SARS-CoV-2 Antigen Detection Kit(Colloidal Gold Method)

Clinical Trial Report

Project name: SARS-CoV-2 Antigen Detection Kit(Colloidal Gold Method) clinical Trial

Trial date: 20201215 to 20210219

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Dr. Salma Center For Kidney Diseases Laboratory

Summary

The comparison and analysis of each sample type and PCR test results of this kit are as follows:

Content		Sensitivity95%CI:	Specificity95%CI:	Accuracy 95%CI:
Nasal swab and PCR	Ct≤25	100%	100% (99.08%,100.00%)	98.37% (96.93%,99.25%)
	Ct≤30	98.44% (94.47%,97.28%)		
	Ct>30	94.12% (89.13%,99.81%)		
	total	94.12% (89.13%,99.81%)		
Throat swab and PCR	Ct≤25	100%	100% (99.08%,100.00%)	97.47%(95.79%,98.61%)
	Ct≤30	96.06%(91.05%, 98.71%)		
	Ct>30	90.85% (85.12%,94.91%)		
	total	90.85% (85.12%,94.91%)		
Saliva and PCR	Ct≤25	100%	100% (92.89%,100.00%)	96.30% (89.56%,99.23%)
	Ct≤30	95.00%(88.78%, 100.00%)		
	Ct>30	90.32% (74.25%,97.96%)		
	total	90.32% (74.25%,97.96%)		

(2) Comparative analysis of nasal swab and throat swab and saliva results

Content		Sensitivity95%CI:	Specificity95%CI:	Accuracy 95%CI:
Nasal swab and PCR	Ct≤25	100%	100% (99.08%,100.00%)	98.77% (93.31%,99.97%)
	Ct≤30	100%		
	Ct>30	96.77% (83.30%,99.92%)		
	total	96.77% (83.30%,99.92%)		
Throat swab and PCR	Ct≤25	100%	100% (99.08%,100.00%)	97.53%(91.36%,99.70%)
	Ct≤30	96.77% (83.30%,99.92%)		
	Ct>30	93.55% (78.58%,99.21%)		
	total	93.55% (78.58%,99.21%)		
Saliva and PCR	Ct≤25	100%	100%	96.30% (89.56%,99.23%)
	Ct≤30	93.55% (78.58%,99.21%)		

Content		Sensitivity95%CI:	Specificity95%CI:	Accuracy 95%CI:
	Ct>30	90.32% (74.25%,97.96%)	(92.89%,100.00%)	
	total	90.32% (74.25%,97.96%)		

Clinical trial institution and investigators

Name of the clinical trial institution	investigator	Position/Title	Task
Dr. Salma Center	Mehdi Hassan	Doctor	test
	Omer Osman	Doctor	test
	Ayman Sulehaby	Doctor	test
	Ayat Omer	Nurse	Sampling
	Sahar Ali	Nurse	Sampling

1. 2.Clinical trial purpose

The nasal swabs, pharyngeal swabs and saliva of clinical samples were detected by using this product and PCR method, and the test results were used to evaluate the clinical efficacy of the product.

2. Clinical trial management

2.1 Laboratory quality control

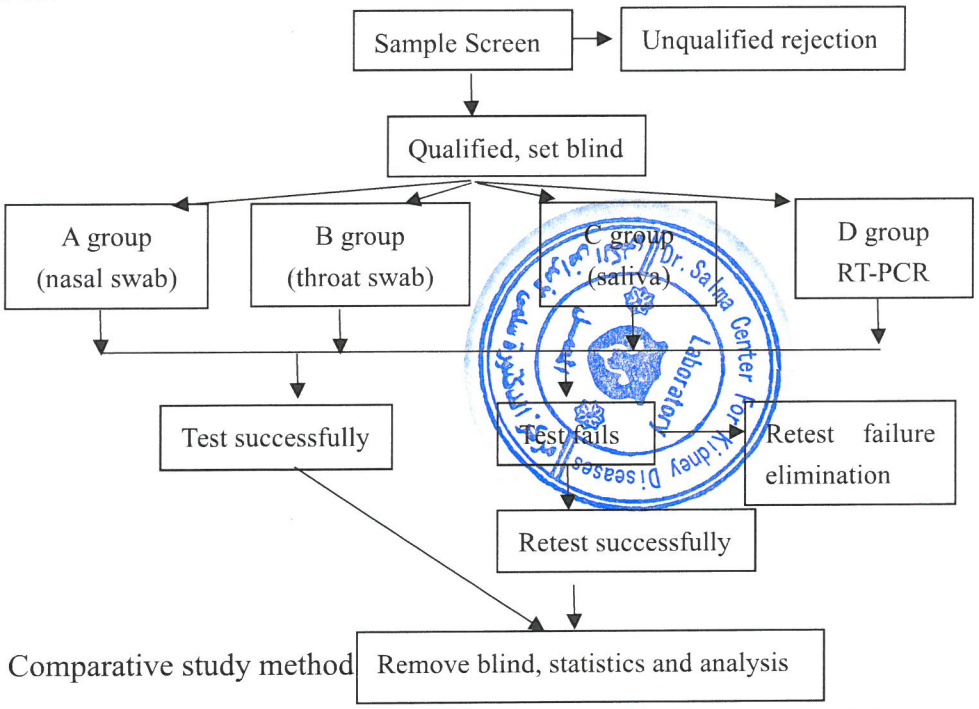
(1) Quality control of clinical test conditions and personnel:

(2) Quality control during the clinical trial:

(3) Quality control of clinical trial results:

2.2 Overall design and description of the clinical trial

In this clinical trial, blind data analysis was adopted and the novel SARS-CoV-2 Antigen Detection Kit(Colloidal Gold Method) produced by Xiamen jiqing biomedical technology Co. Ltd . was used to compare and study the detection results of the samples with the PCR method.After the end of the test, the blinding was uncovered, the cause of the inconsistencies was analyzed, and all the inconsistencies in the test should be fully analyzed in combination with the patient's epidemiological background, clinical symptoms, disease outcome and other information.The specific test process is as follows:



2.3 Comparative study method

It was compared with PCR method（Cobas SARS-COV-2(Roche Diagnostics Inc) or TaqPath™ COVID-19 CE IVD RT PCR Kit (Thermo Fisher Scientific) (with Nimbus Presto Extraction instrument).

2.4 Test sample requirements

2.4.1 The type of clinical trial sample

Sample types were: human nasal swab, throat swab, saliva.

2.4.2 Inclusion/exclusion criteria for clinical trial samples

2.4.2.1 Inclusion criteria

(1) Novel Coronavirus pneumonia suspected case (confirmed case, excluded case) was selected.

(2) No limitation on gender and age.

(3) The corresponding patient information and clinical test/diagnasalis information of the samples can be completely traced.

2.4.2.2 Exclusion criteria

(1) The time or information of sample collection is not clear;

(2) Samples with insufficient sample size: they can meet the requirements of conducting at least two tests;

(3) Samples that have not been stored in accordance with the requirements of the product instructions for evaluation of reagents, or the storage period exceeds the specified period;

(4) Samples that do not meet the testing requirements determined by the researcher.

2.4.2.3 Elimination criteria

(1) Other situations that occurred during the experiment should be eliminated after confirmation by the main researcher. Samples that cannot complete the measurement test process due to equipment or human factors (the sample is contaminated during operation and the sample size is insufficient).

(2) The measurement result does not have the detection data of the evaluation reagent.

(3) The test results of the samples come from samples that have not been stored and tested in accordance with the instructions of the evaluation reagents.

(4) The test fails or the data is abnormal, and the sample still fails or abnormal after the retest. The main researcher decided to exclude the sample.

(5)Other situations that occurred during the experiment should be eliminated after confirmation by the main researcher.

2.4.3 Number of samples

	Nasal swabs	Throat swabs	Saliva
Positive	Nasal swabs were mainly used as samples for at least 100 cases. Days 0-3（40%）; Days 4-7（40%）; Days >7(20%); Post onset of symptoms,The Ct value of the RT-PCR is evenly distributed. At least 20% of specimens should have Ct values > 30 on the comparator PCR assay.	Throat swabs were mainly used as samples for at least 100 cases. Days 0-3（40%）; Days 4-7（40%）; Days >7(20%); Post onset of symptoms,The Ct value of the RT-PCR is evenly distributed. At least 20% of specimens should have Ct values > 30 on the comparator PCR assay.	At least 30 saliva samples homologous to nasopharyngeal swabs.
egative	400 COVID-19 negative specimens (confirmed by RT-PCR), Testing should include all claimed specimen types. at least 30 Samples from influenza virus, HIV and other positive patients were enrolled.		At least 30 saliva samples homologous to nasopharyngeal swabs.

2.5 Sample testing

2.5.1 The samples were tested with clinical research kits

The samples test by refers to the instruction of "SARS-CoV-2 Antigen Detection Kit(Colloidal Gold Method)" of Xiamen jiqing biomedical technology Co. Ltd .Cobas SARS-COV-2(Roche Diagnostics Inc) or TaqPath™ COVID-19 CE IVD RT PCR Kit (Thermo Fisher Scientific) (with Nimbus Presto Extraction instrument).

2.5.2 Treatment and retaking of inconsistent results in samples during clinical trials

For samples that have failed the test or that the researcher considers necessary to be retest (such as the test value is obviously unreasonable and beyond the limit of clinical significance), retest after analyzing and explaining the reason, such as the samples that are still failed or abnormal after retest.After analyzing various reasons, the main researcher made a decision to remove or accept the sample data, and gave reasonable explanations, and finally analyzed and explained the situation in the clinical trial report.If the results are inconsistent, the patient's epidemiological background, clinical symptoms, disease outcome and other information should be fully analyzed.The conclusions of the analysis were summarized in the clinical trial report.

2.6 Statistical analysis

The nasal swabs, pharyngeal swabs and saliva test results were compared with PCR, the sensitivity, specificity and total coincidence rate were calculated, and the 95% confidence intervals were calculated respectively.

project		PCR test results		total
		+	-	
Evaluate reagent test results	+	a	b	a+b
	-	c	d	c+d
total		a+c	b+d	a+b+c+d

NOTE:a is true positive，b is false positive，c is false negative，d is true negative

（1）sensitivity=a/(a+c)*100%；

（2）specificity=d/(b+d) *100%；

（3）accuracy=（a+d）/(a+b+c+d) *100%

3. Clinical trial results and analysis

3.1 Basic data statistics

The summary table of test results is shown in Annex 1 "Summary Table of Clinical Trial Results".

3.1.1 Sample distribution statistics

The general situation is as follows:

course of disease	Number of cases
confirmed case	153
excluded case	400
total	553

3.2 Patient Demographics

Age [mean (min-max), N]	Gender [%F, (n/N)]	Positivity [%, (n/N)]	Symptoms present[%Yes, (n/N)]	Invalid rate (%, n/N)
37.7（2-71），553	49.19%(272/553)	27.76%,153/553	27.76%,153/553	0%,0/553

3.3 Statistical analysis of data

(1)Comparative analysis of nasal swab and PCR results

nasal swab	PCR test results				Total
	+			-	
	Ct≤25	Ct≤30	Ct>30		

Results of SARS-CoV-2 Antigen Detection Kit	+	52	74	18	0	144
	—	0	2	7	400	409
Total		52	76	25	400	553

Clinical Sensitivity= 94.12% 95%CI：（89.13%,99.81%）

Ct≤30 sensitivity= 98.44% 95%CI：（94.47%,97.28%），

C＞30 sensitivity= 94.12% 95%CI：（89.13%,97.28%）

specificity= 100% 95%CI：（99.08%，100.00%）

accuracy= 98.37% 95%CI：（96.93%，99.25%）

Positive results broken down by days since symptom onset.

Days Since Symptom Onset	PCR Positive (+)	Antigen Positive (+)	Positive Percent Agreement 95% Confidence interval
0	5	5	100%
1	10	10	100%
2	37	36	97.30%（85.44%，99.93%）
3	69	68	98.55%（92.19%,99.96%）
4	87	85	97.70%（91.94%，99.72%）
5	106	103	97.17%（91.95%，99.41%）
6	117	113	96.58%（91.48%，99.06%）
7	130	123	94.61%（89.22%，97.81%）
8-14	153	144	94.11%（89.13%，97.28%）

(3) Comparative analysis of throat swab and PCR results

throat swab		PCR test results + Ct≤25	Ct≤30	Ct＞30	Total
Results of SARS-CoV-2 Antigen Detection Kit	+	52	71	16	0	139
	-	0	5	9	400	414
Total		52	76	25	400	553

Clinical Sensitivity= 90.85% 95%CI：（85.12%,94.91%）

Ct≤30 sensitivity= 96.06% 95%CI：(91.05%, 98.71%),

C＞30 sensitivity= 90.85% 95%CI：（85.12%,94.91%）

specificity=100% 95%CI：（99.08%，100.00%）

accuracy= 97.47% 95%CI：（95.79%，98.61%）

Positive results broken down by days since symptom onset.

Days Since Symptom Onset	PCR Positive (+)	Antigen Positive (+)	Positive Percent Agreement 95% Confidence interval

0	5	5	100%
1	10	10	100%
2	37	35	94.59%（81.80%，99.34%）
3	69	65	94.20%（85.82%，98.40%）
4	87	83	95.40%（88.64%，98.73%）
5	106	100	94.34%（88.09%，97.89%）
6	117	108	92.30%（85.90%，96.42%）
7	130	119	91.53%（85.36%，95.70%）
8-14	153	139	90.85%（85.12%，94.91%）

(4) Comparative analysis of saliva and PCR results

saliva		PCR test results				Total
		+			-	
		Ct≤25	Ct≤30	Ct＞30		
Results of SARS-CoV-2 Antigen Detection Kit	+	10	9	9	0	28
	-	0	1	2	50	53
Total		10	10	11	50	81

Clinical Sensitivity= 90.32% 95%CI：（74.25%,97.96%）

Ct≤30 sensitivity= 95.00% 95%CI：(88.78%, 100.00%),

C＞30 sensitivity= 90.32% 95%CI：（74.25%,97.96%）

specificity= 100% 95%CI：（92.89%，100.00%）

accuracy= 96.30% 95%CI：（89.56%，99.23%）

Positive results broken down by days since symptom onset.

Days Since Symptom Onset	PCR Positive (+)	Antigen Positive (+)	Positive Percent Agreement 95% Confidence interval
0	-	-	
1	3	3	100%
2	10	10	100%
3	15	14	93.33%（68.05%，99.83%）
4	21	20	95.24%（76.18%，99.88%）
5	26	24	92.30%（74.87%，99.05%）
6	-	-	-
7	-	-	-
8-14	31	28	90.32（74.25%，97.96%）

(5) Comparative analysis of nasal swab and throat swab and saliva results

Content	Sensitivity95%C I:	Specificity95%C I:	Accuracy 95%C I:

Nasal swab and PCR	Ct≤25	100%	100% (99.08%,100.00%)	98.77% (93.31%,99.97%)
	Ct≤30	100%		
	Ct>30	96.77% (83.30%,99.92%)		
	total	96.77% (83.30%,99.92%)		
Throat swab and PCR	Ct≤25	100%	100% (99.08%,100.00%)	97.53%(91.36%,99.70%)
	Ct≤30	96.77% (83.30%,99.92%)		
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Saliva and PCR	Ct≤25	100%	100% (92.89%,100.00%)	96.30% (89.56%,99.23%)
	Ct≤30	93.55% (78.58%,99.21%)		
	Ct>30	90.32% (74.25%,97.96%)		
	total	90.32% (74.25%,97.96%)		

Positive results broken down by days since symptom onset.

Days Since Symptom Onset	PCR Positive (+)	Antigen Positive (+)		
		Nasal swab	Throat swab	Saliva
0	-	-	-	-
1	3	3	3	3
2	10	10	10	10
3	15	14	14	14
4	21	20	20	20
5	26	25	24	24
6	-	-	-	-
7	-	-	-	-
8-14	31	30	29	28

Nasal swab Clinical Sensitivity= 96.77% 95%CI：（83.30%,99.92%）

Throat swab Clinical Sensitivity= 93.55% 95%CI：（78.58%,99.21%）

Saliva Clinical Sensitivity= 90.32% 95%CI：（74.25%,97.96%）

3.4 Discussion and analysis of results

According to the above statistics, the test results of this kit in each sample type.

Sample distribution statistics

The general situation is as follows:

course of disease	Number of cases

confirmed case	153
excluded case	400
total	553

Patient Demographics

Age [mean (min-max), N]	Gender [%F, (n/N)]	Positivity [%, (n/N)]	Symptoms present[%Yes, (n/N)]	Invalid rate (%, n/N)
37.7（2-71），553	49.19%(272/553)	27.76%,153/553	27.76%,153/553	0%,0/553

The comparison and analysis of each sample type and PCR test results of this kit are as follows:

Content		Sensitivity95%CI:	Specificity95%CI:	Accuracy 95%CI:
Nasal swab and PCR	Ct≤25	100%	100% (99.08%,100.00%)	98.37% (96.93%,99.25%)
	Ct≤30	98.44% （94.47%,97.28%）		
	Ct>30	94.12%（89.13%,99.81%）		
	total	94.12%（89.13%,99.81%）		
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	Ct>30	90.85% (85.12%,94.91%)		
	total	90.85% （85.12%,94.91%）		
Saliva and PCR	Ct≤25	100%	100% (92.89%,100.00%)	96.30% (89.56%,99.23%)
	Ct≤30	95.00%(88.78%, 100.00%)		
	Ct>30	90.32% (74.25%,97.96%)		
	total	90.32% (74.25%,97.96%)		

Comparative analysis of nasal swab and throat swab and saliva results

Content		Sensitivity95%CI:	Specificity95%CI:	Accuracy 95%CI:
Nasal swab and PCR	Ct≤25	100%	100% (99.08%,100.00%)	98.77% (93.31%,99.97%)
	Ct≤30	100%		

Content		Sensitivity95%CI:	Specificity95%CI:	Accuracy 95%CI:
	Ct>30	96.77% （83.30%,99.92%）		
	total	96.77% （83.30%,99.92%）		
Throat swab and PCR	Ct≤25	100%	100% (99.08%,100.00%)	97.53%(91.36%,99.70%)
	Ct≤30	96.77% （83.30%,99.92%）		
	Ct>30	93.55% （78.58%,99.21%）		
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Saliva and PCR	Ct≤25	100%	100% (92.89%,100.00%)	96.30% (89.56%,99.23%)
	Ct≤30	93.55% （78.58%,99.21%）		
	Ct>30	90.32% （74.25%,97.96%）		
	total	90.32% （74.25%,97.96%）		

The sensitivity of the SARS-COV-2 Antigen was slightly higher in nasal swab samples than in throat swab samples and in throat Swab samples than in saliva samples.

3.5 Appendix

Annex 1:Summary of clinical test results.