SARS-CoV-2 Antigen Rapid Test Kit

(Colloidal Gold Immunochromatography)

Diagnostic Sensitivity and Specificity Study Report

Final report date: **2020-05-13**

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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:2020-05-13

Study Summary

The purpose of this study was to obtain accurate information about the diagnostic sensitivity and specificity of the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography), and we have evaluated the clinical effects of the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography). A total of 150 samples were tested by using SARS-COV-2 R-GENE® - Real Time Detection kit produced by BioMérieux, and 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 91.4%-96.8%; diagnostic specificity is 97.5%-99.1%; overall agreement is 97.3%.

1. Purpose

To validate the diagnostic sensitivity and specificity of SARS-CoV-2 Antigen Rapid 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

- Nasal Swab collected by National Institute For Disease Control and Prevention (IVDC), Chinese Center for Disease Control and Prevention (China CDC)
- SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography), Lot. No: 20200323, Production Date: 2020-03-23.
- SARS-COV-2 R-GENE® - Real Time Detection kit produced by BioMérieux (LOT: 1007989610)
- 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 sera collected by IVDC, China CDC.**

Subject was a patient admitted to the hospital due to a respiratory virus infection, total about 150 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 Rapid 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

150 samples were collected from selected subjects, all samples were tested with SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) and SARS-COV-2 R-GENE® - Real Time Detection kit produced by BioMérieux. Calculated the specificity and sensitivity, in which SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) are positive, the results are as follows:

BioMérieux	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)		Total
	POS	NEG	
POS	32	3	35
NEG	1	114	115
Total	33	117	150

Diagnostic Sensitivity: 32/(3+32)×100%=91.4%
Diagnostic Specificity: 114/(1+114)×100%=99.1%
Overall Agreement: (32+114)/150×100%=97.3%

150 samples were collected from selected subjects, all samples were tested with 2 SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) 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 Biosciences	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)		Total
	POS	NEG	
POS	30	1	31
NEG	3	116	119
Total	33	117	150

Diagnostic Sensitivity: 30/(1+30)×100%=96.8%
Diagnostic Specificity: 116/(3+116)×100%=97.5%
Overall Agreement: (30+116)/150×100%=97.3%

7. Conclusion

The clinical evaluation was carried out for the clinical performance of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography). Total 150 samples were tested, of which the diagnostic sensitivity of antigen detection is 91.4%-96.8%; diagnostic specificity is 97.5%-99.1%; overall agreement is 97.3%.

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.