BIOBASE®

BIOBASE CHINA

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





O.E.

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Introduction:

Rapid detection of antigen refers to the application of new coronavirus nucleocapsid protein-specific antibodies in the direct detection of pathogens in a sample, the result can be used as direct evidence of early identification of infection the pathogen or not, detecting a rapid (15min), convenient operation of the New coronavirus detection method. Applicable scenarios:

Weak nucleic acid detection capabilities, insufficient detection capabilities, and places where urgent results are needed. It has been widely used in Europe, America, Asia, Africa and other regions, and together with nucleic acid testing has become an important detection method for the prevention and control of the COVID-19 epidemic.

dvantage:

New Coronavirus antigen detection can directly detect whether the human body contains New Coronavirus, which can be detected at the early stage of virus infection. It is fast, accurate, and requires less equipment and personnel. Using double antibody sandwich method and using two antigen specific antibodies to identify and combine different epitopes of a target antigen, it can greatly reduce the number of cross reactions. So as to improve its specificity.

Features:

- * Independent packaging, more flexible.
- * The use of nasopharyngeal swab.

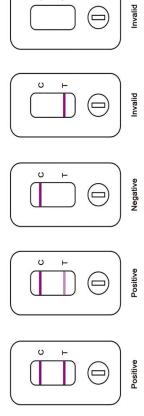
* High accuracy.* Easy to use.

* Rapid detection :15 minutes out of the results.

Sample Collection:
Sample Testing:

The Results of Judgment:

Positive: T-line and C-line present within 15-20 minutes after sample addition.
Negative: only C-line, no T-line, occurs within 15-20 minutes after dropping the sample.
Invalid: As long as there is no line C, this test card is invalid. Please use another test card to retest.



The results are summarized in the following table. The RT-PCR cycle threshold (Ct) is the relevant signal value. Lower Ct value indicate higher viral load. The sensitivity was calculated for the different Ct value range (Ct values33 and Ct values37).

SARS-CoV-2	RT-PCR (Ct values33)		Total	
Antigen	Positive	Negative		
Positive	152	8	155	
Negative	5	601	909	
Total	157	604	761	
Sensitivity (Ct≤33): 96.8% (152/157), (95%CI: 92.8%~98.6%)), (95%CI: 92.8%~98.6%)			
Specificity: 99.5% (601/604), (95%CI: 98.6%~99.7%)	OI: 98.6%~99.7%)			
Accuracy: 98 9%((152+601)/761) (95%CI: 98 2%~99 5%)	95%CI: 98 2%~39 5%)			

Technical Parameters

Product Name	Product Name Main Composition	Testing Time	Testing Time Dimensions	Net Weight	Kit Size	Net Weight Kit Size Package Size Gross Weight	Gross Weight
SARS-CoV-2	SARS-CoV-2 Test card, Sample				20T/box		
Antigen Test Kit	Antigen Test Kit extraction buffer,	15-20min	205*120*75mm	0.3kg	16 boxes	840*560*260mm	14kg
(Colloidal Gold)	(Colloidal Gold) Nasal swab or Throat swab				/carton		