BioTeke Corporation (Wuxi) Co., Ltd.
4th Floor, D5 & 2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719,
Huishan Avenue, Wuxi, Jiangsu, CN 214174
info@bioteke.com

Clinical Report

For nasopharyngeal swabs

SARS-CoV-2 Antigen Test Kit (colloidal gold method)

Manufacturer: BioTeke Corporation (Wuxi) Co., Ltd.

Contents

1. Product name

SARS-CoV-2 Antigen Test Kit (colloidal gold method)

2. Manufacturer

BioTeke Corporation (Wuxi) Co., Ltd.

3. Test Interval

November, 2020 – January, 2021

4. Introduction

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.

This kit is only used for the in vitro qualitative detection of SARS-CoV-2 antigen from human nasopharyngeal swabs specimens.

This kit is suitable for the auxiliary diagnosis of COVID-19, the results are for clinical reference only and cannot be used as the sole basis for diagnosis and exclusion decision. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment responses.

Positive test result needs to be further confirmed, negative result does not preclude SARS-CoV-2 infection.

5. Principle

The kit is immunochromatographic and uses double-antibody sandwich method to detect SARS-CoV-2 N protein antigen. During detection, the treated specimens are loaded into the sample wells of the test card. When the concentration of SARS-CoV-2 antigen in specimen is higher than the minimum detection limit, the viral antigen will form complexes with labeled antibodies first. Under chromatography, the complexes move forward along the nitrocellulose membrane till captured by pre-coated monoclonal antibody of SARS-CoV-2 in detection zone on nitrocellulose film (T) to form a pink/purple reaction line on the detection zone, at this point the result is positive; conversely, if there is no viral antigen or the concentration of antigen in specimen is below the minimum detection limit, no pink/purple reaction line appears in the detection zone, at this point the result is negative. Regardless of whether the

sample contains viral antigens or not, a pink/purple reaction line will appear in the quality control zone (C), the pink/purple reaction line that appears in the quality control zone (C) is the criterion for determining if the chromatography process is normal.

6. Research Purpose

This clinical trial conducted a clinical application study on "SARS-CoV-2 Antigen Test Kit (colloidal gold method)" produced by BioTeke Corporation (Wuxi) Co., Ltd (hereinafter referred to as "BioTeke"). The efficacy and safety of Bioteke reagent clinical application were evaluated.

7. Clinical research samples

7.1 Clinical trial sample size

Sample types in this trial are nasopharyngeal swab. Testing a minimum of 100 positive specimens and 100 negative specimens in a randomized, blinded fashion.

7.2 Sample inclusion criteria and exclusion criteria

7.2.1 Inclusion Criteria

1.Has symptoms that lead the healthcare provider to suspect the individual of possibly having SARS-CoV-2 infection.

2.Was exposed to a COVID-19 patient less than 7 days that leads the healthcare provider to suspect the individual of possibly having SARS-CoV-2 infection.

3. Asymptomatic persons without a risk of exposure to COVID-19.

4.Must be able to provide nasopharyngeal swab samples.

7.2.2 Exclusion Criteria

1) sample volume is insufficient;

2) samples that can not complete the test due to human factors (contamination of samples during operation / improper collection or preservation of samples).

8. Candidate Test & Comparator Test:

8.1 Candidate Test

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8.2 Comparator Test

The comparator RT-PCR tests used in this research has been authorized by EUA / EUL / CE marking / NMPA, used at testing site as the routine testing method for COVID-19 diagnostics.

9. Test Procedure

Perform the test according to the User Instruction Manual package insert.

10. Research methods

The included cases were coded in order and detected by blind method to ensure the objectivity of the test results. The results of Bioteke reagent and comparator method were compared and analyzed to evaluate the clinical application performance of Bioteke reagent.

11. Quality control methods

1) Screening the subjects strictly according to the inclusion criteria of the clinical trial scheme to reduce the selective deviation.

2) Before the start of the trial, Bioteke shall train the researchers involved in the clinical trial program, and if necessary, the use of reagents to ensure the consistency of the clinical trial. And in the clinical trial process to promote communication between clinical trial researchers.

3) Test are conducted strictly according to the kit instructions.

4) Do a good job of supervision to ensure that clinical trials are operated and implemented in strict accordance with the trial plan.

12. Statistical analysis of clinical research data

In this clinical trial, the selected samples were detected by Bioteke reagent, compared with the PCR reagent, and the statistical analysis was carried out to investigate the consistency between the Bioteke reagent and the comparator method.

Effectiveness evaluation method: four-grid table analysis.

The clinical sensitivity, clinical specificity, accuracy and the 95% confidence interval were evaluated, compared with PCR reagent.

12.1 Evaluation criteria

Statistical analysis of the test data is conducted to judge whether each index meets the requirements of clinical performance evaluation standards to verify the agreement between Bioteke reagent and comparator method. The evaluation methods and criteria are as follows:

Percent agreement: the positive percent agreement, negative percent agreement and 95% confidence interval were calculated.

12.2 Statistical methodology

Statistical analysis is handled by Excel and SPSS software.

The main statistical methods of effectiveness are as follows:

1) sensitivity, specificity / negative or positive percent agreement: the sensitivity and

specificity of Bioteke reagent and the negative or positive percent agreement with the comparator method are defined as follows:

Table 1 Qualitative analysis of percent agreement

	Clinical diagnosis/ Comparator method		
Bioteke reagent	Positive	Negative	Total
Positive	a	b	a +b
Negative	c	d	c +d
Total	a +c	b +d	a +b +c +d

Sensitivity/Positive percent agreement

$$\frac{a}{(a+c)}\times 100\% \quad \cdots\cdots(1)$$

Specificity/Negative percent agreement

$$\frac{d}{(b+d)}\times 100\% \quad \cdots\cdots(2)$$

$$\text{Accuracy/Total percent agreement} = \frac{(a+d)}{(a+b+c+d)}\times 100\% \quad \cdots\cdots(3)$$

The 95% confidence interval between the Bioteke reagent and comparator method percent agreement is calculated, and the calculation is based on the normal approximation method. The formula is as follows:

The formula of bilateral confidence interval is :95%CI=p±1.96×[p（1-p）/n]1/2.....(4)

The p is positive percent agreement, negative percent agreement or total percent agreement, and the n is sample number. If the p value is 100%, the p= is 99.99% for analysis.

2) Kappa consistency analysis (specific values of reported Kappa values) was carried out according to the four-grid table data in Table 2 to investigate the consistency of examination reagents and clinical diagnosis results.

$$Kappa = \frac{P_a - P_c}{1 - P_c} \quad \text{P of them}_a =, \text{P}\frac{a+d}{N}_C = \frac{\frac{(a+b)(a+c)}{N} + \frac{(b+d)(c+d)}{N}}{N}$$

13. Result interpretation for Candidate reagent in clinical trial

Quality Control Line (C)	Test Line (T)	Test results
Pink/purple	Pink/purple	Positive
Pink/purple	Colorless	Negative
Colorless	Whether it's color	Invalid test, retest

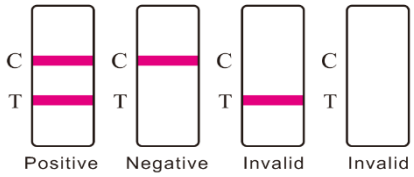

Figure 1

14. Statistical analysis of clinical findings

This clinical trial was conducted with a total of 392 nasopharyngeal swab specimens tested using SARS-CoV-2 Antigen Test Kit (colloidal gold method) to evaluate the effectiveness and safety of the clinical application of the kit.

SARS-CoV-2 Antigen Test Kit (colloidal gold method) Performance against PCR Comparator Method on nasopharyngeal swab specimens.

Bioteke reagent	PCR reagent		Total
	Positive	Negative	
Positive	110	2	112
Negative	4	276	280
Total	114	278	392

Clinical sensitivity = A/(A+C)×100%= 96.49% (95%CI: 91.26%～99.04%)

Clinical specificity = D/(B+D)×100%= 99.28% (95%CI: 97.43%～99.91%)

Accuracy = (A+D)/(A+B+C+D)×100%= 98.47% (95%CI: 96.70%～99.44%)

Kappa value = 0.9627

15. Conclusions

Among a total of 392 nasopharyngeal swabs, 114 cases were tested positive by PCR, 278 cases were tested negative by PCR. Among 114 PCR positive cases, 114 cases were tested positive by Bioteke reagent, whose PCR mean Ct value was 23.2, and the clinical

sensitivity was 96.49%. Among 278 PCR negative cases, 276 cases were tested negative by Bioteke reagent, the clinical specificity was 99.28%. The accuracy was 98.47%. Kappa value was 0.9627＞0.75, with good consistency.

When Ct value of nasopharyngeal swabs specimen≤25, the positive detection rate of this test kit is 97.82%; when Ct value≤26, the positive detection rate is 98.17%; when Ct value≤28, the positive detection rate is 98.21%; when the Ct value of nasopharyngeal swabs specimen＞28, there are 2 PCR positive specimens tested negative by Bioteke reagent.

From the above data we can see that Bioteke reagent has high detection agreement with other PCR reagent.

The clinical results showed that the detection ability of the Bioteke reagent for SARS-CoV-2 antigen was good. The test is reliable, safe and stable, and has high clinical application value.