Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold Immunochromatography)

Diagnostic Sensitivity and Specificity Study Report

Final Report Date: 2020-12-18

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Signature of Study Director and Verification Dates

This study meets the technical requirements of the protocol, also meets the technical specifications for the test

Study Director: Wei Yang

Signature: 

Company: Atlas Link Technology Co., Ltd

Position: Head of R&D Department

Verification Date: 2020-12-18

Study Summary

The aim of this study was to obtain the accurate information on the diagnostic sensitivity and specificity of the Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold Immunochromatography), and to evaluate its clinical effects. cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit produced by GenScript was used as control reagents to test 150 samples. The diagnostic sensitivity of neutralizing antibody detection was 100%, diagnostic specificity was 100%, and the overall consistency was 100%.

1. Purpose

To verify the diagnostic sensitivity and specificity of Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold Immunochromatography).

2. Reference and Compliance

FDA Guidance for In Vitro Diagnostic Medical Device

NMPA Guidance

This study conforms to all applicable laws and regulations.

3. Materials

- Patient serum/plasma/Whole Blood specimens collected by Professional certified laboratory
- Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold Immunochromatography), Lot No.: 20201012, Production Date: 2020-10-12.
- cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit produced by GenScript (Lot No.: L00847)

4. Study Design:

1) Making evaluation for the individuals sera collected by certified laboratory.

- All individuals are non-infected with SARS-CoV-2.
- A total of about 150 samples were collected.

2) Examiner and Clinical Laboratories:

- Clinical Laboratory Department, the Second Affiliated Hospital, Chongqing Medical University, PRC.

3) **Sample Requirements:**

- All the samples were confirmed.
- Samples were randomly selected and double-blind labeled.

4) Test Conduction:

- All tests were performed by clinical technicians in each clinical laboratory according to the manufacturer's instructions on using confirmed samples.
- Visual interpretations of the results of Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold Immunochromatography).
- The testing center was responsible for summarizing the results and sending them 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 Neutralizing Antibody 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 Neutralizing Antibody . 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.

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
Negative (-) : Only C band appears.

6. Results

150 individuals, who were not infected with SARS-CoV-2 virus, were selected for clinical trial. The test was performed by the medical devices, which had been authorized by an Emergency Use Authorization (EUA): cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit produced by GenScript and Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold Immunochromatography). The results of the first test were as follows:

First neutralizing antibodies test for 150 individuals		
Result	GenScript	AtlasLink
Positive	0	0
Negative	150	150

30 individuals, who had been received treatment by the coronaVac vaccine produced by Sinovac were selected for a double-blind test. All individuals took a second neutralizing antibody test 10 days after the clinical trial to calculate the specificity and sensitivity. The results were as follows:

Second neutralizing antibodies test for 150 individuals				
Vaccination individuals		Test result	GenScript	AtlasLink
Accepted	30	Positive	29	29
Unaccepted	120	Negative	121	121
Total	150	Total	150	150

Diagnostic Sensitivity: 29/29×100%=100% 95%CI (88.3%~100%)

Diagnostic Specificity: 121/121×100%=100% 95%CI (96.9%~100%)

Overall Consistency: (29+121)/150×100%=100% 95%CI (97.5%~100%)

7. Conclusion

The clinical performance of Vaperon^{TM} SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold Immunochromatography) was evaluated. A total of 150 samples were tested, of which the diagnostic sensitivity of antibody detection was 100%, the diagnostic specificity was 100% and the overall consistency was 100%.

8. Report

1) Original raw data is archived in Quality Control Department.
2) Original final report is archived in Quality Control Department.