

ANTIBODY RAPID TEST RESULTS REPORT FOR SARS-CoV-2

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 AUTHORIZATION NO.:

The Antibody Rapid Test for SARS-CoV-2 is an in vitro diagnostic test. This test is used in the qualitative detection of IgG and IgM antibodies against SARS-CoV-2 in whole blood, serum or human plasma.

Nor the quantitative level, neither the growth rate in the antibody concentration can be determined by this qualitative test.

The Antibody Rapid Test for SARS-CoV-2 only indicates the presence of antibodies IgM and IgG and should not be used as a unique criteria for the diagnosis of infections by SARS-CoV-2.

IgM antibodies are produced in the initial phase of infection, are detectable from day 5-7 after the onset of symptoms, and can be detectable up to 6 weeks later.

IgG antibodies are produced later in the course of infection, are detectable around day 11-14 after the onset of symptoms, can be detectable for months, and may confer immunity against the virus.

A negative result does not exclude the possibility of infection by SARS-CoV-2.

The test will be negative in the following conditions: antibodies to coronavirus are either not present or at levels undetectable by the test.

The test may be invalid when the patient shows the following blood levels of:

- Bilirubin $\geq 250 \mu\text{mol/L}$
- Triglycerides $\geq 15 \text{ mmol/L}$
- Hemoglobin $> 20 \text{ g/dL}$
- Rheumatoid Factor $\geq 80 \text{ U/mL}$
- Anti-mitochondrial Antibodies $\geq 80 \text{ U/mL}$
- Antinuclear Antibodies $\geq 80 \text{ U/mL}$
- IgM $< 0.15 \text{ g/dL}$
- IgG $< 0.11 \text{ g/dL}$

Sensitivity and specificity (compared with the reference method RT-PCR):

- Sensitivity: 98.90% (CI*: 94.16%-99.81%)
- Specificity: 97.60% (CI*: 93.29%-99.19%)

*Confidence interval

PATIENT'S NAME: NOMBRE APP1 APP2

ID/PASSPORT: IDENTIFICACION

DATE OF BIRTH: 20/11/1995

GENDER: MUJER

REASON: Motivo de la prueba de ejemplo

SAMPLE CODE: TEST CODE

TEST NAME: Antibody Rapid Test for SARS-CoV-2

METHOD: Colloidal Gold, Immunochromatography

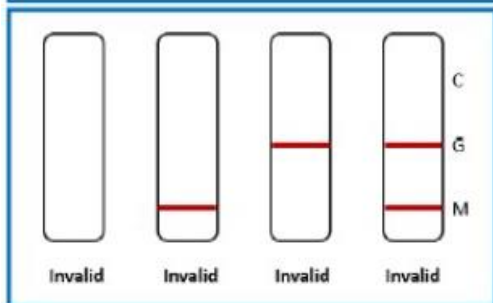
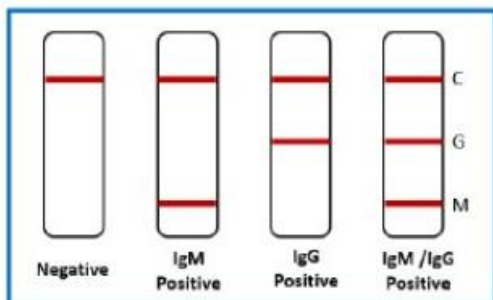
Results:

RESULTADO

IgG: **IGG**

IgM: **IGM**

Interpretation of results



C: Quality Control line
 G: IgG Detection line
 M: IgM Detection line