

COVID-19 Rapid Antigen Test Device

The COVID-19 Rapid Antigen Test Device is an *in vitro* chromatographic immunoassay for direct, qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from nasopharyngeal secretions. This product can be administered at point-of-care to enable rapid identification of potentially contagious individuals.



Advantages

- ✓ Rapid results within 15 minutes
- ✓ Visual-read test
- ✓ No reader or equipment required
- ✓ 20 individually wrapped tests per box

Specifications

Kit size: 20 tests/kit*
Storage: 2-30 °C
Shelf life: 18 months

Contents

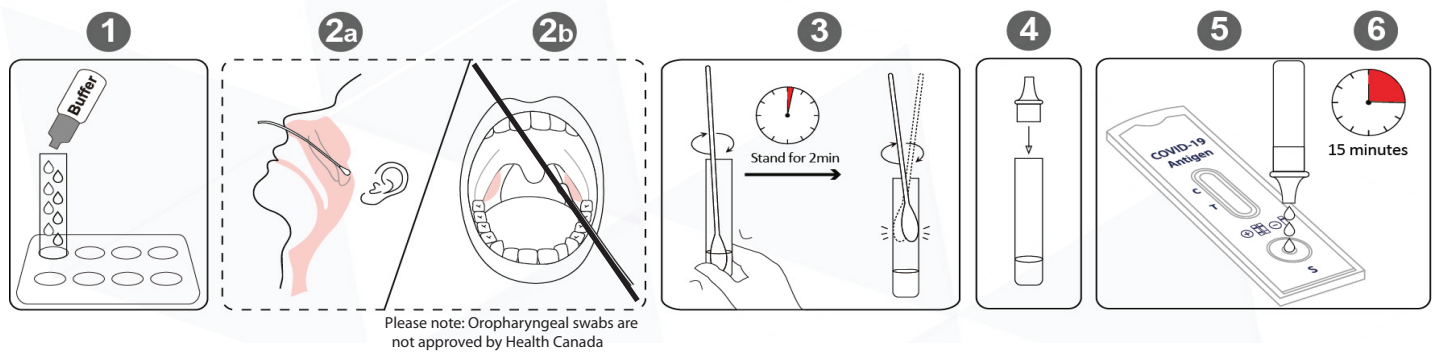
The following components are needed for testing and are included in the kit

- ✓ 20 pcs individually packed swabs
- ✓ Extraction buffer
- ✓ 20 pcs extraction tubes
- ✓ 20 pcs nozzle filter
- ✓ Tube stand

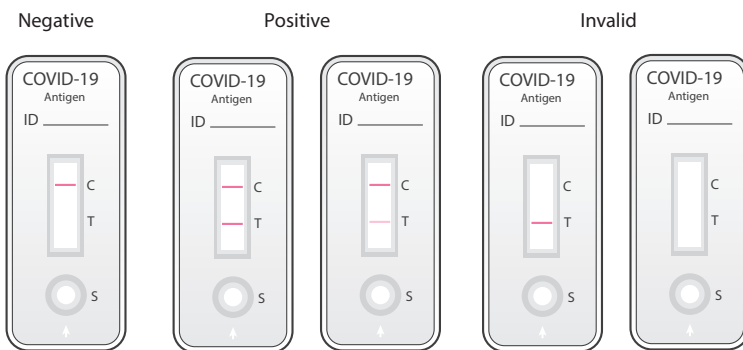
Positive control

Negative control

Test Procedure



Interpretation of Results



POSITIVE: Two colored 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 colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear.

COVID-19 Antigen Rapid Test vs RT-PCR

		RT-PCR		Total
		Positive	Negative	
Covid-19 Antigen Rapid Test	Positive	125	9	134
	Negative	3	1027	1030
		128	1036	1164

Relative Sensitivity:

94.3 % (95% CI:84.6% ~ 98.1%)

Relative Specificity:

98.3 % (95% CI:95.1% ~ 99.4%)

Overall Agreement:

97.4 % (95% CI:94.4% ~ 98.8%)