Vacsure COVID-19 Antigen Detection Kit

Clinical Study Report

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, score throat, muscle aches, and diarrhea.

In response to the emergent market needs, Zhejiang Anji Saianfu Biotech Co.,Ltd. has developed the COVID-19 Antigen Detection Kit. Since studies report that nucleocaspid (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.

Results and analysis

Sample collection, storage, and transportation.

Clinical samples are collected from COVID-19 suspects, and kept frozen at -15°C~-25°C until used.

The “gold standard” reagent

Nucleic acid testing is currently the "gold standard" for COVID-19 diagnosis. A NMPA approved nucleic acid test reagent, namely the Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR Kit. 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 forCOVID-19.

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

Test reagent	COVID-19 Antigen Detection Kit		
Specification	20 Tests/Box	Lot No.	202008001
Period of Validity	2 year	Storage	2°C~30°C
Manufacturer	Zhejiang Anji Saianfu Biotech 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 months	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 agreement rate (%) = [(a + d) / (a + b + c + d)] ×100%

Clinical trial results and analysis

Sample characterization

These samples are taken from 391 suspected patients, of which 211 are female, and 180 are male. Their ages range from 17 to 88 years old, and are 47 years old on average. Cough (61%) and fever (39%) are the most common complained symptoms. Their sampling time is between Day 1 to Day 6 post onset, mainly on Day 2(32.0%).

Result analysis

Product performance in different sample types

In 391 Nasopharyngeal specimens, the PCR test reagent finds out 161 positive results, of which 161 samples are reported positive by both reagents. Testing results are presented in table below.

Anterior Nasal		PCR		Total
		Positive	Negative	
Test reagent	Positive	157	2	159
	Negative	4	228	232
Total		161	230	391

Clinical sensitivity (%) = [157/ (157 + 4)] ×100% = 97.52 %, 95% CI 93.79% to 99.03%

Clinical specificity (%) = [228 / (2 + 228)] ×100% = 99.13%， 95% CI 98.89% to 99.76%

Accuracy (%) = [(157 +228) / (157 +4 +2 +228)] ×100% = 98.47%， 95% CI 96.69% to 99.29%

In 391 Oropharyngeal specimens, the PCR test reagent finds out 161 positive results, of which 161 samples are reported positive by both reagents. Testing results are presented in table below.

Oropharyngeal		PCR		Total
		Positive	Negative	
Test reagent	Positive	157	2	159
	Negative	4	228	232
Total		161	230	391

Clinical sensitivity (%) = [157/ (157 + 4)] ×100% = 97.52 %, 95% CI 93.79% to 99.03%

Clinical specificity (%) = [228 / (2 + 228)] ×100% = 99.13%， 95% CI 98.89% to 99.76%

Accuracy (%) = [(157 +228) / (157 +4 +2 +228)] ×100% = 98.47%， 95% CI 96.69% to 99.29%

Discussion and conclusion

In this clinic trial, performance of the test reagent “COVID-19 Antigen Detection Kit” is evaluated on a collection of 391 clinical samples. Compared to a commercial Real Time Multiplex RT-PCR, for different sample types, the test reagent has shown the sensitivity, specificity, and accuracy are 97.52%, 99.13%, and 98.47% in 391 Nasopharyngeal specimens. the sensitivity, specificity, and accuracy are 97.52 %, 99.13%, and 98.47% in 391 Oropharyngeal specimens. These results suggest a promising future of test reagent in clinical applications.

Although the antigen test directly detects viral proteins without amplification process, which makes it less sensitive than conventional nucleic acid tests, the antigen tests have two inherent advantages for clinical applications. The first advantage is short turnaround time. Antigen tests usually take 15 to 20 minutes, making it possible for point-of-care testing (POCT). However, nucleic acid tests take 2 to 3 hours. In some countries, it may even take days to report a nucleic acid test result to suspects. Such a delay will absolutely hinder the control and prevention of disease transmission. The second advantage of antigen tests is easy-to-use. Antigen tests don’t require large investment in laboratory construction, or complicated procedures like RNA extraction, and reagent preparation. The operators will be able to run a antigen test independently, with a one-hour simple training. Therefore, antigen tests are most suitable for large applications in resource limited areas.

In summary, the current clinical trial has proven the reliable performance of COVID-19 Antigen Detection Kit. This product is promising to assist the diagnosis of COVID-19 cases in large scales.