



**GOLDSITE**



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

**PHONE:012-684 2078**

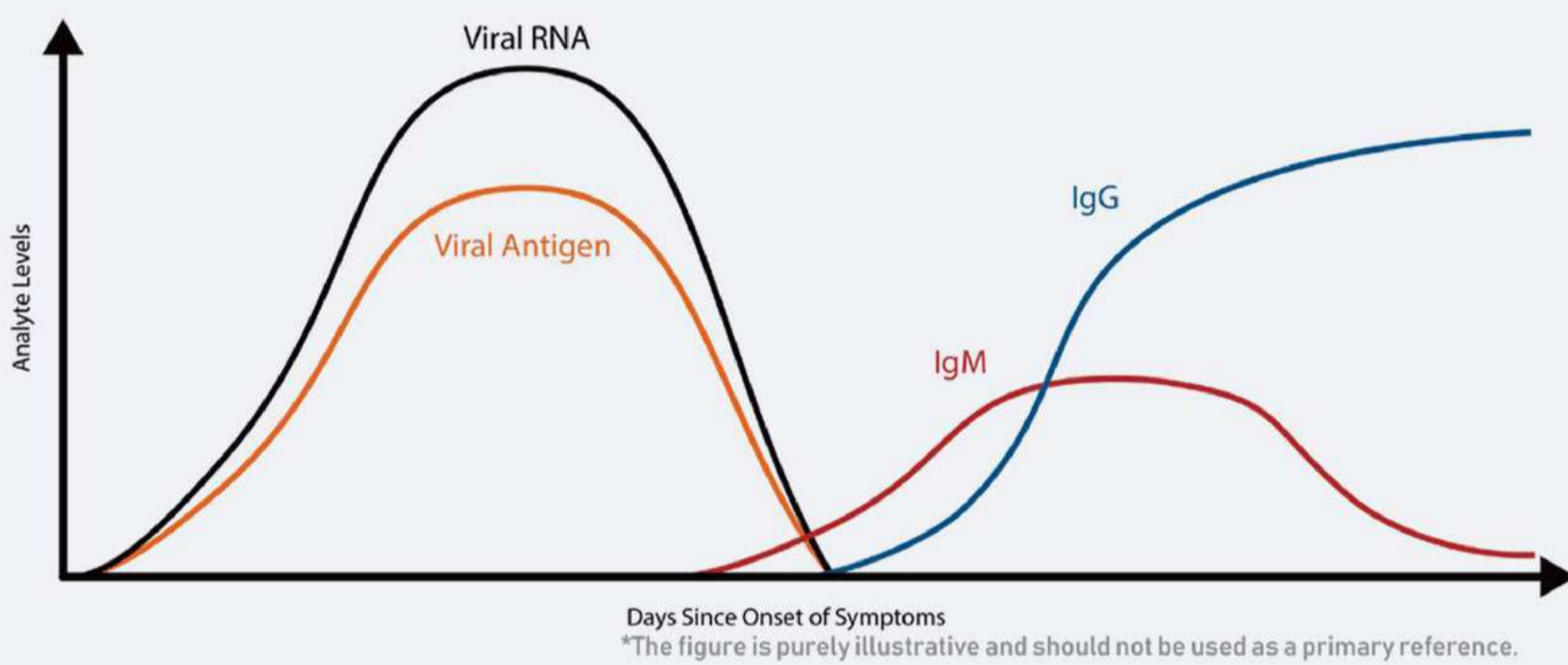
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Goldsite Diagnostics Inc.

## ABOUT THE KIT

SARS-CoV-2 Antigen Test is used for detection of proteins from the virus that causes COVID-19. A positive result indicates the presence of viral antigens, implying current viral infection. Like RT-PCR test, the antigen test also detects the virus directly, and performs best when the person is tested in the early stages of infection with SARS-CoV-2. The antigen test is very specific, indicating that a positive result is highly accurate. Compared with RT-PCR test, the antigen test is much easier, affordable, and faster.

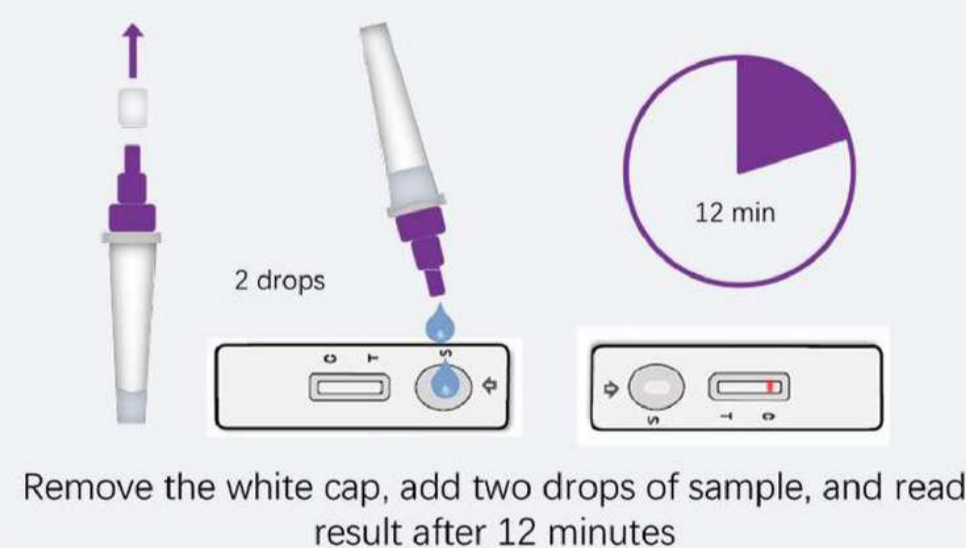
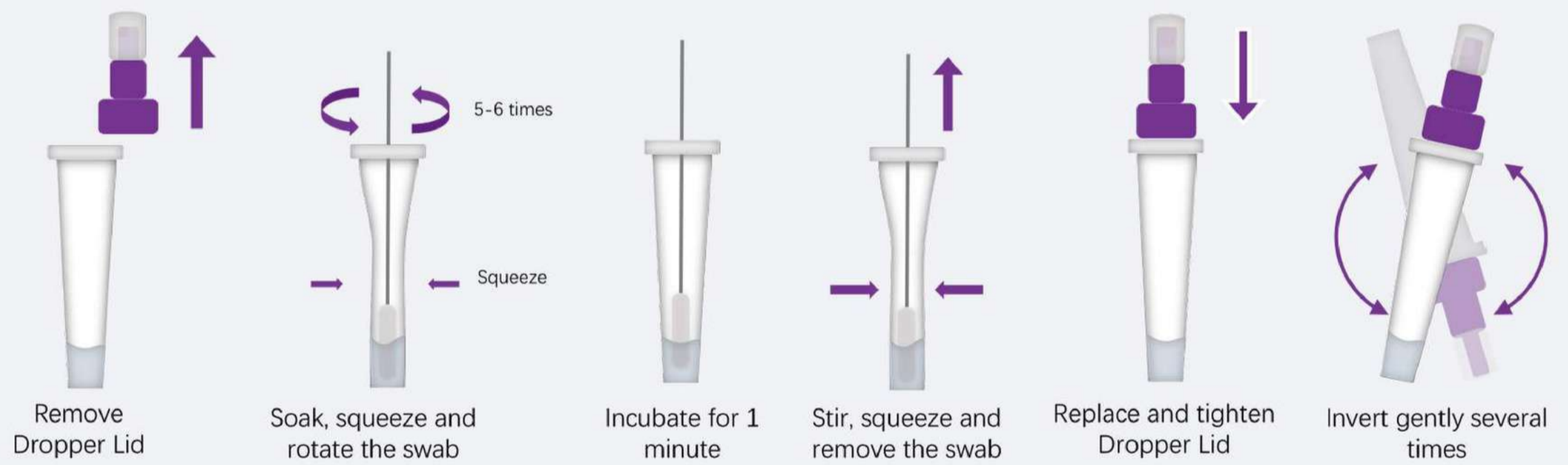


## METHOD OF TESTING

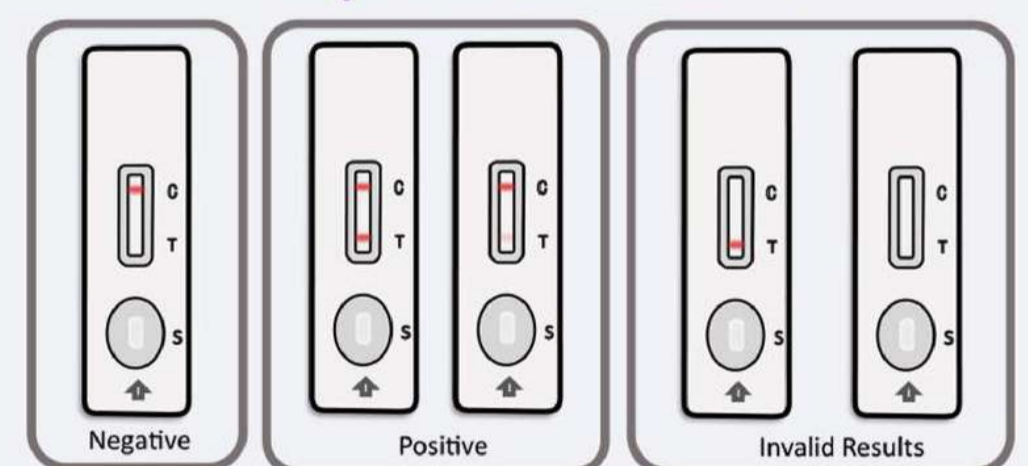
12 mins waiting time

Nasal  
Nasopharyngeal  
Oropharyngeal  
swabs acceptable

Room temperature  
storage



### Interpretation of Results



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

## LAB REPORT

### TECHNICAL REPORT

Page 7 of 8



**LABORATORY ADDRESS:**  
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**HEAD OF LABORATORY:** Sazaly Abu Bakar, Ph.D., FASc

**Table 1.** Detection of SARS-CoV-2 antigen in nasal swab samples using the Goldsite SARS-CoV-2 Antigen Kit.

Tested Device		Real-time RT-PCR		
		Pos	Neg	Total
	Pos	29	0	29
	Neg	1	30	31
Total		30	30	60

**Table 2.** Analysis of SARS-CoV-2 antigen detection using the Goldsite SARS-CoV-2 Antigen Kit on nasal swab samples.

Ct value	Pos	Neg	Sensitivity (95% CI) <sup>a</sup>	Specificity (95% CI)	PPV <sup>b</sup> (95% CI)	NPV <sup>c</sup> (95% CI)	Concordance (Kappa value, κ)
< 30	29	31	96.7% (83.3-99.4)	100% (88.6-100)	100% (88.3-100)	96.8% (83.8-99.4)	0.967 (p<0.001)

<sup>a</sup> Confidence Interval; <sup>b</sup> Positive predictive value; <sup>c</sup> Negative predictive value

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Page 4 of 8



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REPORT TS4-0519-R

Evaluation of COVID-19 In Vitro Diagnostics Medical Devices

#### Product Details

Product: Goldsite SARS-CoV-2 Antigen Kit  
Product code: CG123025  
Lot number: 20210415  
Manufacturer: Goldsite Diagnostic Inc. China  
Requested by:  
Address:

Contact number:  
Email:  
Date of request: 14<sup>th</sup> September 2021  
Type of sample tested: Nasal swab  
Intended use: Professional use

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Page 8 of 8



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#### 4. Conclusion

Evaluation of the Goldsite SARS-CoV-2 Antigen Kit was successfully completed. The device showed that it was able to detect the presence of SARS-CoV-2 antigen in the tested nasal samples with 96.7% sensitivity and 100% specificity.

#### Disclaimer

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## VALIDATED BY

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