Anbio (Xiamen) Biotechnology Co.,Ltd
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Feb 05, 2021

To whom it may concern,

We, Anbio(Xiamen) Biotechnology Co.,Ltd recently has launched our new version COVID19 Antigen test by nasal swab, throat swab, saliva 3 specimens which could greatly improve the specificity of the test by saliva specimen.

In addition, we hereby declare that our COVID19 Antigen test is effective to mutant strain in British and South Africa. Please see below details.

1. The British and South Africa mutant, commonly known as the B.1.1.7 subtype, has been named VOC-202012/01novel coronavirus. The most important mutations in this strain relative to the common strain are three mutations in the RBD region K417N, E484K, and N501Y.These three mutations make it easier for the virus to bind to the ACE2 receptor in the human body, making it easier for the virus to spread.

2. Why our product is still effective: a. What we detected is mainly the N protein of novel coronavirus, which is relatively conservative, and this British & South Africa mutant strain is mainly the gene encoding RBD protein; b. The mutant region of the British & South Africa mutant strain is not within our detection range, so our detection reagent was still effective in detecting the antigen of the mutant strain, but it also means that our reagent could not distinguish the mutant strain from the common strain;

3. Simulated data:

3.1. Detection of recombinant full-length RBD protein of mutant strains:

Detection of recombinant full-length RBD protein of mutant strains of K417N,E484K,N501Y Mutated RBD Protein

mutated recombinant protein	common strain	Sensitivity of national reference
800pg/mL:G4	800pg/mL:G4	S1:G4（6800TCID50）
400pg/mL:G3	400pg/mL:G3	S2:G4（3400TCID50）
200pg/mL:G2	200pg/mL:G2	S3:G3（1700TCID50）
100pg/mL:G1	100pg/mL:G1	S4:G2（850TCID50）
50pg/mL:G0	50pg/mL:G0	S5:G0（425TCID50）

Note: color darker than G0 can be judged positive

3.2. Detection of animal model samples: detection of S protein in Clara cells of respiratory tract infected in mouse model:

concentration（pg/mL）	1600	800	400	200	100	50
results	G5	G4	G3	G2	G0	G0

Your sincerely

厦门安必生物科技有限公司

JieLi Zhang
R&D Director
Anbio Biotechnoloty

National Institutes for Food and Drug Control

Testing Report

Report Number：RZ202009287

Product Name	Rapid COVID-19 Antigen Test （Colloidal Gold）	Inspection item No	RZ2804202014368
Manufacture	Anbio (Xiamen) Biotechnology Co., Ltd.	Lot Number	2020036133
Sample supplier	Fujian Medical Product adminstration	Specification	/
Testing popuse	Registration inspection (IVD/first registration/Quality standard review)	Dosage form/Model	/
Testing Item	All	Package specification	20tests/kit
Datereceived	December 15,2021	Valid until/Limitation date	March 24,2022
Product quantity	6 kits	Number of signings	/
Criteria for examination	Technical Requirements		
Testing Item	Standard and		Result
2.1 Physico-chemical properties			
2.1.1 Appearance	The appearance is complete without damage, and the components are complete; the label content is complete, correct and clear; the Sample Diluent is colorless and transparent liquid		Pass
2.1.2 Width	The width of Membrane strip shall not less than 2.5mm		3.1mm
2.1.3 Liquid velocity	The liguid velocity shall not less than 10mm/min		34mm/min
2.2 Coincidence rate of positive reference	Testing with national positive reference,should all be positive.		P1~P8 Positive Positive coincidence rate is 8/8.
2.3 Coincidence rate of negative reference	Testing with national positive reference,should all be negative.		N1~N20 Negative Negative coincidence rate is 20/20
2.4 Repeatability	Testing national repeatability reference,the result of 10 times of R1 and R2 should be positive , and the color should be uniform and no difference.		Compliance
	R1		The result of 10 times is positive,and

		the color should be uniform and no difference.
	R2	and the color should be uniform and no difference.
2.5 limits of detection	National Limits of detection reference ,S1~S4 should be all positive,S5、S6 no requirement.	S1~S4 positive， S5、S6 is negative
Ramarks:Applicant：Anbio (Xiamen) Biotechnology Co., Ltd.. 1 The reference is national reference for SARS-CoV-2 Antigen test. Batch number is 370095-202001,supplied by National Institutes for Food and Drug Control. 2 The negative reference is stock solution, the other reference is diluted by the extract solution within the Rapid COVID-19 Antigen Test，the volume is70μl.		
Conclusion	According to the technical requirement，the result is compliance with the requirement.	

Signature of authorizer		Date of issue	Dec 31,2020

Clinical Evaluation Report

Product name: Rapid COVID-19 Antigen Test(Colloidal Gold)

Company name: Anbio (Xiamen) Biotechnology Co.,Ltd.

Duration of experiment: August 01,2020 to December 01,2020

Version:V2.0

Draft/ Date： Xinhui Zheng/ December 05,2020

Reviewed By/ Date: Jieli Zhang/ December 05,2020

Approved By/ Date： Daming Wang/ December 05,2020

Signature: Daming Wang

Sign on: January 05,2021

Place: Xiamen,China

Contents

1. Objective

Anbio (Xiamen) Biotechnology Co.,Ltd. intends to introduce Rapid COVID-19 Antigen Test(Colloidal Gold) into the market. The objective of this study was designed to evaluate the user performance of COVID-19 Antigen Colloidal Gold Test .

The test results of samples from clinical cases were compared with PCR results of cases to verify the clinical performance of the test reagent.

2. Background information for clinical evaluation

The novel coronaviruses belong to the β genus.COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. The antigen is generally detectable in upper respiratory samples or lower respiratory samples during the acute phase of infection. The positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. The positive results do not rule out bacterial infection or co-infection with other viruses. The antigen detected may not be the definite cause of disease. The negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2 and confirmed with a molecular assay, if necessary for patient management.

3. Materials and Equipment

(1) Rapid COVID-19 Antigen Test(Colloidal Gold)
Lot:2020066131
Manufacturer:Anbio (Xiamen) Biotechnology Co.,Ltd.

(2) Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV
Lot:S1572054
Manufacturer: BGI Genormics Co,Ltd.

(3) Real time fluorescence quantitative PCR
Type:ABI 7500
Manufacturer:Applied Biosystems

(4)Clinical specimens

4. Evaluation Sites

(1) POC in Guangzhou,China
(2) POC in Xiamen,China
(3) POC in Beijing,China

The above POC are the designated laboratory for COVID-19 testing, and each POC is operated by

3-5 professionals.

5. Number of clinical specimens

Tab1 Number of clinical specimens

Group	PCR result (Nasopharyngeal swab)	Sample type	Number	Collection Day
1	Positive	Saliva	At least 100 cases	2020/8/1 to 2020/11/30
2	Negative	Saliva	At least 100 cases	2020/8/1 to 2020/11/30

6. Criteria for Participant

(1) Gender:Male or female.
(2) Age:no restriction,the neonatal excluded.
(3) Days from Symptom Onset

Days from Symptom Onset	0-3 days	4-7 days	＞7 days
Percentage	40%	40%	20%

(4) Test within 48 hours after sample collection.

7. Clinical specimens storage

(1) Applicable clinical specimens type: Saliva specimen
(2) Storage: Samples should be tested as soon as possible after collection. Processed samples (add Extraction Solution) are stable for up to 24-hours at room temperature or 2° to 8°C and cannot be frozen.
(3) The specimens must be balanced to room temperature before testing.

8. Operation

(1) Specimens collection and information record
The main researchers of the clinical institutions designate special personnel to select the eligible cases according to the enrollment criteria, and collect the clinical information of the enrolled specimens, including: age, gender, clinical symptoms, clinical classification(mild or moderate), sample collection time and other information. The specimens are numbered according to the sequence before and after grouping, i.e. Specimens number.
(2) Specimens blinding
The main researchers of the clinical institution designated the person to randomly number the specimens in the group with the random number generating tool, record the random number of the specimens and the corresponding specimens number, and the person arranged the specimens according to the sequence of the random number, and handed them to the test operator for testing according to this sequence, noting that the person and the test operator cannot be the same person.
(3) Testing
The test operator shall test the specimens and operate according to the instructions. PCR test is used for in vitro qualitative detection of novel coronavirus (2019-nCoV) ORF1ab, N gene and E gene in nasopharyngeal swab, oropharyngeal swab,sputum, and alveolar lavage fluid samples.
(4) Unblinding
At the end of the test, according to the corresponding relationship between random number and

specimens number, record the test results.
(5) Result determination
The test results should be statistically analyzed with clinical diagnosis to evaluate the clinical application performance of the product.

9. Control method

(1) Before the start of clinical research, the enterprise shall train the researchers to make them familiar with and master the operation method and technical performance of the product, so as to minimize the test error.
(2) Researchers should strictly follow the product's operation specifications and related requirements for testing to ensure that the testing error can be minimized.
(3) The supervisors shall check the relevant activities and documents of the clinical trial, whether the trial is conducted in accordance with the test scheme, standard operating procedures and relevant regulations, and whether the test data is recorded in a timely, clear, accurate and complete manner.

10. Data management

(1) Traceability of data, filling and transfer of case report form
Ensure the traceability of clinical trial data. According to the original observation records of the subjects, the researchers recorded the data in the case report form in a timely, complete, accurate and clear manner. The supervisor shall monitor whether the trial is carried out in accordance with the plan, confirm that the case report form is filled in correctly and completely, and is consistent with the original data. In case of any mistake or omission, the researcher shall be required to correct it in time. The original record shall be kept clear and visible during modification, and the correction shall be signed and dated by the researcher.
(2) Data entry and modification
In order to ensure the accuracy of data, two data entry personnel are responsible for independent entry and proofreading. During the data analysis, for the questions in the case report form, the researcher should answer and return them as soon as possible, and the statistician should modify, confirm and input them according to the researcher's answers.
(3) Lock of database
At the end of the test, after data entry, the researcher and the sponsor check the data, and lock the data after confirming that the data is correct, and then lock the data for statistical analysis.

11. Results and Statistical Analysis

11.1 Results for Saliva specimen
(1) Results analysis table

Tab2 Analysis table of clinical specimens results

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	217(a)	0(b)	217(a+b)

Antigen Test(Colloidal Gold) result	Negative	4(c)	123(d)	127(c+d)
	Total	221(a+c)	123(b+d)	344(a+b+c+d)

(2) Coincidence rate and 95% confidence interval

Tab3 Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	98.19%	95.43%~99.50%
Clinical specificity	100%	97.05%~100%
Total coincidence rate	98.84%	97.05%~99.68%

(3) Statistical Analysis

Kappa value(K) calculation

K=0.9749>0.75 indicates that the high consistency of two methods and equiwalence of two such systems.

11.2 Separate analysis

Tab4 Analysis table of different days from symptom onset

	0-3 days	4-7 days	>7 days
PCR result	89	88	44
Product result	87	86	44
PPA	97.75%	97.73%	100%

11.3 Analysis on samples with inconsistent results

No.	Sampling day	Age	Sex (F/M)	Days from Symptom Onset	Collection Day	Test Day	Saliva result	PCR result			
								Chanel A (RdRP)	Chanel B (N gene)	Chanel C (E gene)	result
3	2020/8/1	67	F	2	2020/8/1	2020/8/1	-	42	37	39	+
20	2020/8/11	83	M	5	2020/8/11	2020/8/11	-	37	35	36	+
42	2020/9/1	51	F	4	2020/9/1	2020/9/1	-	36	/	38	+
89	2020/10/9	37	M	2	2020/10/9	2020/10/9	-	37	36	/	+

12. Conclusion

(1) 344 samples were tested in this clinical trial. Among them, there were 340 cases with product test results consistent with PCR result in this clinical trial,included 217 cases were positive, 123 cases were negative.

(2) There were 4 cases of product test results inconsistent with PCR result in this clinical trial.

(3) The sensitivity, specificity and total coincidence rate of product testing and PCR result are 98.19%,100% and 98.84% respectively. The sensitivity is more than 90%, The specificity is more than 95%.

(4) K=0.9749>0.75 indicates that the high consistency of two methods and equiwalence of two such systems.