

Novel Coronavirus Antigen Detection Kit (Colloidal Gold)

Clinical Study Report

Abstract

Name of IVD: Novel Coronavirus Antigen Detection Kit (Colloidal Gold)

REF: COVID-19/NG02 / CODE 88021 / NEWGENE2

Specifications: 25 Tests/Box

Report Date: August 29th, 2020

Summary

The Novel Coronavirus Antigen Detection Kit (Colloidal Gold) can quickly and qualitatively detect the nucleocapsid protein of novel coronavirus (SARS-COV-2) in human sputum/stool samples. It can be used as a supplementary test for COVID-19 diagnosis. According to the clinical trial plan, the Novel Coronavirus Antigen Detection Kit (Colloidal Gold) or “test reagent”, is to test sputum/stool samples from COVID-19 suspects. Test results are compared with another commercial SARS-COV-2 nucleic acid detection kit with NMPA approval, which is defined as the “gold standard”. The sensitivity, specificity, and total agreement rate are used to evaluate the reliability of the test reagent in clinical applications. Method: A collection of clinical samples are examined by the test reagent and the gold standard in parallel, to calculate the clinical sensitivity, clinical specificity, and total agreement rate of the test reagent. Standard of criteria for a qualified test reagent: Clinical sensitivity $\geq 90\%$, clinical specificity $\geq 90\%$, and total agreement rate $\geq 90\%$.

Results

Compared to the gold standard, **the clinical sensitivity of test reagent is 96.0%, the clinical specificity is 97.0%, and the total agreement rate is 96.7%.**

Conclusion

Compared to the gold standard reagent, the test reagent has reliable performance in diagnosing COVID-19 cases. The sampling method with Sputum sample is relatively easy for detection of the virus. Because of the uneven distribution of the virus on the nasopharyngeal mucosa appearance, it is likely that no virus or very small amount of virus is taken while sampling and lead to false negative results, when sampling with throat swab. Therefore the accuracy of throat swab sampling is lower than with sputum sampling.