# Clinical Performance Evaluation Report

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**Product Name:** SARS-CoV-2 Antigen Kit (Colloidal Gold)

**Manufacturer:** Goldsite Diagnostics Inc.

**Test Category:** Comparison Experiment

**Institute:** Shenzhen Center for Disease Control and Prevention

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# SARS-CoV-2 Antigen Kit (Colloidal Gold)

**Institute:** Shenzhen Center for Disease Control and Prevention (hereinafter referred to as Shenzhen CDC)

**Assay for evaluation:** SARS-CoV-2 Antigen Kit (Colloidal Gold)

**Comparator reagents:** Novel Coronavirus (2019-nCoV) Nucleic Acid Detection Kit (PCR-Fluorescence Probing) (Shanghai BioGerm Medical Biotechnology Co., Ltd.)

**Date:** 2020/4/23- 2020/11/05

## 1. Abstract

**1** Purpose: To evaluate the clinical performance of SARS-CoV-2 Antigen Kit (Colloidal Gold) from Goldsite Diagnostics Inc. by method comparison studies using clinical samples.

**2** Design: Prospective comparative clinical study.

**3** Statistics: The clinical performance of SARS-CoV-2 Antigen Kit (Colloidal Gold) was determined by testing nasal and nasopharyngeal swabs from 370 persons suspected of COVID-19. The samples were collected within 7 days post onset of symptoms or suspected exposure. For each individual, two swabs were collected. The first nasal swab was tested directly with SARS-CoV-2 Antigen Kit (Colloidal Gold) at the site. The second, a nasopharyngeal swab was placed in virus transport medium, shipped to laboratory, and determined to be positive or negative using an NMPA (National Medical Products Administration, China) approved RT-PCR method, i.e., the comparator method.

**4** Results: The result comparison between the two methods showed that the clinical performance of SARS-CoV-2 Antigen Kit (Colloidal Gold) were: Positive coincidence rate (Clinical sensitivity): 93.04%, 95% confidence interval: 86.75% - 96.95%; Negative coincidence rate (Clinical specificity): 100.00%, 95% confidence interval: 98.56% - 100.00%; Overall percent agreement: 97.84%, 95% confidence interval: 95.78% - 99.06%. The mean Ct value of the positive specimens is 22.6 and stratification of the positive specimens with Ct values ≤ 33 has a detection rate (sensitivity) of 93.46% and Ct values ≤ 25 has a detection rate (sensitivity) of 94.87%.

**5** Conclusion: Good consistency was proved in direct detecting of SARS-CoV-2 between the SARS-CoV-2 Antigen Kit (Colloidal Gold) from Goldsite Diagnostics Inc. and the comparator reagent.

## 2. Test Design

### 1 Sample Collection and Testing (prospective study)

From 2020/4/23 to 2020/11/05, a total of 370×2 swab samples were collected from patients suspected of COVID-19 who provided informed consent for their samples to be used for research purpose. The samples were collected within 7 days post onset of symptoms (ranging from mild to moderate) or suspected exposure. For each individual, two swabs were collected. The first one was a nasal swab and was tested directly at the

collection site with SARS-CoV-2 Antigen Kit (Colloidal Gold). The second swab was a nasopharyngeal swab which was then placed in virus 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 Kit (Colloidal Gold) | 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：

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

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

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

$$P_e = [(a+b) (a+c)+(c+d) (b+d)]/ (a+b+c+d)^2 \quad (3)$$

According to antigen test evalution protocol in WHO FINDdx website, the detection rate (sensitivity) of the postive samples were further statified in relation with their PCR ct values and the mean Ct value of the postive samples was documented.

## 3. Result analysis

| 2 × 2 table for calculation of coincidence rate | | | | |
|---|---|---|---|---|
| | | Comparator reagents | | Total |
| | | Positive | Negative | |
| SARS-CoV-2 Antigen Kit (Colloidal Gold) | Positive | 107 | 0 | 107 |
| | Negative | 8 | 255 | 263 |
| | Total | 115 | 255 | 370 |

| | | |
|---|---|---|
| Positive coincidence rate (Clinical sensitivity) | 107/115 | 93.04% |
| Negative coincidence rate (Clinical specificity) | 255/255 | 100.00% |
| Overall percent agreement (Accuracy) | 362/370 | 97.84% |

Positive coincidence rate (Clinical sensitivity): 107/115*100%=93.04%,

95% confidence interval: 86.75% - 96.95%

Negative coincidence rate (Clinical specificity): 255/255 * 100% = 100.00%,

95% confidence interval: 98.56% - 100.00%

Overall percent agreement (Accuracy): 362/370*100%=97.84%,

95% confidence interval: 95.78% - 99.06%

KAPPA value: 0.9485, 95% confidence interval: 0.9133 - 0.9838

The positive results stratified by the Ct values of PCR were as follows:

| Ct value | Number of samples | Antigen detected (+) | Sensitivity |
|---|---|---|---|
| Ct ≤ 33 | 107 | 100/107 | 93.46% |
| Ct ≤ 25 | 78 | 74/78 | 94.87% |
| Total ($Ct_{mean}$ = 22.6) | 115 | 107/115 | 93.04% |

## 4 Conclusion

In this evaluation, 370 pairs of swab samples were collected from individuals suspected of COVID-19. Based on the RT-PCR results, i.e. the comparator method results, there were

115 positive samples and 255 negative samples. The comparison results are as follows:

Positive coincidence rate (Clinical sensitivity): 93.04%, 95% confidence interval: 86.75% - 96.95%; Negative coincidence rate (Clinical specificity): 100.00%, 95 confidence interval: 98.56% - 100.00%; Overall percent agreement (Accuracy): 97.84%, 95% confidence interval: 95.78% - 99.06%; KAPPA: 0.9485, 95% confidence interval: 0.9133 - 0.9838. The mean Ct value of the positive samples is 22.6 and stratification of the positive samples with Ct values ≤ 33 has a detection rate (sensitivity) of 93.46% and Ct values ≤ 25 has a detection rate (sensitivity) of 94.87%.

In conclusion, the SARS-CoV-2 Antigen Kit (Colloidal Gold) from Goldsite Diagnostics Inc. is highly consistent with the comparator reagent. Therefore, this product is safe and effective for the detection of SARS-CoV-2 antigen in human nasal swab samples.