SARS-CoV-2 Antigen Rapid Test Kit

(Colloidal Gold Immunochromatography)

Analytical sensitivity 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: 5.1.2e

Signature: 5.1.2e

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

Position: 5.1.2e

Verification Dates:2020-05-13

Study Summary

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) could identify all the positive samples and showed similar sensitivity as the standards panel: SARS-CoV-2 Antigen Panel (370095-202001).

The Limit of Detection (LoD) of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) study was established by using limiting dilutions. Result prove that the LoD of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) is 50 $TCID_{50}$/mL. Under this dilution 100% specimen are detected. The N-protein control Study also prove that 200pg/mL is LoD of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography).

1. Purpose

To validate that if SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) could reach similar sensitivity as the SARS-CoV-2 Antigen Panel (370095-202001). To ensure limit of Detection (LoD) with virus culture and N-protein standard.

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

- SARS-CoV-2 Antigen Panel (370095-202001)
- SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography), Lot No.: 20200323, Production Date: 2020-03-23
- SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography), Lot No.: 20200324, Production Date: 2020-03-24
- SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography), Lot No.: 20200325, Production Date: 2020-03-25
- virus culture
- N-protein
- Assay diluent, Lot No.: 20200323, 20200324, 20200325.

4. Study Design:

Test three different Lots of the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) with SARS-CoV-2 Antigen Panel (370095-202001).Results were recorded to verify the sensitivity should be same as standard Panel.

Test random Lot of the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) with treated virus cultures. The material was supplied at a concentration of 2.5×10^5 $TCID_{50}$/mL. Dilute material into a series of concentrations and tested using SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) and observe the number of positive specimen in total. Each dilution tested in 20 times. The lowest result considered as LoD.

Dilute COVID-19 N-protein standard into a series of concentrations and tested using SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) and observe the number of positive specimen in total. Each dilution tested in 20 times. The lowest result considered as LoD.

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.

Positive（+++）：Both C and T lines appear regardless of color intensity. T line strong.

Positive（++）：Both C and T lines appear regardless of color intensity. T line medium.

Positive（+）：Both C and T lines appear regardless of color intensity. T line weak.

Invalid:

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

6. Results

Table 1- Results of sensitive compared with panel

SARS-CoV-2 Antigen Panel (370095-202001)	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)		
	20200323	20200324	20200325
P1	+++	+++	+++
P2	+++	+++	+++
P3	+++	+++	+++
P4	++	++	++
P5	++	++	++
P6	++	++	++
P7	+	+	+
P8	+	+	+
S1	++	++	++
S2	+	+	+
S3	+	+	+
S4	+	+	+
R1	++	++	++
R2	+	+	+

Table 2-Results of $TCID_{50}$(Lot: 20200323)

Starting Material Concentration	Diluent Concentration				
$2.5*10^5$ $TCID_{50}$/mL	200	150	100	50	25
POS/Total	20/20	20/20	20/20	20/20	14/20

Table 3-Results of $TCID_{50+}$(Lot: 20200323)

	Diluent Concentration				
Concentration of nCoV-19 N-protein control	5ng/mL	1ng/mL	0.5ng/mL	0.2ng/mL	0.1ng/mL
POS/Total	20/20	20/20	20/20	20/20	13/20

7. Conclusion

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) could identify all the positive samples and showed similar sensitivity as the standards panel: SARS-CoV-2 Antigen Panel (370095-202001).

The limit of Detection (LoD) of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) study was established by using limiting dilutions. Result prove that the LoD of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) is 50 $TCID_{50}$/mL. Under this dilution 100% specimen are detected. The N-protein control study also prove that 200pg/mL is LoD of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography).

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.