

COVID-19 ECOTEST

ANTIGEN & ANTIBODY RAPID TEST



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.

ANTIBODY RAPID TEST



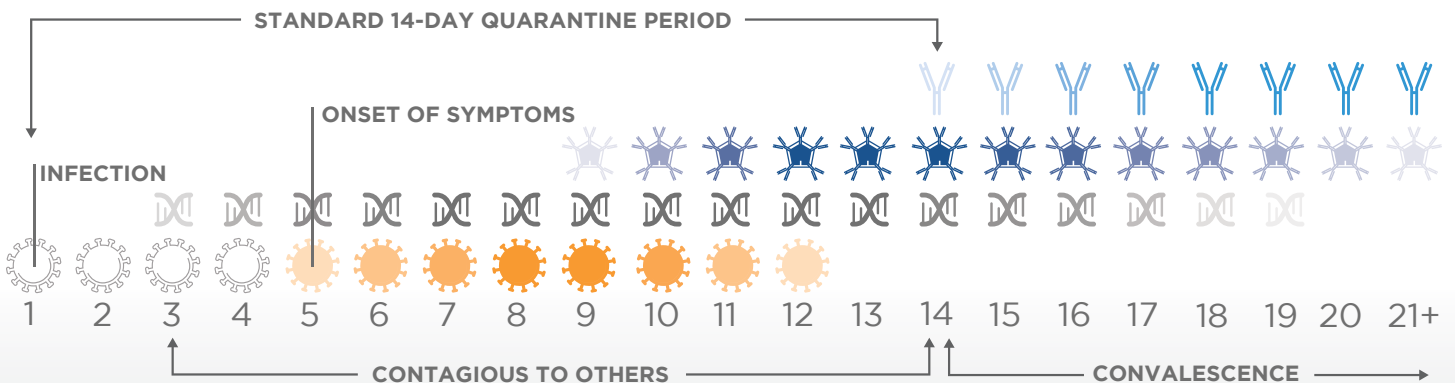
FINGERSTICK WITH LANCET

Detect the presence of SARS-CoV-2 IgM and IgG antibodies instantly from a whole blood sample collected from a minimally-invasive fingerstick blood collection process.

ANTIGEN & IgM/IgG DETECTABLE TEST WINDOW

The COVID-19 ECOTEST Antigen Rapid test will detect the antigen for 5 days after symptoms first appear.

The COVID-19 ECOTEST Antibody Rapid test will detect antibodies 5 to 7 days after symptoms first appear.



ANTIGEN

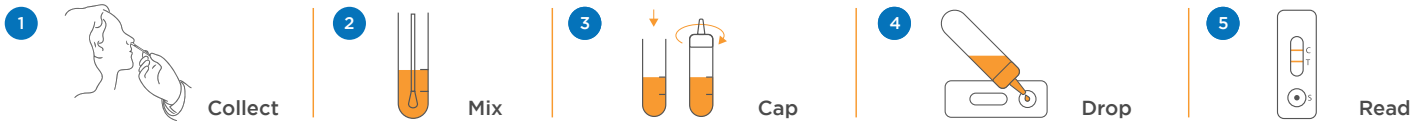
PCR (NUCLEIC ACID)

IgM ANTIBODIES

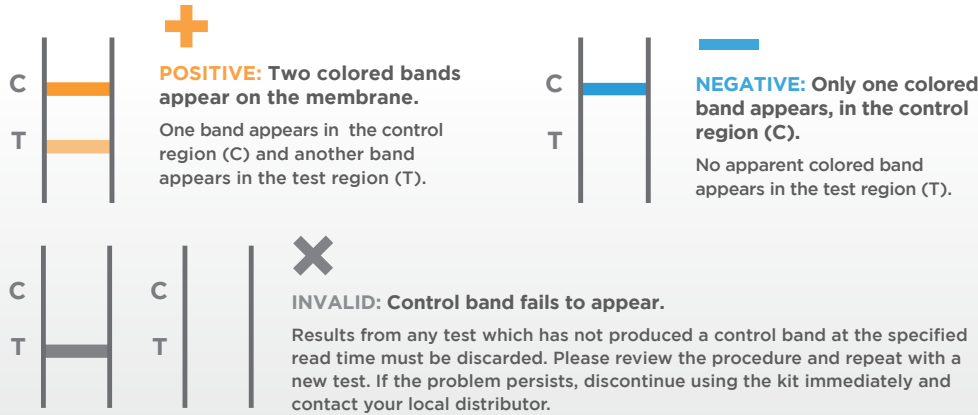
IgG ANTIBODIES

PROCEDURES AND READING RESULTS

ANTIGEN STEPS



RESULT INTERPRETATION

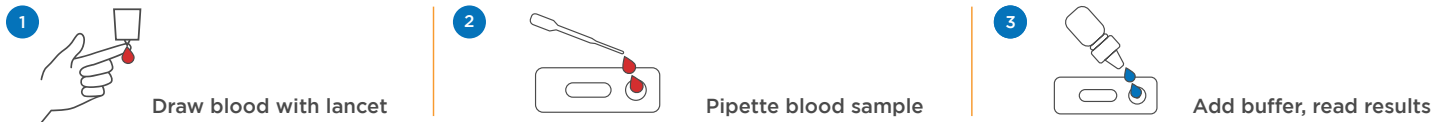


NOTES:

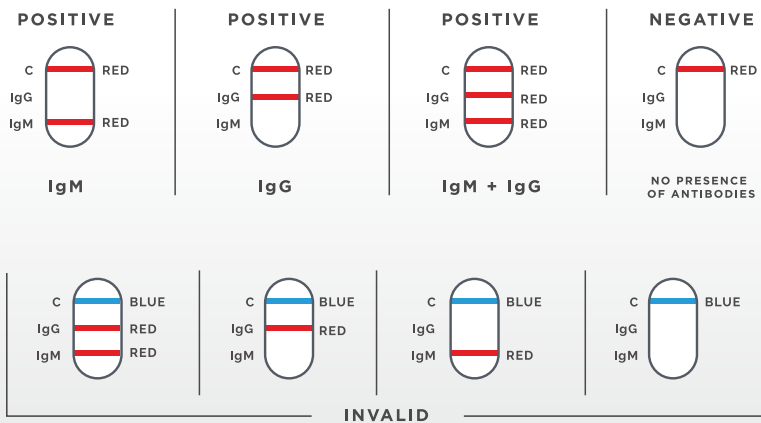
- The colour intensity in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.
- This test is intended for professional use only and should not be used as the sole basis for the diagnosis of an infection.

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%)

ANTIBODY STEPS



RESULT INTERPRETATION



NEGATIVE

The coloured line in the control line region (C) changes from blue to red. No line appears in the test line regions M or G.

The result is Negative.

IgM POSITIVE

The coloured line in the control line region (C) changes from blue to red, and a coloured line appears in test line region M.

The result is anti-COVID-19 IgM Positive.

IgG POSITIVE

The coloured line in the control line region (C) changes from blue to red, and a coloured line appears in test line region G.

The result is anti-COVID-19 IgG Positive.

IgG and IgM POSITIVE

The coloured line in the control line region (C) changes from blue to red, and two coloured lines appear in test line regions M and G.

The result is anti-COVID-19 IgM and IgG Positive.

INVALID

Control line is still completely or partially blue, and fails to completely change from blue to red. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new cassette. If the problem persists, discontinue using the kit immediately and contact your distributor.

IgM: Relative sensitivity: 93.7% (86.0%-97.3%)*
 Relative specificity: 99.1% (96.8%-99.8%)*
Overall agreement: 97.7% (95.4%-98.9%)*
 *95% Confidence Interval

IgG: Relative sensitivity: 98.8% (93.5%-99.8%)*
 Relative specificity: 98.7% (96.2%-99.5%)*
Overall agreement: 98.7% (96.7%-99.5%)*
 *95% Confidence Interval