1. Diagnostic specificity and Diagnostic Sensitivity

1.1 Summary:

The diagnostic specificity indicates the probability that the test gives a negative result in the absence of the target analyte. True negative indicates a specimen known to be negative for the target analyte and correctly classified by the test. False positive indicates a specimen kn own to be negative for the target analyte and misclassified by the test.

The diagnostic sensitivity indicates the probability that the test gives a positive result in the presence of the target analyte. True positive indicates a specimen known to be positive for t he target marker and correctly classified by the test. False negative indicates a specimen kno wn to be positive for the target marker and misclassified by the test.

102 COVID-19 positive specimens and 500 COVID-19 negative specimens confirmed by PCR and clinical Symptoms were used in clinical study. Commercial PCR served as the reference method for the GA CoV-2 Antigen Rapid Test (Nasopharyngeal Swab). The result shows the GA CoV-2 Antigen Rapid Test has a high restive sensitivity and high relative specificity when tested with the 204 specimens.

1.2 Background:

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus in 2019 causes coronavirus diseaseCOVID-19.[1] The new coronavirus is called 2019-nCoV or SARS-COV-2. Due to the rapid spread of SARS-CoV-2, COVID-19 is now a pandemic affecting many countries globally. As of May 24th, there were 5.2 million confirmed cases worldwide and 337 000 reported deaths [2]. The clinical presentation of infection include respiratory symptoms, fever, and cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.[3]

1.3 Objective:

Do clinical studies of GA CoV-2 Antigen Rapid Test (Nasopharyngeal Swab) with the COVID-19 positive specimens and negative specimens which confirmed with PCR method.

1.4Operation Method:

1. GA CoV-2 Antigen Rapid Test can be applied to nasopharyngeal swab.
2. Do not return the nasopharyngeal swab to the original paper packaging.
3. For best performance, direct nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and

avoid possible contamination, it is highly recommended the nasopharyngeal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15℃-30℃) for up to 1 hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose the sample. A new sample must be collected for testing.

4. If specimens are to be transported, they should be packed in compliance with local regulations covering the transportation of etiological agents.
5. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
6. Open the cap of the extraction tube, put the nasopharyngeal swab with the sample into the extraction tube and rotate it 10 times, squeeze the wall of the extraction tube by hand and take out the swab, cover the cap of the extraction tube, set aside.
7. Take the test cassette from the packaging bag, place it on a table, and add 2 drops of the sample into the sample hole vertically.
8. Read the result after 15 minutes. If left unread for 20 minutes or more the results are invalid and a repeat test is recommended.

1.5 Statistical analysis Method of test result:

This test adopt statistical analysis on pair enumeration data, and will record analysis in the form of fourfold table, see below:

Table 1: fourford table for evaluting diagnostic test

		Comparison Test		
		positive	negative	
Test	positive	a	b	Y1
	negative	c	d	Y2
Total		C1	C2	N

Positive conformity rate = $\frac{a}{(a+c)} * 100\%$

Negative conformity rate = $\frac{d}{(b+d)} * 100\%$

Total conformity rate = $\frac{(a+d)}{(a+b+c+d)} * 100\%$

1.6 The results:

Positive results:

NO.	Days after symptom onset	RT-PCR		GA CoV-2 Antigen Rapid Test
		Ct	Result	
1	10	35	+	+
2	2	23	+	+
3	7	33	+	+
4	9	28	+	+
5	11	37	+	+
6	14	36	+	+
7	15	35	+	+
8	16	36	+	+
9	15	39	+	+
10	16	37	+	+
11	13	37	+	+
12	15	35	+	+
13	16	36	+	+
14	9	38	+	-
15	7	31	+	+
16	8	28	+	+
17	14	39	+	+
18	15	38	+	+
19	17	35	+	+
20	16	39	+	+
21	10	36	+	+
22	13	34	+	+
23	15	37	+	+
24	16	38	+	+
25	9	28	+	+
26	14	35	+	+
27	17	39	+	+
28	15	36	+	+
29	11	33	+	+
30	8	35	+	+
31	2	24	+	+
32	3	24	+	+
33	11	30	+	+
34	5	39	+	-
35	4	23	+	+
36	6	25	+	+
37	13	36	+	+
38	7	24	+	+
39	9	39	+	+

40	4	27	+	+
41	1	35	+	-
42	2	21	+	+
43	3	25	+	+
44	2	23	+	+
45	5	24	+	+
46	6	28	+	+
47	13	35	+	+
48	6	27	+	+
49	3	18	+	+
50	10	37	+	+
51	5	25	+	+
52	4	24	+	+
53	2	18	+	+
54	9	35	+	+
55	5	26	+	+
56	11	37	+	+
57	2	23	+	+
58	6	26	+	+
59	13	29	+	+
60	12	30	+	+
61	7	29	+	+
62	11	31	+	+
63	9	35	+	+
64	5	27	+	+
65	6	34	+	+
66	4	23	+	+
67	7	30	+	+
68	10	35	+	+
69	4	30	+	+
70	5	29	+	+
71	7	29	+	+
72	5	25	+	+
73	6	24	+	+
74	4	25	+	+
75	4	22	+	+
76	5	28	+	+
77	3	23	+	+
78	2	23	+	+
79	1	23	+	+
80	7	32	+	+
81	6	28	+	+
82	5	30	+	+
83	2	21	+	+
84	3	19	+	+

85	3	25	+	+
86	5	22	+	+
87	6	28	+	+
88	4	25	+	+
89	7	31	+	+
90	6	23	+	+
91	1	25	+	+
92	5	28	+	+
93	3	24	+	+
94	2	25	+	+
95	5	32	+	+
96	6	27	+	+
97	7	29	+	+
98	5	24	+	+
99	4	27	+	+
100	7	26	+	+
101	6	25	+	+
102	3	21	+	+

Negative results:

NO.	RT-PCR	GA CoV-2 Antigen Rapid Test
1	-	-
2	-	-
3	-	-
4	-	-
5	-	-
6	-	-
7	-	-
8	-	-
9	-	-
10	-	-
11	-	-
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1.7 The results:

GA CoV-2 Antigen Rapid Test		Comparison Test (RT-PCR)		Total
		positive	negative	
Covid-19 Antigen	positive	99	4	103
	negative	3	496	123
Total		102	500	602
Relative Sensitivity		97,1 % (95%CI*: 91,6 %~99.4%)		
Relative Specificity		99,2% (95%CI*: 98 %~99.8%)		
Accuracy		98.8 % (95%CI*: 97,6%~99.5%)		

1.8 GA CoV-2 Antigen Rapid Test Positive Results by time from symptom onset:

Days post symptom onset	Number of samples	PCR positive	GA CoV-2 Antigen Rapid Test
≤3	20	20	19/20=95.0%
4~7	43	43	42/43=97.7%
8~14	25	25	24/25=96.0%
> 14	14	14	14/14=100.0%
Total	102	102	99/102=97.1% 95% CI: (91.64%∽99.39%)

The performance of GA CoV-2 Antigen Rapid Test with positive results stratified by the comparator method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, estimating the viral titer present in the clinical sample. As presented in the table below, the positive agreement of the GA CoV-2 Antigen Rapid Test is higher with samples of a Ct count <35.

GA CoV-2 Antigen Rapid Test performance against the Comparator Method – by Cycle Threshold Counts.

GA CoV-2 Antigen Rapid Test	RT-PCR(Positive by Ct Category)	
	Positive(Ct < 35)	Positive(Ct≥35)
Positive	70	29
Negative	0	3
Total	70	32
Positive Agreement (95% CI)	100.0%(94.87%∽100.00%)	90.6%(74.98%∽98.02%)

1.9 Conclusion:

The overall clinical performance of the GA CoV-2 Antigen Rapid Test was comparable with the data obtained in the Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR assay and supports the use of the GA Generic Assays GmbH assay in the detection of SARS-CoV-2.

1. Limit of Detection

Study objective:

A recombine COVID-19 protein was diluted with dilution to a low concentration to determine detection level. The assays were performed according to the package insert.

Method:

Recombinant SARS-COV-2 N protein was diluted in assay sample buffer at concentrations of 100ng/mL, 10ng/mL, 1ng/mL, 500pg/mL, 200pg/mL, 100pg/mL, and 50pg/mL. The resultant dilutions were tested in replicates of 20 in the GA CoV-2 Antigen Rapid Test. LOD was estimated from the lowest dilution that gave a positive result in the assay.

Materials:

GA CoV-2 Antigen Rapid Test
Lot 1: 21 3985 01/1
Lot 2: 21 3985 02/1
Lot 3: 21 3985 03/1

Results:

The results were read in 15 minutes for all the dilutions prepared.

The results are as follows and a 20/20 indicates that all 20 samples were positive whist a 0/20 indicates that no positivity was detected

The results are presented in the Tables below:

	21 3985 01/1			21 3985 02/1			21 3985 03/1		
Time	15			15			15		
Repeat	1	2	3	1	2	3	1	2	3
100ng/mL	+	+	+	+	+	+	+	+	+
10ng/mL	+	+	+	+	+	+	+	+	+
1ng/mL	+	+	+	+	+	+	+	+	+
500pg/mL	+	+	+	19/20	+	+	+	19/20	+
200pg/mL	+	+	+	19/20	+	+	+	19/20	+
100pg/mL	19/20	+	+	19/20	+	+	+	19/20	+
50pg/mL	6/20	7/20	7/20	11/20	8/20	9/20	10/20	8/20	8/20
Dilution	−	−	−	−	−	−	−	−	−

"+" mean, the 20 Samples are with positive result, "-" mean, the 20 Samples are with negative result.

Conclusion:

From the above it was concluded that the limit of detection (LOD) of GA CoV-2 Antigen Rapid Test is 100pg/mL recombinant SARS-COV-2 N protein.

2. Positive coincidence rate

Use GA CoV-2 Antigen Rapid Test product to detect the positive L and H quality control products as the evaluation sample, and each batch of reagents is tested in replicates of 3, and the results are required to be positive.

Materials:

GA CoV-2 Antigen Rapid Test
Lot 1: 21 3985 01/1
Lot 2: 21 3985 02/1
Lot 3: 21 3985 03/1

Results：

The results are presented in the Tables below:

Positiv control	Lot 1			Lot 2			Lot 3		
	1	2	3	1	2	3	1	2	3
L	+	+	+	+	+	+	+	+	+
H	+	+	+	+	+	+	+	+	+

Conclusion:

From the above it was concluded that all levels of the recombinant GA CoV-2 Antigen Rapid Test were correctly detected, and the positive compliance rate meets the acceptable criteria.

3. Negative coincidence rate

The negative coincidence rate was calculated by testing 9 samples (N1-N9) in duplicate from healthy individuals in 3 lots of the GA CoV-2 Antigen Rapid.

Materials:

GA CoV-2 Antigen Rapid Test
Lot 1: 21 3985 01/1
Lot 2: 21 3985 02/1
Lot 3: 21 3985 03/1

Results:

The results are presented in the Tables below:

Negative sample	Lot 1	Lot 2	Lot 3
	15 Min.		
N1	-	-	-
N2	-	-	-
N3	-	-	-
N4	-	-	-
N5	-	-	-
N6	-	-	-
N7	-	-	-
N8	-	-	-
N9	-	-	-

Conclusion:

From the above it was concluded that all negative samples were correctly identified in three kit lots, and the negative compliance rate meets the acceptable criteria.

6. Cross-reactivity and Interference test

Study objective:

The objective of this study was to evaluate possible cross reactivity with other pathogens and the effect of potentially interfering substances found in the sample.

Cross-reactivity:

Materials:

GA CoV-2 Antigen Rapid Test
Lot 1: 21 3985 01/1
Lot 2: 21 3985 02/1
Lot 3: 21 3985 03/1

Method:

Cross reactivity and potential interference of the GA CoV-2 Antigen Rapid Test was evaluated by testing 21 pathogenic microorganisms that may be present in the clinical specimen and could potentially cross-react with the assay

HCoV-229E	HCoV-OC43	HCoV-NL63	MERS-CoV
HCoV-HKU1	Human RSV	Human Enterovirus	Human Rhinovirus
Human Metapneumovirus	Mycoplasma pneumoniae	Parainfluenza virus	Adenovirus
Influenza B virus (Victoria line)	H1N1 (2009) influenza virus	Influenza A H3N2 virus	Avian influenza virus H7N9
Influenza B virus (Yamagata series)	Seasonal Influenza A H1N1	Neisseria meningitidis	Streptococcus pneumoniae
Staphylococcus aureus			

Results:

The results are presented in the Tables below:

Cross-reactive substances	Lot 1	Lot 2	Lot 3
	15 Min		
HCoV-229E	-	-	-
HCoV-OC43	-	-	-
HCoV-NL63	-	-	-
MERS-CoV	-	-	-
HCoV-HKU1	-	-	-
Human RSV	-	-	-
Human Enterovirus	-	-	-
Human Rhinovirus	-	-	-
Human Metapneumovirus	-	-	-
Mycoplasma pneumoniae	-	-	-
Parainfluenza type 2	-	-	-
Adenovirus type 3	-	-	-
Influenza B virus (Victoria line)	-	-	-
H1N1 (2009) influenza virus	-	-	-
Influenza A H3N2 virus	-	-	-
Avian influenza virus H7N9	-	-	-
Influenza B virus (Yamagata series)	-	-	-
Seasonal Influenza A H1N1	-	-	-
Neisseria meningitidis	-	-	-
Streptococcus pneumoniae	-	-	-
Staphylococcus aureus	-	-	-

Conclusion:

The results show that no cross-reactivity with other viruses.

Interference test

The interference study was performed to identify the effect of potentially interfering substances found in the sample.

Materials:

GA CoV-2 Antigen Rapid Test
Lot 1: 21 3985 01/1
Lot 2: 21 3985 02/1
Lot 3: 21 3985 03/1

Method:

Recombinant SARS-COV-2 N protein positive and negative controls with the following interference substances:

substance	concentration
Aspirin	30ug/dL
Ascorbic Acid	20mg/dL
Ibuprofen	200ug/dL
Bilirubin	60mg/dL
Chloramphenicol	3ug/dL

Results:

The results are presented in the Tables below:

Lot	Lot 1						Lot2						Lot 3					
Substance ↓	15 Min																	
	Negative			Positive			Negative			Negative			Negative			Negative		
Aspirin	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Ibuprofen	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Chloramphenicol	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+

Conclusion:

The results show that at the concentrations used the interfering substances studied had no impact on the performance of the the GA CoV-2 Antigen Rapid Test.

7. Intra assay

Intra assay precision was tested using a negative (N1), a low (L) and a high (H) QC control sample made from recombinant SARS-COV-2 N protein in the GA CoV-2 Antigen Rapid Test. Testing in replicates of 10 was performed across 3 lots over three separate days by three different operators.

Materials:

GA CoV-2 Antigen Rapid Test
Lot 1: 21 3985 01/1
Lot 2: 21 3985 02/1
Lot 3: 21 3985 03/1

Results:

The results are presented in the Tables below:

Day1 Operator 1

No.	Lot 1			Lot 2			Lot 3		
	N1	L	H	N1	L	H	N1	L	H
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+

Day3 Operator 2

No.	Lot 1			Lot 2			Lot 3		
	N1	L	H	N1	L	H	N1	L	H
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+

Day5 Operator 3

No.	Lot 1			Lot 2			Lot 3		
	N1	L	H	N1	L	H	N1	L	H
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+

Conclusion:

The results show that the intrassay precison in the 3 lots of kits tested was aceptable and no unexplained results were observed.

8. Inter assay

Materials:

GA CoV-2 Antigen Rapid Test
Lot 1: 21 3985 01/1
Lot 2: 21 3985 02/1
Lot 3: 21 3985 03/1

Results:

The results are presented in the Tables below:

No.	N1			L			H		
	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3
1	-	-	-	+	+	+	+	+	+
2	-	-	-	+	+	+	+	+	+
3	-	-	-	+	+	+	+	+	+
4	-	-	-	+	+	+	+	+	+
5	-	-	-	+	+	+	+	+	+
6	-	-	-	+	+	+	+	+	+
7	-	-	-	+	+	+	+	+	+
8	-	-	-	+	+	+	+	+	+
9	-	-	-	+	+	+	+	+	+
10	-	-	-	+	+	+	+	+	+

Conclusion:

The results show that the inter assay precison in the 3 lots of kits tested was aceptable and no unexplained results were observed.