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CLIA WAIVED

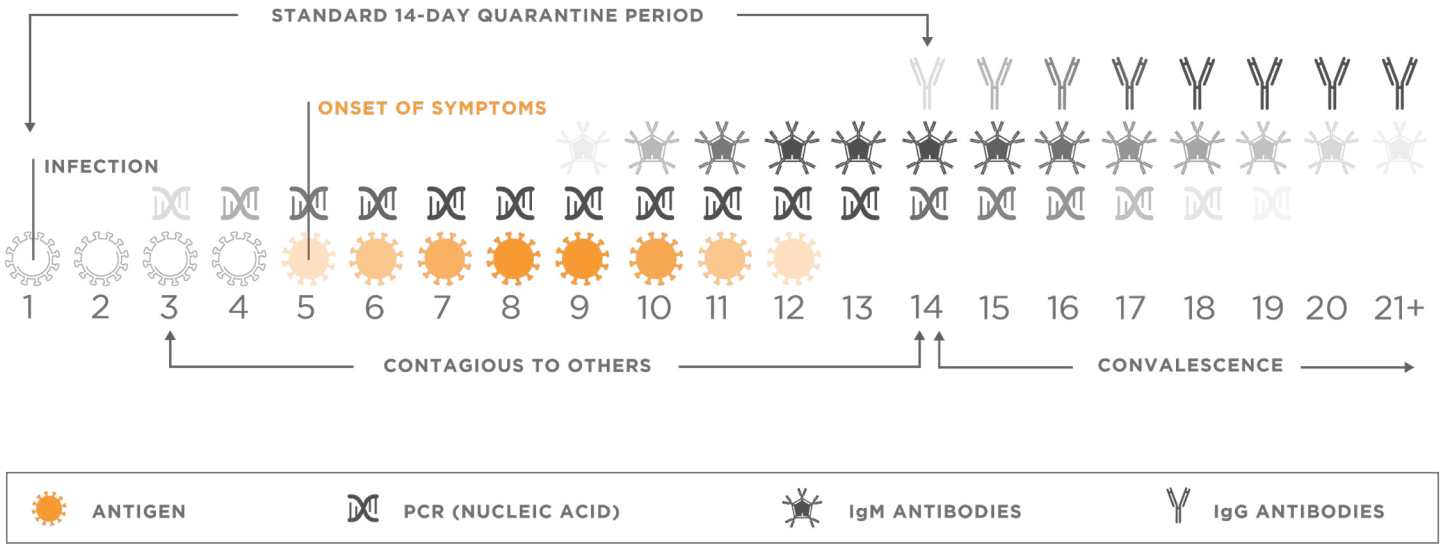
COVID-19 ECOTEST
ANTIGEN RAPID TEST

NASOPHARYNGEAL SWAB

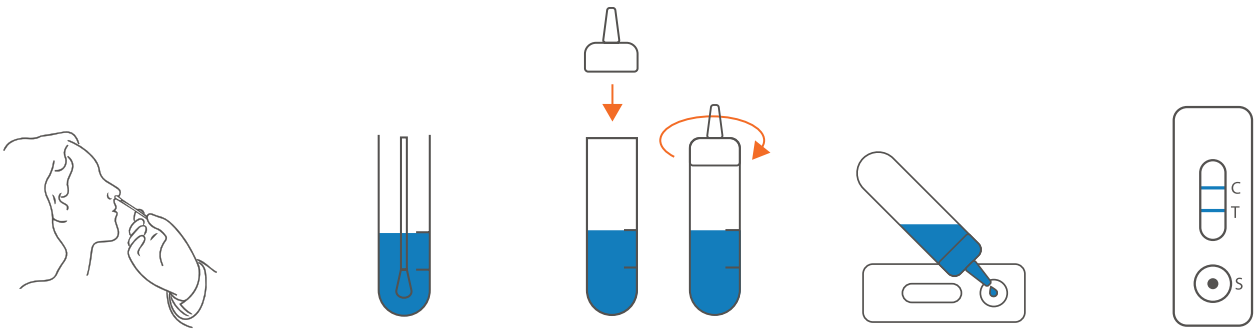
The COVID-19 antigen rapid test device is a lateral flow in vitro immunoassay intended to be used for the qualitative detection of the SARS-CoV-2 viral nucleoprotein. This device will detect both viable and nonviable virus in both nasopharyngeal and oropharyngeal secretions.

HEALTH CANADA AUTHORIZED

VIRUS DETECTABLE TEST WINDOW



5 EASY STEPS



Collect **Mix** **Cap** **Drop** **Read**

KIT CONTAINS:

- Test Cassettes (20)
- Nasopharyngeal / Oropharyngeal Swabs (20)
- Mixing Tubes + Dropper Cap (20)
- Mixing Tube Holder Tray for 8 Samples (1)
- Diluent Buffer (1 bottle)

ASSAY CLINICAL STUDY RESULTS

Positive Percent Agreement (PPA): 94.3 % (95% CI:84.6% - 98.1%)
Negative Percent Agreement (NPA): 98.3 % (95% CI:95.1% - 99.4%)
Overall Agreement: 97.4 % (95% CI:94.4% - 98.8%)

		RT-PCR		TOTAL
		POSITIVE	NEGATIVE	
COVID-19 ANTIGEN RAPID TEST	POSITIVE	50	3	53
	NEGATIVE	3	174	177
TOTAL		53	177	230

Based on relative sensitivity and relative specificity of the test in clinical trials.

Source: COV-S23 Product Insert (2021-02-20)

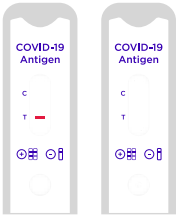
RESULT INTERPRETATION

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.

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.

NOTES:

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 color 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.
3. This test is intended for professional use only and should not be used as the sole basis for the diagnosis of an infection.

CLINICAL DATA

TEST RESULTS				SIGNIFICANCE
PCR	Ag	IgM Ab	IgG Ab	
+	+	−	−	Patient may be in the "incubation period" of SARS-CoV-2 infection.
+	+	+	−	Patient may be in the early stages of infection, and the body's immune response first produced the antibody IgM, but no IgG was produced or the IgG content did not reach the detection limit of the diagnostic reagent.
−/+	−/+	+	−	Patient may be in the middle stage of SARS-CoV-2 infection.
−	−	+	+	Patient is in the late stage of infection, but the human body has developed some immunity SARS-CoV-2 (the persistent antibody IgG has been produced)
−	−	−	+	Patients may have been infected with SARS-CoV-2 in the past, but the patient has recovered or the virus in the body has been cleared.
+	+	−	+	Patient may be in a reccurrent stage of infection.

CROSS REACTIVITY:

Cross reactivity with the following organisms has been studied.

Samples positive for the following organisms were found negative when tested with the COVID-19 Antigen Rapid Test Device.

HCOV-HKU1	INFLUENZA A (H5N1)	COXSACKIE VIRUS A16
HCOV-OC43	HCOV-OC43	NOROVIRUS
HCOV-NL63	INFLUENZA A (H7N7)	MUMP VIRUS
HCOV-229E	INFLUENZA B VICTORIA LINEAGE	LEGIONELLA PNEUMOPHILA
MEASLES VIRUS	INFLUENZA B YAMAGATA LINEAGE	MYCOPLASMA PNEUMONIAE
STREPTOCOCCUS PNEUMONIAE	RESPIRATORY SYNCYTIAL VIRUS	CHLAMYDIA PNEUMONIAE
EPSTEIN-BARR VIRUS	ADENOVIRUS	STREPTOCOCCUS PYOGENES
BORDETELLA PARAPERTUSSIS	PARAINFLUENZA 1/2/3 VIRUS	STREPTOCOCCUS AGALACTIAE
INFLUENZAA (H1N1)PDM09	HUMAN METAPNEUMOVIRUS	GROUP C STREPTOCOCCUS

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