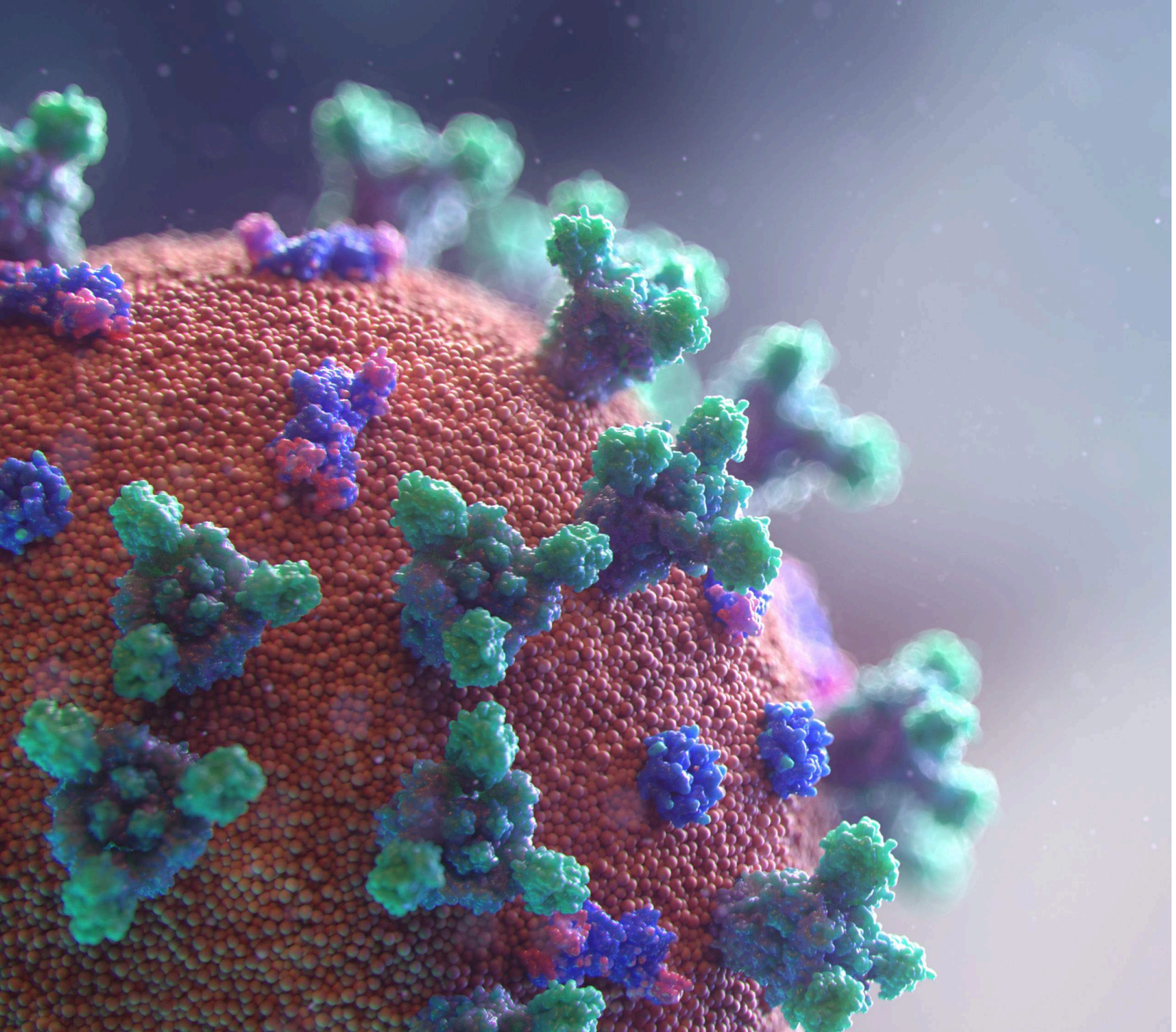
Boson Rapid SARS-CoV-2 Antigen Test Device

Point of Care Use

Health Canada IO Number: 323096

Health Canada



Intended Use

Rapid SARS-CoV-2 Antigen Test Card is a lateral flow immunoassay intended for the comparative detection of nucleocapsid protein from SARS-CoV-2 in nasal swab specimens. Samples are to be collected within 7 days of symptom onset by professional POC healthcare providers in response to individuals reporting suspected symptoms of COVID-19.

Product Features

High Accuracy

Straight forward nasopharyngeal swab collection with clinically proven high accuracy results

Affordability

Any qualified Health Care professionals can easily use our three-step, cost-effective portable testing kit

Easy to Use

Testing can be easily administered in almost any environment without additional special equipment. Easy to transport with no special storage requirements, a test kit is all you need.

Rapid Result

Compared to standard RT-PCR tests which could take multiple days for patients to receive their results, Boson Antigen testers will show results within 15–20 minutes.

Product Information

Quantity	20 tests/kit
Sample type	Nasopharyngeal swab
Storage temperature	2–30°C
Shelf life	18 months
Test time	15–20 minutes (do not read results after 20 minutes)

Kit Contents: Everything needed to run a test

Materials Provided in Each Kit:

- 20 Rapid SARS-CoV-2 Antigen Test Cards (Individually packaged)
- 2 Sample Buffer
- 20 Sterilized swabs (Individually packaged)
- 20 Extraction tubes (Individually packaged)
- 1 Instructions for use
- 1 Tube rack (for 6 tubes/rack)

Specifications

97.46%
ACCURACY

93.75%
SENSITIVITY

98.04%
SPECIFICITY

International Approval Standard

MHRA

CE

European Commission

Bundesinstitut für Arzneimittel und Medizinprodukte

Who is it for?

Personal Care Services

Dentists, Chiropractors, RMT’s

Personal Services – Hair and Aesthetic Salons

Hospitality and Events

Hospitality

Events Sector

Restaurants

Hotels

Production and Transportation

Warehouses

Manufacturing Plants

Public Sector Facilities

Schools

Nursing Homes

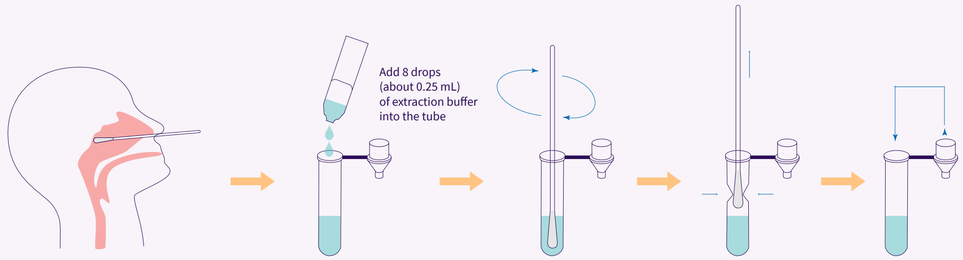
Prisons

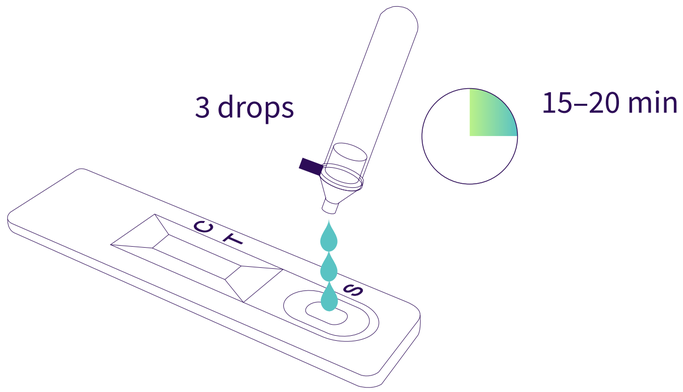
Government Buildings

Instruction

Specimen Preparation

1. Carefully insert the swab into the nasal cavity to the nasopharynx.
2. Add **8 drops (about 0.25 mL)** of extraction buffer into the extraction tube.
3. Place the swab with specimen into the extraction tube. Roll the swab three to five (3–5) times. **Leave the swab in the extraction buffer for 1 minute.**
4. Pinch the extraction tube with fingers and remove the solution from the swab as much as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
5. Install the nozzle cap onto the sample extraction tube tightly. Use extraction solution as test specimen.





Procedure

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the card. Once opened, the test card must be used within 1 hour. Label the test card with patient identity.
3. Invert the extraction tube and add **2–3 drops (50-76 mL)** of test specimen into the specimen well (S) by gently squeezing the extraction tube. The formation of air bubbles in the specimen well (S) must be avoided.
4. Read the results at **15–20 minutes.**

Note: Results after 20 minutes may not be accurate.

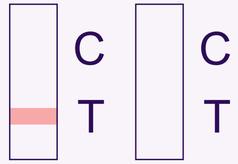
Result Interpretation

Positive

If two coloured bands appear within 15–20 minutes with one coloured band in the Control Zone (C) and another in the Test Zone (T), the test result is positive and valid. No matter how faint the coloured band is in the Test Zone (T), the result should be considered as positive. A positive result does not rule out co-infections with other pathogens.

Negative

If one coloured band appears in the Control Zone (C) and no coloured band appears in the Test Zone (T) within 15–20 minutes, the test result is negative and valid. A negative result does not exclude SARS-CoV-2 viral infection and should be confirmed by molecular diagnostic method if COVID-19 disease is suspected.



Invalid Result

The test result is invalid if there is no coloured band in the Control Zone (C) within 15–20 minutes. Repeat the test with a new test device.

Detection Window