Clinical Performance Evaluation Report

(2021) FT category No.3

Product Name: SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold)

Test Category: Comparison Experiment

Institute: Multibrands Trading (Suzhou) Co., Ltd.

Clinical Performance Evaluation Report

of

SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold)

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Assay for evaluation: SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold)

Comparator reagents: COVID-19 (SARS-CoV-2) nucleic acid test kit (fluorescence PCR method) (Huada Biotechnology (Wuhan) Co., Ltd.)

Date: 2021/10/14 - 2021/10/18

1. Abstract

1 Purpose: To evaluate the clinical performance of SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold) Rapid Detection Test from Multibrands Trading (Suzhou) Co., Ltd. by method comparison studies using the paired clinical samples.

2 Method: In this evaluation, the principle of parallel comparison was used to qualitatively analyze the paired qualitative data.

3 Statistics: The clinical performance of SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold) Rapid Detection Test was determined by testing paired nasopharyngeal (NP) swab and saliva samples from 350 people suspected of COVID-19 infection. The samples were collected within 5 days post onset of symptoms or suspected exposure. The NP samples were shipped to laboratory and determined to be positive or negative using RT-PCR method, i.e., the comparator method. The saliva samples were tested directly at the collection site with the SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold) Rapid Detection Test.

4 Results: The result comparison between the paired NP and saliva results showed that the clinical performance of SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold) Rapid Detection Test were: Positive coincidence rate (Clinical sensitivity): 106/110*100%=96.36%, 95% confidence interval: 90.95% ～99.00% . Negative coincidence rate (Clinical specificity): 239/240* 100%=99.58%, 95% confidence interval: 97.70%～99.99%. Overall percent agreement (Accuracy): 345/350* 100%=98.57%, 95% confidence interval: 96.70%～99.53%. KAPPA value: 0.9666

5 Conclusion: Good consistency was proved in detecting the SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold) Rapid Detection Test from Multibrands Trading (Suzhou) Co., Ltd. and the comparator reagent.

2. Test Design

1 Samples Collection and Testing

From 2021/10/14 to 2021/10/18, a total of 350x2 paired NP and saliva samples were collected from patients suspected of COVID-19. The samples were collected within 5 days post onset of symptoms or suspected exposure. At the collection site, the saliva samples were tested directly with SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold) Rapid Detection Test. The matched NP samples were kept in transport medium and shipped to laboratory for RT-PCR testing using the comparator method.

2 Statistical Analysis

The positive coincidence rate (Clinical sensitivity), negative coincidence rate (Clinical specificity), total coincidence rate and the corresponding 95% confidence interval were analyzed. The following table was used to summarize and calculate the statistics (Table 1). Kappa (or Chi-square) test was performed to evaluate the consistency between the two reagents.

Table 1. Statistical table of paired data

		Comparator method		Total
		Positive	Negative	
SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold) Rapid Detection Test	Positive	a	b	a + b
	Negative	c	d	c + d
	Total	a + c	b + d	a+b+c+d

Kappa consistency analysis was performed using data in the table above. Kappa coefficient >0.75 was considered to be highly consistent and the two systems were considered to be equivalent. Kappa coefficient > 0.4 was considered consistent, but further statistical analysis was needed. If Kappa coefficient < 0.4, the two systems are considered inconsistent and not equivalent.

The Kappa coefficient is calculated as follows:

$Kappa = (P_A - P_e)/ (1 - P_e)$----------(1)

Where, P_A stands for "actual consistency rate" and P_e for "theoretical consistency rate". Taking Table 1 as an example, the calculation method is as follows:

$P_A = (a+d)/ (a+b+c+d)$---------- (2)

$P_e = [(a+b) (a+c) + (c+d) (b+d)]/ (a+b + c+d)2$---------- (3)

3. Result analysis

Statistical analysis

2x2 table for calculation of coincidence rate				
		Comparator method		Total
		Positive	Negative	
SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold) Rapid Detection Test	Positive	106	1	107
	Negative	4	239	243
	Total	110	240	350

Positive coincidence rate (Clinical sensitivity)	106/110	96.36%
Negative coincidence rate (Clinical specificity)	239/240	99.58%
Overall percent agreement (Accuracy)	345/350	98.57%

Positive coincidence rate (Clinical sensitivity): 106/110*100%=96.36%,
95% confidence interval: 90.95%～99.00%

Negative coincidence rate (Clinical specificity): 239/240* 100%=99.58%,
95% confidence interval: 97.70% ～99.99%

Overall percent agreement (Accuracy):345/350* 100%=98.57%,
95% confidence interval: 96.70%～99.53%

KAPPA value: 0.9666

4. Conclusion

In this evaluation, 350 pairs of NP and saliva samples were collected from individuals suspected of COVID-19. Based on the NP swab results, i.e. the comparator RT-PCR method, there were 110 positive samples and 240 negative samples. The comparison results are as follows:

Positive coincidence rate (Clinical sensitivity): 106/110*100%=96.36%,
95% confidence interval: 90.95%～99.00%

Negative coincidence rate (Clinical specificity): 239/240* 100%=99.58%,
95% confidence interval: 97.70% ～99.99%

Overall percent agreement (Accuracy): 345/350* 100%=98.57%,
95% confidence interval: 96.70%～99.53%

KAPPA value: 0.9666

In conclusion, SARS-CoV-2 ANTIGEN SALIVA TEST KIT (Colloidal Gold) Rapid Detection Test from Multibrands Trading (Suzhou) Co., Ltd. is highly consistent with the comparator reagent. Therefore, this product is safe and effective for the detection of SARS-CoV-2 antigen in human saliva samples.