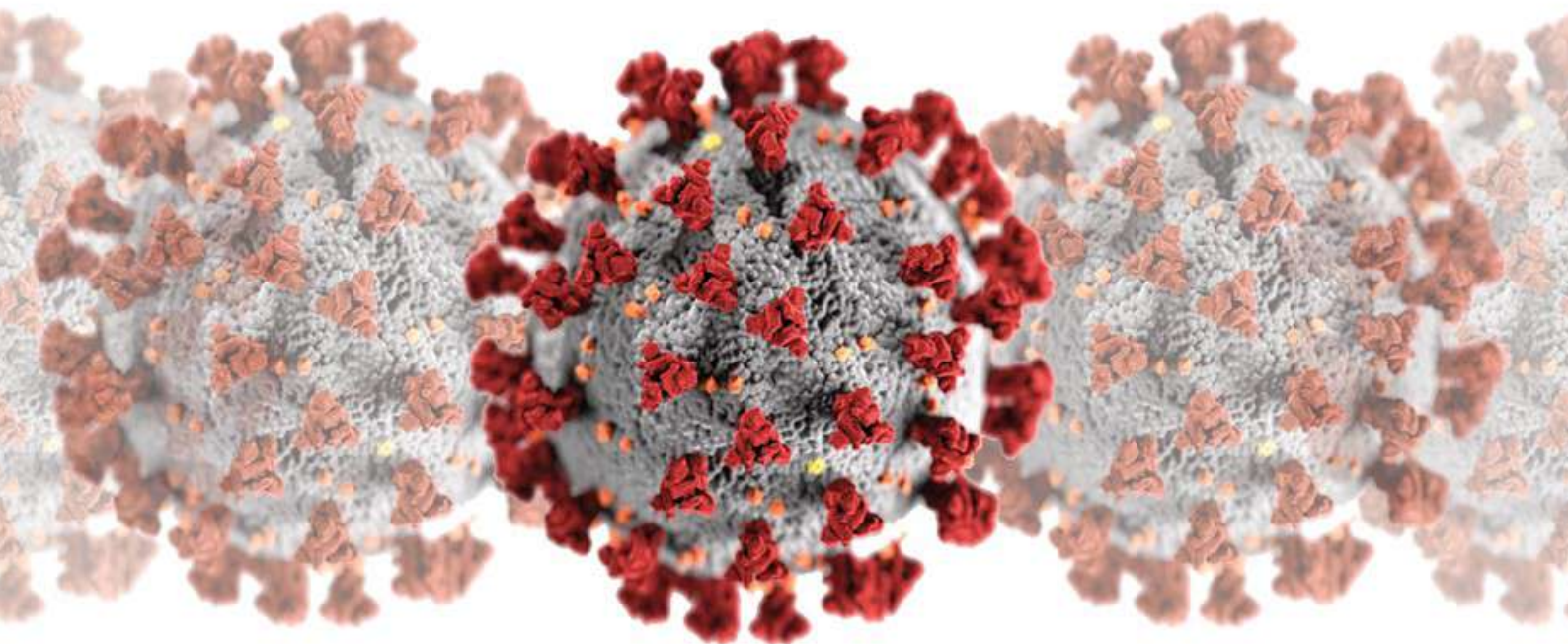


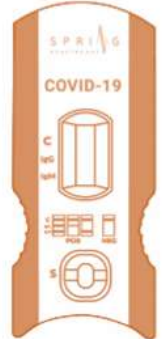
THE NEW COVID - 19 RAPID TEST KIT



THE NEW COVID - 19 RAPID TEST

WHAT IS COVID - 19 RAPID TEST?

COVID – 19 IgG/IgM Rapid test is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma specimen with only 10 minutes assay time. The combination use of IgG and IgM test can detect virus infection and immune status of the body effectively.



BENEFITS OF COVID - 19 RAPID TEST

- High accuracy with more than 92.9%
- Fast Results with 10 minutes Assay time
- Simple operation without any equipment
- CE-IVD Certified
- ISO 13485:2016



TYPE OF PRODUCTS AVAILABLE

- Rapid test whole blood specimen
- Single use kit with fingerstick whole blood specimen

Cat. #	Product	Format	Specimen	Status
BNCP 402	Rapid Test	Cassette	W/S/p	CE
BNCP 402	RT Single use	Cassette	Fingerstick WB	CE

ORDER CONDITIONS

- Minimum order quantity is 100,000 units
- Delivery in 14 days
- 50% Payment in advance, balance with AWB #

HOW TO ORDER

- Order placements : info@aitkenspencer.com
- For more information : +351 910 492 092





COVID-19 IgK/IgM Rapid Test

For Reliable Coronavirus Disease 2019 (COVID-19) Diagnosis

- * The novel coronavirus pneumonia (NCP), or "COVID-19" (Corona Virus Disease), was discovered from the 2019 Wuhan Viral Pneumonia case in China and was named by the World Health Organization on January 12, 2020.
- * COVID-19 is caused by 2019 novel coronavirus (COVID-19), mainly transmitted through respiratory droplets.
- * On January 30, 2020, WHO released the new coronavirus infection pneumonia epidemic as a public health emergency of international concern.
- * Currently, the COVID-19 is occurring in many parts of the world, especially in China, which has the largest population in the world.

COVID-19 IgK/IgM Rapid Test Offers:

- ✓ High Accuracy with more than 92.9%
- ✓ Fast Results with 10 minutes Assay Time
- ✓ Simple Operation without Equipment Required

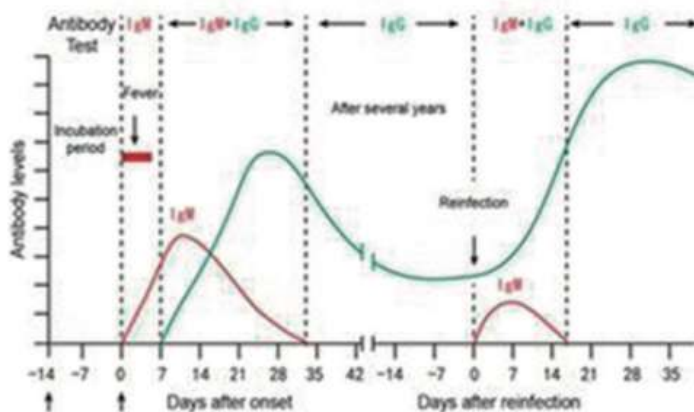
Single use kit with fingerstick whole blood specimen is also available!



COVID-19 IgK/IgM Rapid Test

For Reliable Coronavirus Disease 2019 (COVID-19) Diagnosis

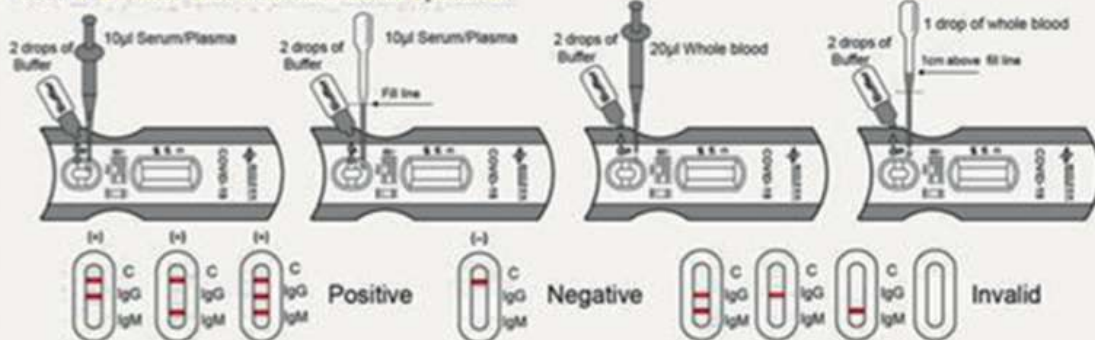
- * COVID-19 IgK/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of IgK and IgM antibodies to COVID-19 in human whole blood, serum or plasma specimen with only 10 minutes assay time
- * The combination use of IgM and IgK test can reflect virus infection and the immune status of the body effectively.



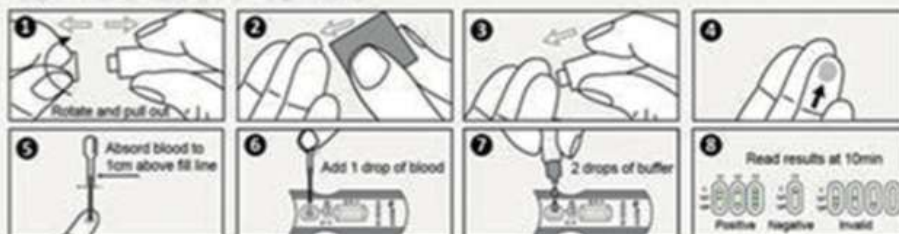
Applications:

- ✓ Doctors / Nursing Homes / Polyclinics engaged in infectious Disease or Respiratory Department.
- ✓ Labs getting prescription from such doctors / hospitals / Nursing Homes.
- ✓ Specially designed COVID-19 epidemic centric hospitals in China or other countries.
- ✓ Emergency Department.

Test with Whole Blood/Serum/Plasma Specimen



Test with Fingertick Whole Blood Specimen



Ordering Information:

Cat. No.	Product:	Format:	Specimen:	Pack:	Status:
BNCP-402	COVID-19 IgK/IgM Rapid Test	Cassette	WB/S/p	30T	CE
BNCP-402	COVID-19 IgK/IgM Rapid Test(Single Use Kit)	Cassette	Fingertick Whole Blood	20T	CE



Clinical Study Report of 2019-nCoV IgG/IgM Rapid Test Cassette

Ref.: BNCP-402/BNCP-402S

	Name	Department	Date
Prepared by	Tomy Panga	R&D	2020.02.13
Reviewed by	Kael Chan	R&D	2020.02.13

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1. Purpose

Do clinical studies of 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) with the 2019-nCoV positive specimen and negative specimen which confirmed with PCR method.

2. Materials

- 2019-nCoV Rapid Test Cassette Lot: COV20020001-R
- 2019-nCoV Rapid Test Cassette single use kit Lot: COV20020002-R
- 20 2019-nCoV clinical positive specimen
- 50 2019-nCoV clinical negative specimen

3. Operation Method

- 3.1. Place the cassette on a clean and level surface. Hold the dropper vertically, transfer 10µL serum, plasma specimen or 20µL whole blood specimen to the sample well(S). Then add 2 drops of buffer (approximately 80 L) and start the timer.
- 3.2. Read the results at 10 minutes, do not interpret the results after 20 minutes.

4. Test Results

Table- Test Results of BNCP-402

No.	Gender	Age	Result		
			AllTest Kit		PCR Results
			IgG	IgM	
1	Female	45	+	+	+
2	Female	34	+	+	+
3	Male	31	+	+	+
4	Male	36	+	+	+
5	Female	55	+	+	+
6	Female	63	+	+	+
7	Female	38	+	+	+
8	Male	74	+	+	+
9	Male	74	+	-	+
10	Male	51	+	+	+
11	Male	83	+	-	+
12	Female	65	+	+	+
13	Female	59	+	+	+
14	Female	48	+	+	+
15	Male	36	+	+	+
16	Female	81	+	-	+
17	Male	85	+	+	+
18	Male	39	+	+	+
19	Female	84	+	+	+
20	Male	91	+	+	+

21	Male	39	-	-	-
22	Female	80	-	-	-
23	Female	96	-	-	-
24	Male	85	-	-	-
25	Female	77	-	-	-
26	Female	71	-	-	-
27	Male	51	-	-	-
28	Female	73	-	+	-
29	Male	74	-	-	-
30	Female	26	-	-	-
31	Female	60	-	-	-
32	Male	67	-	-	-
33	Male	38	-	-	-
34	Male	82	-	-	-
35	Female	63	-	-	-
36	Male	90	-	-	-
37	Female	69	-	-	-
38	Male	56	-	-	-
39	Male	68	+	-	-
40	Male	59	-	-	-
41	Female	66	-	-	-
42	Female	17	-	-	-
43	Female	85	-	-	-
44	Male	31	-	-	-
45	Female	68	-	-	-
46	Male	59	-	-	-
47	Female	71	-	-	-
48	Male	36	-	-	-
49	Male	39	-	+	-
50	Male	82	-	-	-
51	Female	49	-	-	-
52	Male	62	-	-	-
53	Male	71	-	-	-
54	Female	38	-	-	-
55	Male	82	-	-	-
56	Female	63	-	-	-
57	Male	74	-	-	-
58	Male	69	-	-	-
59	Male	56	-	-	-
60	Female	68	-	-	-
61	Male	59	-	-	-
62	Female	46	-	-	-
63	Female	17	-	-	-

64	Male	85	-	-	-
65	Female	31	-	-	-
66	Male	68	-	-	-
67	Male	52	-	-	-
68	Female	81	-	-	-
69	Male	66	-	-	-
70	Female	27	-	-	-

Note: "+" mean positive result, "-" mean negative result

Table- Test Results of BNCP-402S

No.	Gender	Age	Result		
			AllTest Kit		PCR Results
			IgG	IgM	
1	Female	45	+	+	+
2	Female	34	+	+	+
3	Male	31	+	+	+
4	Male	36	+	+	+
5	Female	55	+	+	+
6	Female	63	+	+	+
7	Female	38	+	+	+
8	Male	74	+	+	+
9	Male	74	+	-	+
10	Male	51	+	+	+
11	Male	83	+	-	+
12	Female	65	+	+	+
13	Female	59	+	+	+
14	Female	48	+	+	+
15	Male	36	+	+	+
16	Female	81	+	-	+
17	Male	85	+	+	+
18	Male	39	+	+	+
19	Female	84	+	+	+
20	Male	91	+	+	+
21	Male	39	-	-	-
22	Female	80	-	-	-
23	Female	96	-	-	-
24	Male	85	-	-	-
25	Female	77	-	-	-
26	Female	71	-	-	-
27	Male	51	-	-	-
28	Female	73	-	+	-
29	Male	74	-	-	-
30	Female	26	-	-	-

31	Female	60	-	-	-
32	Male	67	-	-	-
33	Male	38	-	-	-
34	Male	82	-	-	-
35	Female	63	-	-	-
36	Male	90	-	-	-
37	Female	69	-	-	-
38	Male	56	-	-	-
39	Male	68	+	-	-
40	Male	59	-	-	-
41	Female	66	-	-	-
42	Female	17	-	-	-
43	Female	85	-	-	-
44	Male	31	-	-	-
45	Female	68	-	-	-
46	Male	59	-	-	-
47	Female	71	-	-	-
48	Male	36	-	-	-
49	Male	39	-	+	-
50	Male	82	-	-	-
51	Female	49	-	-	-
52	Male	62	-	-	-
53	Male	71	-	-	-
54	Female	38	-	-	-
55	Male	82	-	-	-
56	Female	63	-	-	-
57	Male	74	-	-	-
58	Male	69	-	-	-
59	Male	56	-	-	-
60	Female	68	-	-	-
61	Male	59	-	-	-
62	Female	46	-	-	-
63	Female	17	-	-	-
64	Male	85	-	-	-
65	Female	31	-	-	-
66	Male	68	-	-	-
67	Male	52	-	-	-
68	Female	81	-	-	-
69	Male	66	-	-	-
70	Female	27	-	-	-

Note: "+" mean positive result, "-" mean negative result

5. Result Analysis

Table: Clinical study result of BNCP-402

IgG Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test Cassette (WB/S/P)	Results	Positive	Negative	
	Positive	20	1	21
	Negative	0	49	49
Total Results		20	50	70

Relative Sensitivity: >99.9% (95%CI*: 86%-100%)

Relative Specificity: 98.0% (95%CI*: 89.4%-99.9%)

Accuracy: 98.6% (95%CI*: 92.3%-99.96%)

*Confidence Intervals

IgM Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test Cassette (WB/S/P)	Results	Positive	Negative	
	Positive	17	2	19
	Negative	3	48	51
Total Results		20	50	70

Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%)

Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)

Accuracy: 92.9% (95%CI*: 84.1%-97.6%)

*Confidence Intervals

Table: Clinical study result of BNCP-402S

IgG Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick Whole Blood)	Results	Positive	Negative	
	Positive	20	1	21
	Negative	0	49	49
Total Results		20	50	70

Relative Sensitivity: >99.9% (95%CI*: 86%-100%)

Relative Specificity: 98.0% (95%CI*: 89.4%-99.9%)

Accuracy: 98.6% (95%CI*: 92.3%-99.96%)

*Confidence Intervals

IgM Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick Whole Blood)	Results	Positive	Negative	
	Positive	17	2	19
	Negative	3	48	51
Total Results		20	50	70

Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%)

Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)

Accuracy: 92.9% (95%CI*: 84.1%-97.6%)

*Confidence Intervals

6. Conclusion

The relative sensitivity of 2019-nCoV IgG/IgM Rapid Test Cassette (BNCP-402 and BNCP-402S) was more than 99.9% for IgG and 85.0% for IgM, the relative specificity was 98.0% for IgG and 96.0% for IgM compare with PCR result.