SARS-CoV-2 IgM-IgG combined rapid test kit user manual

Manual version: V1.4

Product name:

nCoV-K003: SARS-CoV-2 IgM-IgG combined rapid test kit

Quantity: 20 tests.

Usage:

This kit is used to qualitatively detect IgG and IgM antibodies of the novel coronavirus in human serum, plasma or whole blood in vitro.

Structure of the cassette:

(1) Sample well

(2) Nitrocellulose membrane

(3) PVC cassette

(4) Control line

(5) IgG line

(6) IgM line

Test Principle:

This Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 is designed based on lateral flow immune-chromatography method.

Each cassette contains:

(1) Sample well: sample pad, to absorb liquid sample.

(2) Conjugation pad: contains colloidal gold-labeled SARS-CoV-2 antigen together with colloidal gold-labeled control antibody.

(3) Nitrocellulose membrane (NC membrane).

IgM-IgG combined test cassette: M line is coated with mouse anti-human IgM monoclonal antibody, G line is coated with mouse anti-human IgG monoclonal antibody and C line is coated with control antibody.

SARS-CoV-2 IgM-IgG:

After the sample is loaded into the sample pad (sample well) on the cassette, it will move forward automatically along the arrow direction (capillary action). If the sample contains SARS-CoV-2 induced human IgM and/or IgG, the antibody(ies) will bind to the colloidal gold-labeled SARS-CoV-2 antigen. The IgM-SARS-CoV2-gold and/or IgG-SARS-CoV2-gold complex(es) will be captured at M line or G line, respectively. Then a red (or purple) line will appear at M and/or G line. It indicate that the sample contains SARS-CoV-2 induced human IgM and/or IgG antibody.

In any situation that C line failed to appear, the test is considered failed and the sample shall be tested with a new cassette. The used cassette shall never be reused.
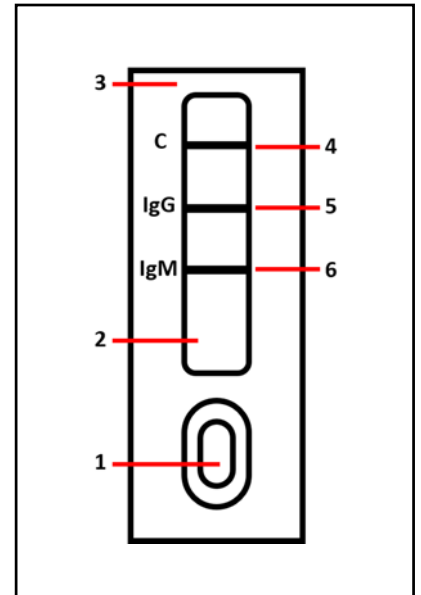
Package content: 20 cassettes, sample dilution buffer, user manual.

Notice: In any situation that the "dilution buffer" is not available, you may use PBS (pH=7.2) instead.

Storage: The unopened kit is stable at room temperature for 6 months and 4°C - 8°C for 12 months.

Samples requirements:

1. Serum. EDTA, heparin or sodium citrate treated plasma or whole blood.

2. Sample shall be mixed gently for 5 – 10 times before testing.

3. The sample shall be tested immediately after taken. If the sample can not be tested immediately, please keep the sample between 2°C - 8°C for up to 48h, or -20°C for up to 3 months. Please test in small quantity before working with large amount of sample.

4. Hemolyzed sample may interfere the test result. Sample from hyperlipaemia source may cause fake result. Please test before running real sample.

Operation protocol:

1. If the test cassette is stored in fridge, please take out of fridge and keep it stay in room temperature for at least 30min.
2. Open the aluminum foil bag and put the test cassette on the table horizontally.
3. Add 10µL sample into the sample pad (sample well) then add 60µL sample dilution buffer immediately.
4. Leave it on the table for 15min, then see the result and record it.

Result analysis:

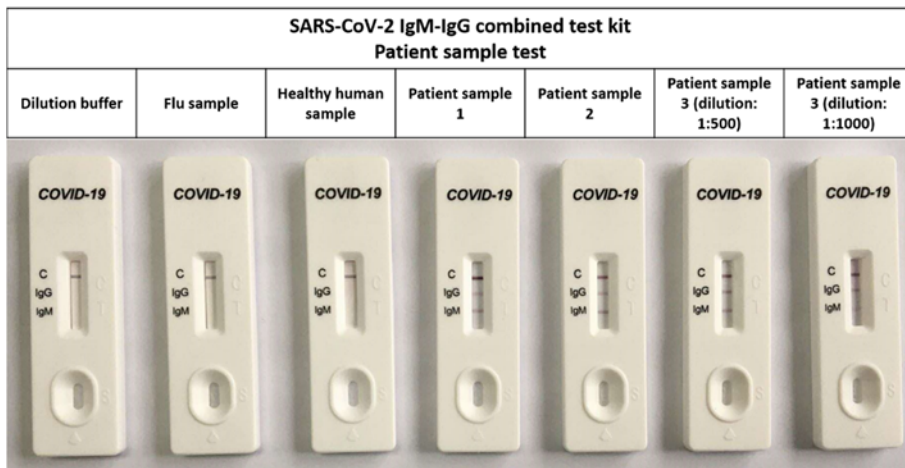|	M line	G line	C line	Result
SARS-CoV-2 IgM-IgG combined test cassette	+	+	+	Sample contains SARS-CoV-2 induced IgM and IgG.
	-	+	+	Sample contains SARS-CoV-2 induced IgG, but does NOT contain SARS-COV-2 induced IgM.
	+	-	+	Sample does NOT contain SARS-CoV-2 induced IgG, but contains SARS-CoV-2 induced IgM.
	-	-	+	Sample does NOT contain both SARS-CoV-2 induced IgG and IgM.
	+ or -	+ or -	-	Failed.

Kit performance:

Negative samples: 68 healthy human samples are tested by the kit. 100% are tested negative.

Positive samples: 46 samples from clinical diagnosed patients. 10 patients have been infected 4 – 10 days, and 36 patients have been infected for 11 – 24 days.

Amount of samples	Days post infection	IgM positive	IgG positive	Total positive
10 samples	4 - 10	7 (70%)	2 (20%)	7 (70%)
38 samples	11 - 24	34 (94.4%)	36 (100%)	36 (100%)

Test result 1

Test result 2