COVID-19 IgM, IgG, IgM/IgG Rapid Test Package Insert

REF VID35-08-011 English

PRINCIPLE AND INTENDED USE

VivaDiag™ COVID-19 IgM, IgG, IgM/IgG Rapid Test is an *in vitro* diagnostic test for the qualitative determination of COVID-19's IgM and IgG antibodies in human whole blood, serum, plasma and fingertip blood.
The test kit consists of test devices and buffer. The test kit and analyzer are for *in vitro* diagnostic use only, and can be used in point-of-care testing settings and central laboratories.
The Test Kit is based on immunoassay technology. The test devices contains: 1) Binding pad: recombinant COVID-19 antigen labeled with colloidal gold and quality control antibody gold marker. 2) NC membrane--IgM single test device: coated with mouse anti human IgM antibody detection line and quality control C line; IgG single test device: coated with mouse anti human IgG antibody detection line and quality control C line; IgM / IgG double detection test device: coated with two detection lines (G line and M line) and one quality control line (C line). The M line coated with rat anti human IgM monoclonal antibody detects the new coronavirus IgM antibody. The G line coated with rat anti human IgG monoclonal antibody detects the new coronavirus COVID-19 antibody.
When an appropriate amount of sample is added to the sample hole of the test device, the sample will move forward along the test device. If the sample contains IgM antibodies, the antibody will bind to the virus antigen labeled with colloidal gold. The immune complex forms a sandwich complex with the coated anti human IgM monoclonal antibody at the M line with purple, prompting the COVID-19 IgM antibody is positive.
If the sample contains IgG antibodies, the antibody will bind to the virus antigen labeled with colloidal gold. The immune complex forms a sandwich complex with the coated anti human IgG monoclonal antibody at the G line with purple, prompting the COVID-19 IgG antibody is positive.
If both lines G and M don't show color, the negative result will be displayed. The test device also contains a quality control line C. whether there is a test line or not, the purple red quality control line C should appear. It indicates that the test result is invalid if quality control line C does not appear. This sample needs to be retested.

COMPOSITION

Each test kit contains the test device, buffer and package insert.

STORAGE AND HANDLING

- Store the test kit in a cool, dry place between 2-30°C (36-86°F). Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may result in inaccurate results.
- Do not freeze or refrigerate.
- Use the test kits at temperatures between 18-25°C.
- Use the test kits between 10-90% humidity.
- Do not use your test kits beyond the expiry date (printed on the foil pouch and box label).

Note: *The test kit is recommended to store between 2-8°C if it not used in a short time.*
All expiry dates are printed in Year-Month format. 2021-06 indicates June, 2021.

TEST PROCEDURE

1. Take out the test kit and leave it at room temperature for 30 minutes at least.
2. Set a test device on a dust-free clean surface.
3. Apply 10μL whole blood / serum / plasma onto the sample well of a Test Device first, and then apply 80μL buffer onto the sample well of a Test Device.
4. Read the result after 15 minutes.

Note:

- *For in vitro diagnostic use.*
- *Do not mix components from different kit containers.*
- *Avoid contact with eyes and skin. Flush abundantly with water upon disposal if reagents are spilled.*

LIMITATIONS

- The test result can not be used for confirmed diagnosis. If the result is not matched the clinical evaluation, please do more testing.
- Please do not use highly hemolytic and lipid blood samples .
- Please do not reuse the test device.
- This test kit can only use with whole blood, serum and plasma. If use other samples, it may cause wrong results.
- [illegible]sure read the result at 15 minutes. If at other time, it may cause wrong results.
- [illegible] the package insert when testing.

INTERPRETATION OF TEST RESULTS

1. Negative result:
If there is only quality control line C is colored, G and M detection lines are not colored, the COVID-19 IgM/IgG antibody is not detected, that means the result is negative.
2. Positive result:
IgM antibody single test device: The COVID-19 IgM antibody is detected if the quality control line C and the detection line M are both chromogenic, that means the COVID-19 IgM antibody is positive.
IgG antibody single test device: The COVID-19 IgG antibody is detected if the quality control line C and the detection line G are both chromogenic, that means the COVID-19 IgG antibody is positive.
IgM / IgG double test device: The COVID-19 IgM antibody is detected if the quality control line C and the detection line M are both chromogenic, and the test G line is not colored, that means the COVID-19 IgM antibody is positive. The COVID-19 IgG antibody is detected if the quality control line C and the detection G line are both chromogenic, and the detection M line is not colored, that means the COVID-19 IgG antibody is positive. The COVID-19 IgG and IgM antibodies are detected if the quality control line C, the detection line M and G are chromogenic, that means both the COVID-19 IgG and IgM antibodies are positive.
3. Invalid result:
If the quality control line C is not colored, no matter whether the detection line G / M is colored or not, the result is invalid and needs to be tested again.

PERFORMANCE

[illegible]idence rate: 100% (detection of 68 healthy people);
Positive coincidence rate: As follows (detection of 48 patients)

Positive cases	Infection time	Positive coincidence rate (IgM)	Positive coincidence rate (IgG)	Positive coincidence rate (total)
12	4-10 days	7 (70%)	2 (20%)	7 (70%)
36	11-24 days	34 (94.4%)	36 (100%)	36 (100%)

INDEX OF SYMBOLS

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
	Storage temperature limitations		Manufacturer		Do not reuse
	Authorized Representative				

VivaChek Laboratories, Inc.

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