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:

The 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 Nasal. LOD was estimated from the lowest dilution that gave a positive result in the assay.

Materials:

GA CoV-2 Antigen Rapid Nasal
Lot 1: 21 3987 01/1
Lot 2: 21 3987 02/1
Lot 3: 21 3987 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:

	GCOVGDEV001			GCOVGDEV002			GCOVGDEV003		
Repeat Times	1	2	3	1	2	3	1	2	3
100ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
10ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
1ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
500pg/mL	20/20	20/20	20/20	19/20	20/20	20/20	20/20	19/20	20/20
200pg/mL	20/20	20/20	20/20	19/20	20/20	20/20	20/20	19/20	20/20
100pg/mL	19/20	20/20	20/20	19/20	20/20	20/20	20/20	19/20	20/20
50pg/mL	6/20	7/20	7/20	11/20	8/20	9/20	10/20	8/20	8/20
Dilution	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20

"+" 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 Nasal is 100pg/mL recombinant SARS-COV-2 N protein.

2. Positive coincidence rate

Use GA CoV-2 Antigen Rapid Nasal 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 Nasal
Lot 1: 21 3987 01/1
Lot 2: 21 3987 02/1
Lot 3: 21 398703/1

Results：

As per the standard assay protocol, the results were read after 15 minutes.

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	+	+	+	+	+	+	+	+	+

("+" indicates a positive result, "-" indicates a negative result)

Conclusion:

From the above it was concluded that all levels of the recombinant GA CoV-2 Antigen Rapid Nasal 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 Nasal.

Materials:

GA CoV-2 Antigen Rapid Nasal
Lot 1: 21 3987 01/1
Lot 2: 21 3987 02/1
Lot 3: 21 398703/1

Results:

As per the standard assay protocol, the results were read after 15 minutes.

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	-	-	-

("+" indicates a positive result, "-" indicates a negative result)

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.

4. 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 Nasal
Lot 1: 21 3987 01/1
Lot 2: 21 3987 02/1
Lot 3: 21 3987 03/1

Method:

Cross reactivity and potential interference of the GA CoV-2 Antigen Rapid Nasal 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:

As per the standard assay protocol the results were read in 15 minutes and the results were as follows

Cross-reactive substances	Lot 1	Lot 2	Lot 3
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	-	-	-

("+" indicates a positive result, "-" indicates a negative result)

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 Nasal
Lot 1: 21 3987 01/1
Lot 2: 21 3987 02/1
Lot 3: 21 3987 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:

As per the standard assay protocol, the results were read in 15 minutes. The results are as follows:

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

("+" indicates a positive result, "-" indicates a negative result)

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 Nasal.

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 Nasal. Testing in replicates of 10 was performed across 3 lots over three separate days by three different operators.

Materials:

GA CoV-2 Antigen Rapid Nasal
Lot 1: 21 3987 01/1
Lot 2: 21 3987 02/1
Lot 3: 21 3987 03/1

Results:

As per the standard operating protocol the results were read after in 15 minutes. The results are as follows

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	-	+	+	-	+	+	-	+	+

("+" indicates a positive result, "-" indicates a negative result)

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	-	+	+	-	+	+	-	+	+

("+" indicates a positive result, "-" indicates a negative result)

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	-	+	+	-	+	+	-	+	+

("+" indicates a positive result, "-" indicates a negative result)

Conclusion:

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

Inter assay

Intra assay precision was tested using a negative (N1), a low (L) and a high (H) QC control sample made from recombinant COVID-19 Protein in the GA CoV-2 Antigen Rapid Nasal. Testing in replicates of 10 was performed across 3 lots by the same operator.

Materials:

GA CoV-2 Antigen Rapid Nasal

Lot 1: 21 3987 01/1

Lot 2: 21 3987 02/1

Lot 3: 21 3987 03/1

Results:

As per the standard operating protocol the results were read after in 15 minutes. The results are as follows:

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

("+" indicates a positive result, "-" indicates a negative result)

Conclusion:

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