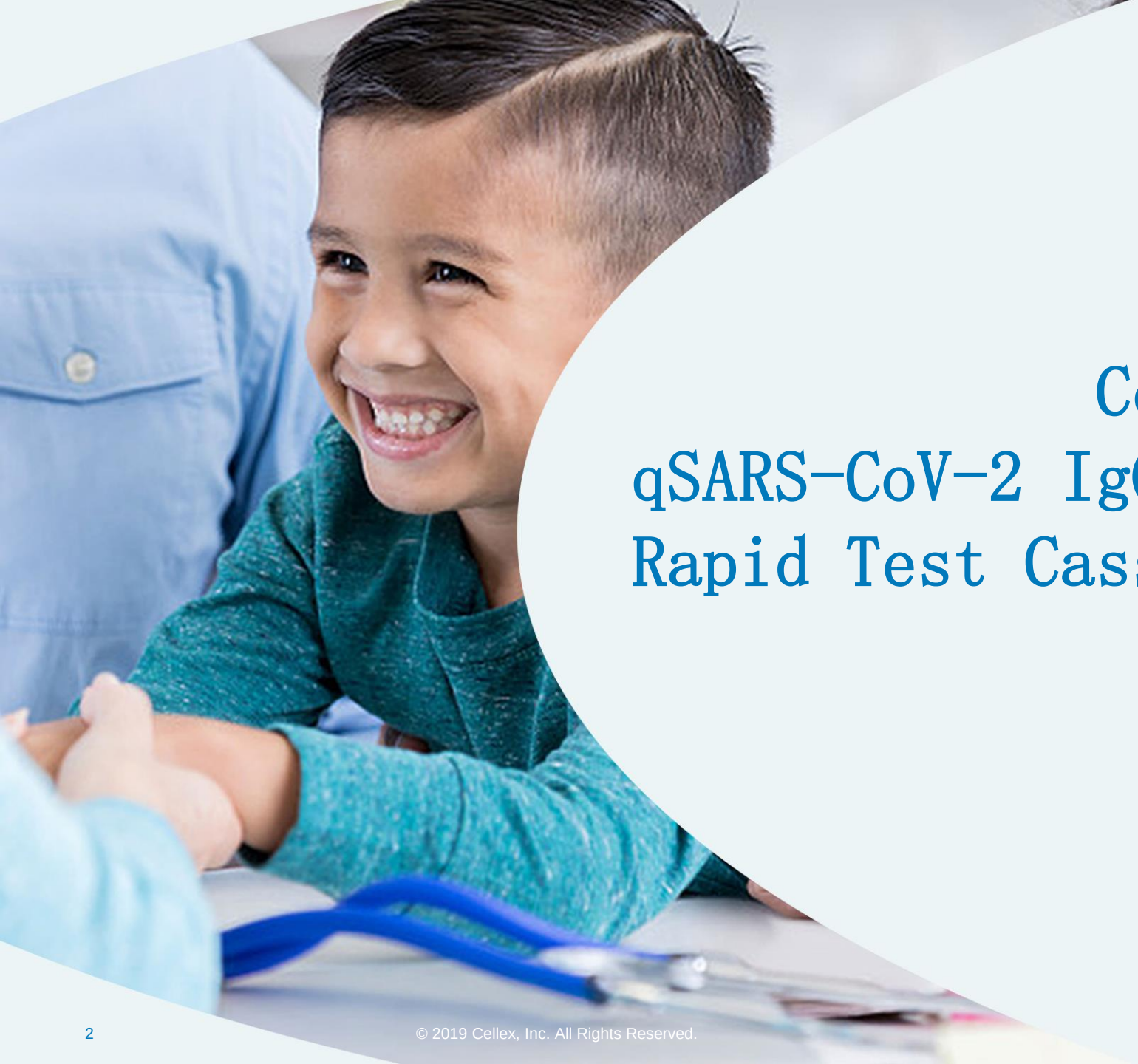
Cellex



Cellex qSARS-CoV-2 IgG/IgM Rapid Test Cassette

Name of Virus & Disease

SARS stands for severe acute respiratory syndrome.

CoV is an abbreviation for Coronavirus.

The virus that caused SARS in 2003 was named SARS-CoV.

SARS-CoV-2： On February 11, ICTV officially identified the new coronavirus as a sister virus associated with SARS-CoV, based on phylogeny, taxonomy, and existing practices associated coronavirus and named it SARS-CoV-2. Previously, CSG had evaluated and tentatively named the virus 2019-nCoV.

COVID-19： Coronavirus disease 2019 is a name for the disease, including what is currently called neo-coronary pneumonia and other symptoms caused by the virus infection.

Virus-specific antibody detection is a powerful complement to nucleic acid detection

In the past virus epidemic prevention and control process, there are many examples of immunodiagnostic reagents as auxiliary diagnosis:

- In 2003's SARS, Chinese Academician Zhong Nanshan mentioned that "combination with specific diagnostic methods (coronary virus RT-PCR, ELISA, IgG and IgM immunofluorescence detection) should be considered."
- In the second edition of the H7N9 Avian Influenza Diagnosis and Treatment Program in 2013, it was clearly stated that screening for viral antigens could be used as a preliminary screening method.
- In the second edition of the Zika virus disease diagnosis and treatment plan in 2016, the detection of IgM antibodies was explicitly used as a means of diagnosis and identification.

If the new coronavirus (SARS-COV-2) IgM/IgG antibody diagnostic reagent can be used to screen patients with new coronavirus infections as soon as possible, it will be helpful to stop the spread of the current epidemic.

Related Test of COVID-19

Suggested instrument when suspected COVID-19 patient enters medical system
Screening stage Immune detection and POCT for fast screening
Diagnosis stage Nucleic acid detection by fluorescent quantitative PCR instrument and Gene sequencer, etc
Treatment stage Instrument used for the monitoring of treatment process and prognosis monitoring, and instrument for systemic response detection after virus stimulation, such as pulmonary embolism detection equipment, coagulometer, blood gas analyzer, etc.
SARS-CoV-2 virus test method Nucleic acid detection: gene sequencing and real-time fluorescence quantitative PCR (rt-PCR). Immunoassay: Detection of viral antigens and antibodies (IgM/IgG); Colloidal gold, immunofluorescence chromatography, chemiluminescence, etc; POCT, high-throughput automatic detection platform;
Experts call for IgM/IgG screening A. There are immuno kits based on different methodologies and flexible applications, including immunocolloid gold, ELISA, chemiluminescence immunoassay(CLIA), etc .; B. IgM detection is featured by strong specificity and high diagnostic accuracy, which is conducive to early diagnosis and exclusion of suspicious cases; C. Immuno kits are affordable, fast and massive samples operation than PCR and gene sequencing; D. Rapid tests are sensitive, stable, reproducible, easy to operate and good for massive screening. E. The test specimen is serum, plasma and whole blood.

Nucleic acid testing as "gold standard"

Usually we say that nucleic acid test is the "gold standard" for confirming an infection. This "gold standard" is only for "positive" results.

As for false positives, it is usually caused by cross-contamination between specimens or contamination of laboratory amplification residual during lab operation. At present, the quality control strategy “three negative samples are randomly tested together with clinical samples at the same time.” Under the “full process” is adopted in China, so false positive results can be effectively avoided, which is also the basis for "positive" results confirmation.

If the test result is "negative", it cannot be used as a "gold standard" to tell if the patient is infected.

"False negative" of nucleic acid test is inevitable

To detect an infected patient by nucleic acid method, the following four conditions must be met at the same time:

A. There is a certain amount of virus in the cells of the infected person: but for a specific patient suspected of infection, the concentration of the virus in different parts of the body at different stages of disease will vary;

B. Virus-containing cells should be collected during specimen collection: the training of specimen collection personnel needs to be strengthened.

C. Reliable reagent: By conducting research on the evaluation of reagent detection performance at the national level and discussing the existing problems, the quality of reagents and the sensitivity of analysis can be further improved. In addition, the clinical laboratory can perform pre-use quality inspection on several batches of reagents with known negative and positive samples stored, which is also an effective measure. However, the analytical sensitivity of the reagent is limited, and the amount of virus in the sample is lower than a certain level, so the reagent cannot be detected.

D. Standardized clinical laboratory: Specimen transportation and storage conditions, standardized operation of clinical laboratories, interpretation of results, and quality control are also key factors to ensure accurate and reliable test results.

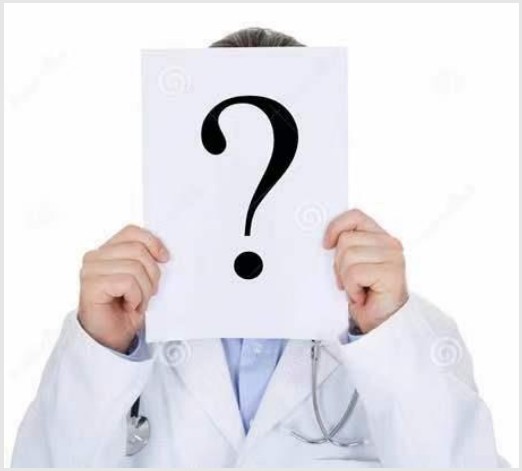
Precautions for detection of IgM and IgG antibodies

Antibody testing has low requirements for clinical laboratory operations, can be performed quickly and in large quantities, and can be completed in small and medium laboratories, which is of great significance for effectively controlling the large-scale transmission of new coronaviruses.

Antibody detection is susceptible to the presence of some interfering substances in the blood sample (such as rheumatoid factor, non-specific IgM, high concentration of hemoglobin caused by hemolysis, etc.) and a "false positive" result appears.

Antibody detection is suggested by performing both IgM and IgG test. And usually multiple dynamic detection is required for confirmation.

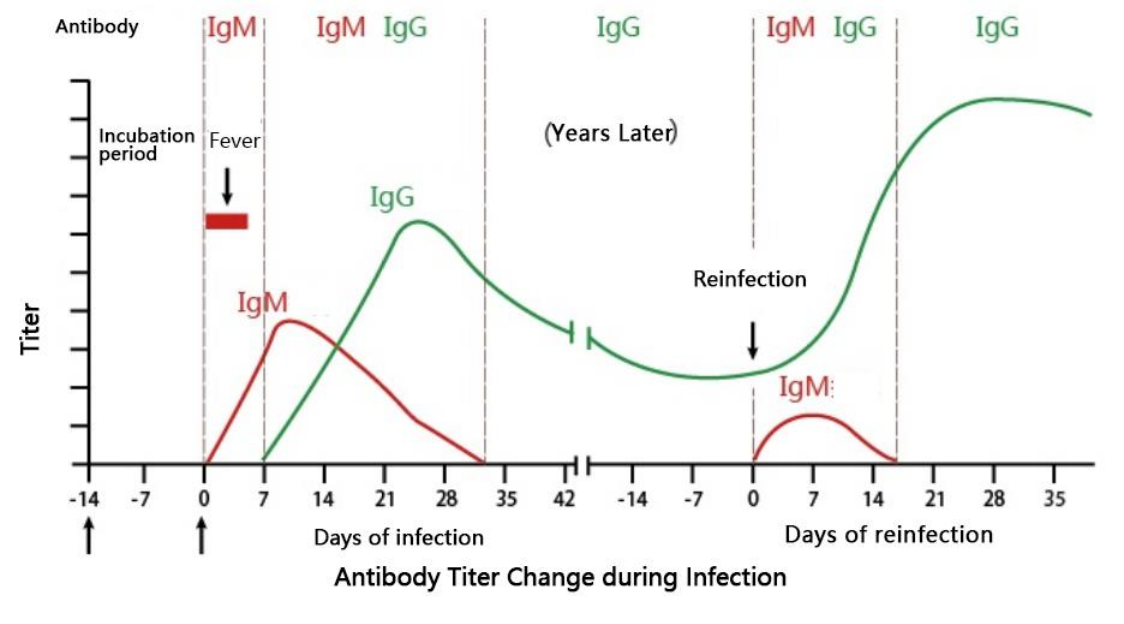
Applicable scenario of Cellex SARS-CoV-2 IgM/IgG rapid test cassette



Whether the patient "has been recently or previously infected with a new coronavirus?"

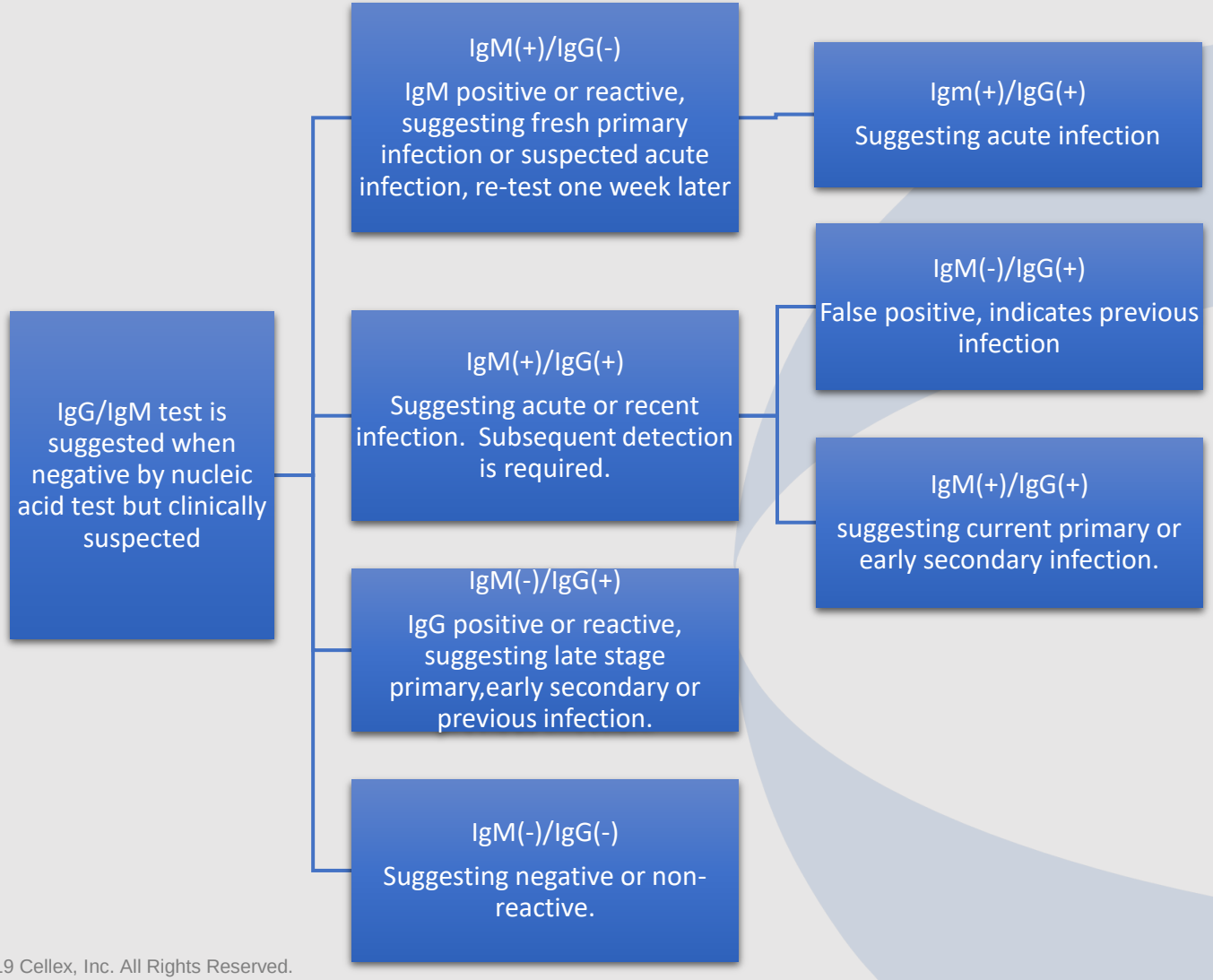
- Rapid test can assist in the confirmation when there is negative by nucleic acid detection but clinically suspected
- Screening for suspected infection
- Screening for mild or asymptomatic syndrome
- Screening for high-risk population after quarantine
- ……

Virus-specific antibody detection is a powerful complement to nucleic acid detection



Antibodies are the products of a humoral immune response after the body is infected with a virus. Generally, IgM antibodies appear early in the infection, and IgG antibodies appear in the middle and late stages of the infection. There is a continuous increase in the titer and it remains in the blood circulation for a long time.

IgM/IgG detection procedure and interpretation of results



Cellex SARS-CoV-2 specific IgM/IgG rapid test cassette

Cellex SARS-CoV-2 specific IgM and IgG antibody rapid test cassette is a lateral flow immunoassay for the qualitative detection of SARS-CoV-2 in serum, plasma or whole blood specimens. It is intended for use as a screening test and aid in the diagnosis of SARS-CoV-2 viral infections.

Clinical Performance		Reference PCR		Total
		+	-	
Cellex RDT	+	26	1	27
	-	4	9	13
Total		30	10	40

A total of 40 patient samples from susceptible subjects were tested by the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test and by a commercial PCR. Comparison for all subjects is shown in the table.
Relative Sensitivity: 86.7%.
Relative Specificity: 90%.
Overall Agreement: 87.5%.

Advantages of Cellex SARS-CoV-2 IgM/IgG rapid test cassette

- 15 minutes to get result, quick and convenient
- Sample type: serum, plasma or whole blood
- Easy sample collection and operation in clinics, medical lab and hospitals
- IgM/IgG antibodies detection in one time if both are presented in specimen
- Incubation period: IgM reaches peak in one week after infection and IgG in three weeks.
- Affordable for all medical units
- Accuracy upto 85% for positive detection
- To provide guidance treatment and monitoring
- To provide epidemiologic information for CDC

Product package

Product Name	Pack Size	Specimen type	Shelflife	Storage
qSARS-CoV-2 IgM/G Rapid Test Cassette	25 T	Serum/Plasma/Whole Blood	18months	4-30℃

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