SARS-CoV-2 Ag Saliva Rapid Test Clinical

Study Report

Name of in vitro diagnostic reagents used in the test: SARS-

CoV-2 Ag Saliva RapidTest

Specifications: 15 Tests/Box

Start and end time of the test: August 11th, 2020 - August 25th,2020

Report Date: September 6th, 2020

Summary

The SARS-CoV-2 Ag Saliva Rapid Test can quickly and qualitatively detect the nucleocapsid protein of novel coronavirus (SARS-COV-2) in human saliva samples. It can be used as a supplementary test for COVID-19 diagnosis.

According to the clinical trial plan, the SARS-CoV-2 Ag Saliva Rapid Test or "test reagent", is to test saliva samples from healthy subjects and confirmed COVID-19 patients. Test results are compared with another commercial SARS-COV-2 nucleic acid detection kit with NMPA approval, which is defined as the "gold standard". The sensitivity, specificity, and total agreement rate are used to evaluate the feasibility of the test reagent in clinical applications.

Method: A collection of clinical samples are examined by the test reagent and the gold standard in parallel, to calculate the clinical sensitivity, clinical specificity and total agreement rate of the test reagent. Standard of criteria for a qualified test reagent: Clinical sensitivity ≥90%, clinical specificity ≥90%, and total agreement rate ≥90%.

Results:

Compared to the gold standard, the clinical sensitivity of test reagent is 91.59%, and the 95% confidence interval is 84.78%-95.51%； The clinical specificity is ≥99.99%, and the 95% confidence interval is 96.47%-100%； and the total agreement rate is 95.75% in saliva sample ;

Conclusion: Compared to the gold standard reagent, the test reagent has reliable performance in diagnosing COVID-19 cases.

Acronyms

Test reagent: SARS-CoV-2 Ag Saliva Rapid Test developed by Hangzhou Jucheng Medical Products Co., Ltd

SARS-COV-2: Novel Corona Virus 2019

Main contents

Introduction

The novel coronavirus SARS-COV-2 is the causative pathogen for the global pandemic of COVID-19. It is contagious in humans, either symptomatically or asymptomatically. Based on current epidemic knowledge, the asymptomatic infection may last for 1 day to 14 days, mainly 3 days to 7 days. Symptoms of COVID-19 include fever, fatigue, and cough. Some patients also complain about nasal obstruction, runny nose, sore throat, muscle aches, and diarrhea.

In response to the emergent market needs,the SARS-CoV-2 Ag Saliva Rapid Test was developed . Since studies report that nucleocapsid (N protein) is the most abundant viral protein during infection, N protein is chosen as the detection target of this product to achieve its best sensitivity in clinical applications.

Production of the SARS-CoV-2 Ag Saliva Rapid Test is implemented in Class 100,000 cleanrooms, by proficient operators. Multiple quality control processes are included in the manufacturing procedures to

examine the quality of raw materials, semi-finished products, and finished products. The construction of cleanrooms, personnel training, and manufacturing practices are implemented under relevant laws and regulations.

To evaluate the clinical performance of the SARS-CoV-2 Ag Saliva Rapid Test, the current clinical trial is jointly carried out by the applicant and a clinical site. The applicant is responsible for providing test reagents and training relevant personnel with the operating procedures and technical principles to minimize operational bias. The clinical site is responsible for the collection and storage of clinical trial samples, the implementation of clinical trials, the compilation of clinical trial records, and the composing of clinical trial reports.

Trial objective

The objective of the current trial is to evaluate the performance of the test reagent in clinical applications, using an NMPA approved commercial SARS-COV-2 nucleic acid detection reagents the “gold standard” reagent.

Trail design

Clinical samples for the current trial are collected by the clinical site. Each sample is tested by both the test reagent and gold standard reagent. The clinical sensitivity, clinical specificity, and total agreement rate of the test reagent are calculated based on the test results.

Results and analysis

Determining the sample size.

Considering the uncertainty of obtaining positive samples, the number of samples for this clinical The trial shall be no less than 200, of which the number of positive samples shall not be less than 100.

The “gold standard” reagent

Nucleic acid testing is currently the "gold standard" for COVID-19 diagnosis. An NMPA approved nucleic acid test reagent, namely the Novel Coronavirus (SARS-COV-2) Real-Time Multiplex RT-PCR Kit produced by Shanghai ZJ Bio-Tech Co., Ltd. is chosen as the “gold standard” reagent. It targets the ORF1ab gene, N gene, and E gene of the SARS-COV-2, and is used as an auxiliary diagnosis and emergency reserve reagent for COVID-19.

Information of test reagent and the "gold standard" reagent.

Test reagent	SARS-CoV-2 Ag Saliva Rapid Test		
Specification	25 Tests/Box	Lot:	200801
Period of Validity	2 years	Storage:	2°C~30°C
Manufacturer	Hangzhou Jucheng Medical Products Co., Ltd		

Gold Standard reagent	Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR Kit		
Approval Number	NMPA NO:20203400057		
Specification	50 Tests/Box		
Period of Validity	Six month	Storage:	Store at -20±5°C, keep away from light
Manufacturer	Shanghai ZJ Bio-Tech Co., Ltd.		

Quality control methods

The clinical trial is strictly implemented in accordance with the corresponding instruction manual.

Statistical analysis method of clinical trial data

		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	a	b	a + b
	Negative	c	d	c + d
Total		a + c	b + d	a + b + c + d

Clinical sensitivity (%) = [a / (a + c)] ×100%

Clinical specificity (%) = [d / (b + d)] ×100%

Total coincidence rate (%) = [(a + d) / (a + b + c + d)] ×100%

Clinical trial results and analysis Trail Results

A collection of 107 samples were tested with test reagents. Includes 107 saliva samples and 107 nasopharyngeal swab samples. These samples are taken from 107 confirmed patients, of which 56 (52.3%) are female, and 51 (47.7%) are male. Their ages range from 17 to 78 years old and are 43 years old on average. Cough (66.4%) and fever (72.9%) are the most common complained symptoms. Their sampling time is between Day 1 to Day 7 post-onset, mainly on Day 2 (23.9%).

In addition, we collected 105 saliva samples from 105 healthy people, of which 54 (51.4%) are female, and 51 (48.6%) are male. Their ages range from 19 to 82 years old and are 43 years old on average. Compared with the novel coronavirus (SARS-COV-2) real-time multiplex RT-PCR kit, the testing results of sensitivity and specificity of the SARS-CoV-2 Ag Saliva Rapid Test are presented in the table below. Throughout the experiment, the saliva sample and the nasopharyngeal swab sample used for comparison must come from the same patient. We test our test regent on saliva samples，and test RT-PCR testing on nasopharyngeal swab samples. In the end, all the results will be summarized, compared and analyzed.

Test results are as follows:

	Test reagent	RT-PCR
	saliva	Nasopharyngeal swab
Health 1	-	-
Health 2	-	-
Health 3	-	-
Health 4	-	-
Health 5	-	-
Health 6	-	-
Health 7	-	-
Health 8	-	-
Health 9	-	-
Health 10	-	-
Health 11	-	-
Health 12	-	-
Health 13	-	-
Health 14	-	-
Health 15	-	-
Health 16	-	-
Health 17	-	-
Health 18	-	-
Health 19	-	-
Health 20	-	-
Health 21	-	-
Health 22	-	-
Health 23	-	-
Health 24	-	-
Health 25	-	-
Health 26	-	-

Health 27	-	-
Health 28	-	-
Health 29	-	-
Health 30	-	-
Health 31	-	-
Health 32	-	-
Health 33	-	-

Health 34	-	-
Health 35	-	-
Health 36	-	-
Health 37	-	-
Health 38	-	-
Health 39	-	-
Health 40	-	-
Health 41	-	-
Health 42	-	-
Health 43	-	-
Health 44	-	-
Health 45	-	-
Health 46	-	-
Health 47	-	-
Health 48	-	-
Health 49	-	-
Health 50	-	-
Health 51	-	-
Health 52	-	-
Health 53	-	-
Health 54	-	-

Health 55	-	-
Health 56	-	-
Health 57	-	-
Health 58	-	-
Health 59	-	-
Health 60	-	-
Health 61	-	-
Health 62	-	-
Health 63	-	-
Health 64	-	-
Health 65	-	-
Health 66	-	-
Health 67	-	-
Health 68	-	-
Health 69	-	-
Health 70	-	-
Health 71	-	-

Health 72	-	-
Health 73	-	-
Health 74	-	-
Health 75	-	-
Health 76	-	-
Health 77	-	-
Health 78	-	-
Health 79	-	-
Health 80	-	-
Health 81	-	-
Health 82	-	-

Health 83	-	-
Health 84	-	-
Health 85	-	-
Health 86	-	-
Health 87	-	-
Health 88	-	-
Health 89	-	-
Health 90	-	-
Health 91	-	-
Health 92	-	-
Health 93	-	-
Health 94	-	-
Health 95	-	-
Health 96	-	-
Health 97	-	-
Health 98	-	-
Health 99	-	-
Health 100	-	-
Health 101	-	-
Health 102	-	-
Health 103	-	-
Health 104	-	
Health 105	-	

	Test reagent	RT-PCR
	saliva	Nasopharyngeal swab
Confirmed cases 1	+	+

Confirmed cases 2	+	+
Confirmed cases 3	+	+
Confirmed cases 4	+	+
Confirmed cases 5	+	+
Confirmed cases 6	+	+
Confirmed cases 7	-	+
Confirmed cases 8	+	+
Confirmed cases 9	+	+
Confirmed cases 10	+	+
Confirmed cases 11	+	+
Confirmed cases 12	+	+
Confirmed cases 13	+	+
Confirmed cases 14	+	+
Confirmed cases 15	+	+
Confirmed cases 16	+	+
Confirmed cases 17	+	+
Confirmed cases 18	+	+
Confirmed cases 19	-	+
Confirmed cases 20	-	+
Confirmed cases 21	+	+
Confirmed cases 22	+	+
Confirmed cases 23	+	+
Confirmed cases 24	+	+
Confirmed cases 25	+	+
Confirmed cases 26	+	+
Confirmed cases 27	+	+
Confirmed cases 28	+	+
Confirmed cases 29	+	+

Confirmed cases 30	+	+
Confirmed cases 31	+	+
Confirmed cases 32	+	+
Confirmed cases 33	+	+
Confirmed cases 34	+	+
Confirmed cases 35	+	+
Confirmed cases 36	+	+
Confirmed cases 37	-	+
Confirmed cases 38	+	+
Confirmed cases 39	+	+

Confirmed cases 40	+	+
Confirmed cases 41	+	+
Confirmed cases 42	+	+
Confirmed cases 43	+	+
Confirmed cases 44	+	+
Confirmed cases 45	+	+
Confirmed cases 46	+	+
Confirmed cases 47	+	+
Confirmed cases 48	+	+
Confirmed cases 49	+	+
Confirmed cases 50	+	+
Confirmed cases 51	+	+
Confirmed cases 52	+	+
Confirmed cases 53	+	+
Confirmed cases 54	-	+
Confirmed cases 55	+	+
Confirmed cases 56	+	+
Confirmed cases 57	+	+

Confirmed cases 58	+	+
Confirmed cases 59	+	+
Confirmed cases 60	+	+
Confirmed cases 61	+	+
Confirmed cases 62	+	+
Confirmed cases 63	-	+
Confirmed cases 64	+	+
Confirmed cases 65	+	+
Confirmed cases 66	+	+
Confirmed cases 67	+	+
Confirmed cases 68	+	+
Confirmed cases 69	+	+
Confirmed cases 70	+	+
Confirmed cases 71	+	+
Confirmed cases 72	+	+
Confirmed cases 73	-	+
Confirmed cases 74	+	+
Confirmed cases 75	+	+
Confirmed cases 76	+	+
Confirmed cases 77	+	+
Confirmed cases 78	+	+
Confirmed cases 79	+	+
Confirmed cases 80	+	+
Confirmed cases 81	+	+
Confirmed cases 82	+	+
Confirmed cases 83	+	+
Confirmed cases 84	+	+
Confirmed cases 85	+	+

Confirmed cases 86	+	+
Confirmed cases 87	+	+
Confirmed cases 88	+	+
Confirmed cases 89	+	+
Confirmed cases 90	+	+
Confirmed cases 91	+	+
Confirmed cases 92	+	+
Confirmed cases 93	+	+
Confirmed cases 94	+	+
Confirmed cases 95	-	+
Confirmed cases 96	+	+
Confirmed cases 97	+	+
Confirmed cases 98	+	+
Confirmed cases 99	+	+
Confirmed cases 100	+	+
Confirmed cases 101	+	+
Confirmed cases 102	-	+
Confirmed cases 103	+	+
Confirmed cases 104	+	+
Confirmed cases 105	+	+
Confirmed cases 106	+	+
Confirmed cases 107	+	+

The above results are summarized as follows：

saliva sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	98	0	98
	Negative	9	105	114
Total		107	105	212

Result analysis saliva samples: The SARS-CoV-2 Ag Saliva Rapid Test showed 91.59% sensitivity and ≥99.99% specificity in saliva samples.

Clinical sensitivity (%) = [98/ (98+ 9)] ×100% =91.59%, and the 95% confidence interval is 84.78%95.51%
Clinical specificity (%) = [105/ (0+ 105)] ×100% = 100%, and the 95% confidence interval is 96.47%-100%;
Total agreement rate (%) = [(98 +105) / (98+ 9+ 0+ 105)] ×100% = 95.75%, and the 95% confidence interval is 92.13%-97.75%

Discussion and conclusion

The SARS-CoV-2 Ag Saliva Rapid Test can quickly and qualitatively detect SARS-COV-2 in human saliva samples. It can be used as a supplementary test for COVID-19 diagnosis.

In this clinic trial, the Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR Kit produced by Shanghai ZJ Bio-Tech Co., Ltd., a commercial SARS-COV-2 kit approved by NMPA, is used as the "gold standard" reagent.

Compared to the gold standard, the clinical sensitivity of test reagent is 91.59%, and the 95% confidence interval is 84.78%-95.51%; The clinical specificity is ≥99.99%, and the 95% confidence interval is 96.47%-100%； and the total agreement rate is 95.75% in saliva sample;

In summary, the overall agreement rate between the test reagent and the gold standard reagent is relatively high, and the test reagent can be used clinically for the diagnosis of cases of SARS-COV-2.

Notes on special circumstances in clinical trials

In the actual sampling process, some patients were unable to provide saliva samples due to individual differences. For these patients, oropharyngeal saliva (mucus coughed up from the deep throat) was substituted for the saliva sample.