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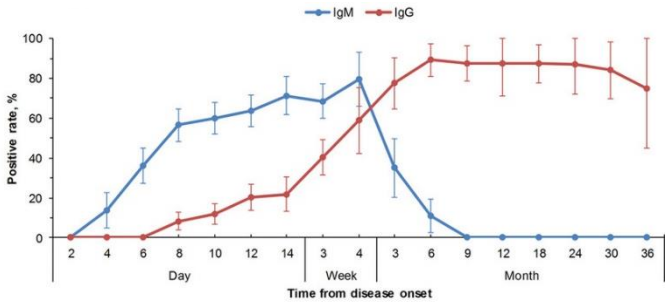
SGTi-flex COVID-19 IgM/IgG

WHY must IgM & IgG test

- COVID-19, speedy and sustainable community spread even without identifying exactly who and how to spread.
- COVID-19, onset of disease without or with very mere symptom but still highly infective and this can be extended up to 1 month.
- So, COVID-19 the RT-PCR searching for genetic material of virus from patient's nasal of oral swab could show very limited sensitivity (even less than 30% for the previous corona case*) and huge drawback.

HOW great IgM & IgG test

- Every COVID-19 patients without exception 100% generates very specific antibody against corona virus, SARS-CoV-2.
- COVID-19 virus specific IgM the first antibody, detected before 1 week of onset and IgG follows. If both analyzed, strong and sustainable diagnosis capability can be secured.



<Kinetics of Seroconversion for IgM and IgG>

Strength of **Sugentech SGTi-flex COVID-19 IgM/IgG**

[Outstanding performance]

TOTAL		RT-PCR	
		Pos	Neg
SGTi-flex COVID-19 IgM/IgG	Pos	47	4
	Neg	3	96
	Total	50	100

Accuracy	Kappa
95.3 %	0.90

Total Enroll	150	Sensitivity	Specificity
		94 %	96 %

Reference

- Kinetics of Severe Acute Respiratory Syndrome (SARS)Coronavirus-Specific Antibodies in 271 Laboratory-Confirmed Cases of SARSCLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY, July 2004
- Clinical progression and viral load in a community outbreak of coronavirus-associated SARS pneumonia: a prospective study. THE LANCET • Vol 361 • May 24, 2003
- Antibody responses in COVID-19 patients, preprint in the progress of review https://doi.org/10.1101/2020.03.02.20030189
- WHO guideline in the MERS
- https://www.cdc.gov/coronavirus/2019-ncov/about/testing.html

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Strength of Sugentech SGTi-flex COVID-19 IgM/IgG

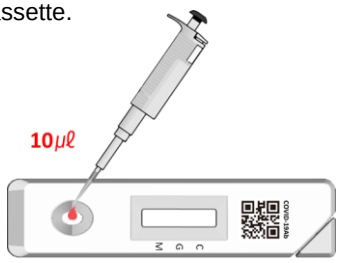
[Good Usability] *Test procedure for COVID-19 IgM/IgG*

1 Collecting of Sample

For test, 10 µl of whole blood, plasma or serum is used.
Collect the blood sample obtained by venipuncture into blood collection tube or use fingertip blood.

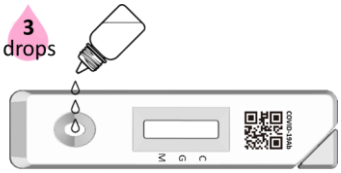
2 Adding of Sample

Add the collected serum/plasma/whole blood to the sample well of the test cassette.



3 Dropping of Sample buffer

Add 3 drops (~90µl) of sample into the sample well of the test cassette.



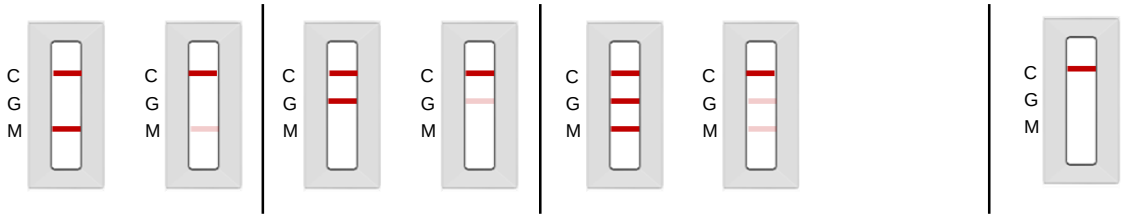
4 Reading Test result

Read test result at 10~15 minutes.

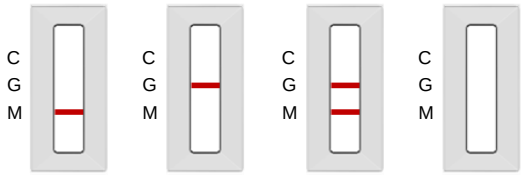
Read after 10 mins.

Do not read after 30 mins.

[Good Usability] *Interpretation of Test Result*



IgM Positive | **IgG Positive** | **IgM/ IgG Positive** | **Negative**



Invalid & Retest required

1. The test is for qualitative detection of anti-COVID-19 antibody in human whole blood, serum or plasma and does not indicate the quantity of the antibodies.
2. The test is for in vitro diagnostic use only.
3. As in case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single but should rather be made after test all the clinical findings have been evaluated.

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