

**SARS-CoV-2 Antigen Saliva Test Kit**  
**(Colloidal Gold Immunochromatography)**

**Diagnostic Sensitivity and Specificity Study Report**

**Final report date: 2020-12-18**

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## Study Director Signature and Verification Dates

**This study meets with the technical requirements of the protocol. The study also meets with technical specification for the test.**

**Study Director:** Wei Yang

**Signature:**

**Company:** Atlas Link Technology Co., Ltd

**Position:** Head of R & D Department

**Verification Dates:**2020-12-18

## Study Summary

The purpose of this study was to obtain accurate information about the diagnostic sensitivity and specificity of the SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography), and we have evaluated the clinical effects of the SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography). A total of 230 samples were tested by using BD Veritor™ System for Rapid Detection of SARS-CoV-2 produced by BD Biosciences. as control reagents, of which the diagnostic sensitivity of antigen detection is 97.4%; diagnostic specificity is 100.0%; overall agreement is 99.1%.

## 1. Purpose

To validate the diagnostic sensitivity and specificity of SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography).

## 2. Reference and Compliance

FDA guidance for In vitro diagnostic medical device

NMPA guidance

The present study conformed to all applicable laws and regulations

## 3. Materials

- Saliva collected by National Institute For Disease Control and Prevention (IVDC), Chinese Center for Disease Control and Prevention (China CDC)
- SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography), Lot. No: 20200518, Production Date: 2020-05-18.
- BD Veritor™ System for Rapid Detection of SARS-CoV-2 produced by BD Biosciences. (LOT: 500048916)

## 4. Study Design:

### 4.1 Making evaluation for patient saliva collected by IVDC, China CDC.

Subject was a patient admitted to the hospital due to a respiratory virus infection, total about 230 samples were collected.

### 4.2 Examiner and clinical laboratories

- IVDC, China CDC

### 4.3 Sample requirement:

All the samples were confirmed.

Samples were to be randomly chosen and double-blind labeled.

### 4.4 Test conduction:

All tests were performed by the clinical technicians in each clinical laboratory according to the manufacturer's instructions using the confirmed samples.

Visual interpretations of the results of SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography) were made independently by the clinical technician.

The testing center was responsible to summarize the result and send to Atlas Link.

## 5. Evaluation Criteria

Negative

If only the C band is present, the absence of any burgundy color in the test band

indicates that no SARS-CoV-2 antigen is detected in the specimen. The result is negative.

Positive

In addition to the presence of C band, if test band is developed, the test indicates for the presence of SARS-CoV-2 antigen. The result is positive.

Invalid

If no C band is developed, the assay is invalid regardless of any burgundy color in the test band as indicated below. Repeat the assay with a new device.

## 6. Results

230 samples were collected from selected subjects, all samples were tested with SARS-CoV-2 Antigen Saliva Test Kit and BD Veritor™ System for Rapid Detection of SARS-CoV-2 produced by BD Biosciences. Calculated the specificity and sensitivity, the results are as follows:

BD Veritor™	FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography)		
	Positive	Negative	Total
Positive	74	2	76
Negative	0	154	154
Total	74	156	230

Diagnostic Sensitivity:  $74/(2+74) \times 100\% = 97.4\%$  95% CI(90.9%~99.3%)

Diagnostic Specificity:  $154/(0+154) \times 100\% = 100.0\%$  95% CI(97.6%~100.0%)

Overall Agreement:  $(74+154)/230 \times 100\% = 99.1\%$  95% CI(96.9%~99.8%)

## 7. Conclusion

The clinical evaluation was carried out for the clinical performance of SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography). Total 230 samples were tested, of which the diagnostic sensitivity of antigen detection is 97.4%; diagnostic specificity is 100.0%; overall agreement is 99.1%.

## 8. Report

8.1 Original raw data is archived at Quality Control Department

8.2 The original final report is archived in Quality Control Department.