Sugentech

SGTi-flex

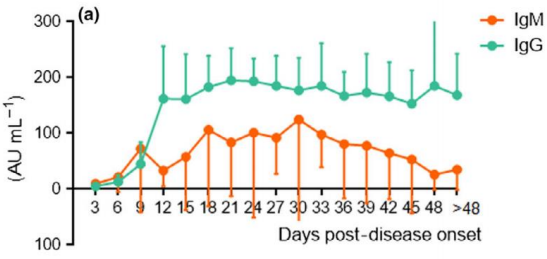
# COVID-19 IgG

**FDA Emergency Use Authorized.**

**Healthcare professional use only**

## COVID-19 IgG test?

- IgG antibody was generated for COVID-19 within 1 week after symptom onset and remains in the blood after recovery. Moreover, IgG has much better neutralizing activity and the so more elongated expression.
- IgG tests is intended for use as an aid in identifying individuals with an adaptive immune response to SARSCoV-2, indicating recent or prior infection.




Hou H, Wang T, Zhang B et al. . Detection of IgM and IgG antibodies in patients with coronavirus disease 2019. Clin Transl Immunology 2020; 9(5): e01136.

## IgG and Immunity

- IgG tests can help determine the proportion of a population previously infected with SARS-CoV-2 and provide information about populations that may be immune and potentially protected.
- Serologic test results may assist with identifying persons potentially infected with SARS-CoV-2 and determining who may qualify to donate blood that can be used to manufacture convalescent plasmaexternal icon as a possible treatment for those who are seriously ill from COVID-19.

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**[25 tests/kit]**

## performance

### Clinical Performance analysis

| TOTAL | | Real Time RT-PCR | | |
|---|---|---|---|---|
| | | Pos | Neg | Total |
| SGTi-flex COVID-19 IgG | Pos | 171 | 2 | **173** |
| | Neg | 14 | 232 | **246** |
| | Total | **185** | **234** | **419** |

- **Sensitivity : 92.43%** (171/185, 95% CI: 87.70%~95.44%)
- **Specificity : 99.15%** (232/234, 95% CI: 96.94%~99.77%)

### Positive Agreement by Days Post-Symptom Onset

| Days from symptom onset | Number of samples tested | IgG Positive Results | IgG PPA (95% CI) |
|---|---|---|---|
| 0~7 days | 17 | 7 | 41.2% (21.61%~63.99%) |
| 8~14 days | 24 | 22 | 91.7% (74.15%~97.68%) |
| 15~21 days | 45 | 43 | 95.6% (85.17%~98.77%) |
| ≥ 22 days | 99 | 99 | 100.00% (96.26%~100.00%) |

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## Test Procedure

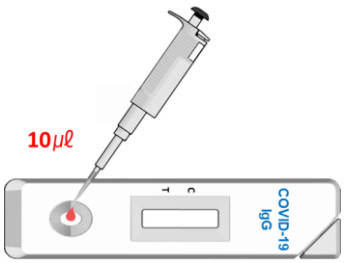
### 1 Collecting of Sample

For the test, 10 µl of whole blood, plasma or serum is used.

- Collect fingertip blood using a pipette or blood transfer pipette.
- Or use a blood sample obtained by venipuncture.

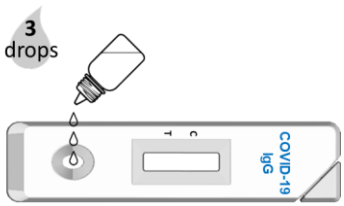

### 2 Adding of Sample

Add the collected sample (whole blood/serum/ plasma) 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

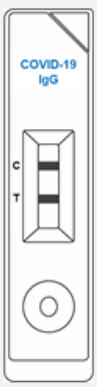
Read the results after 10-15 min.
The results are invalid after 30 min.


**Read after 10 min.**

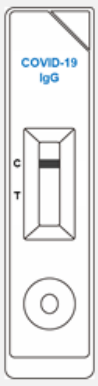
**Do not read after 30 min.**

## Interpretation

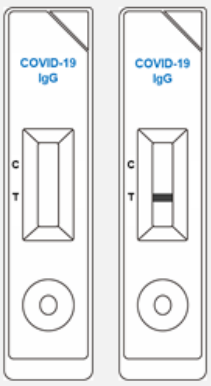
**Positive**




**Negative**




**Invalid/Retest**




1. The test is for in vitro diagnostic use only.
2. 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.
3. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
4. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
5. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

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