isotek
Advancing Healthcare

AccuBioTech Co.,Ltd
Accurate, Reliable, Cost Effective

# ACCU-TELL®COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)

- 10 minutes to read result
- Clinical evaluated


## Catalogue

| Product Name | Specimen | Catalog No. | Quantity/box | Certificate |
|---|---|---|---|---|
| COVID-19 Rapid Test Cassette | Whole blood/Serum/Plasma | ABT-IDT-B352 | 25 test | CE |

## Sensitivity & Specificity

Sensitivity and Specificity ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) was compared with clinical diagnosis (Confirmed). The study included 446 specimens for IgG and 456 specimens for IgM.

| IgG | | IgM | |
|---|---|---|---|
| **Diagnostic sensitivity** | 100.0% (95%CI: 96.1%~100.0%)* | **Diagnostic sensitivity** | 91.8 %( 95%CI: 83.8%-96.6%)* |
| **Diagnostic specificity** | 99.5% (95%CI: 98.1%~99.9%)* | **Diagnostic specificity** | 99.2 %( 95%CI: 97.7%~99.8%)* |
| **Accuracy** | 99.6 %( 95%CI: 98.4%~99.9%)* | **Accuracy** | 97.8 %( 95%CI: 96.0%~98.9%)* |

*confidence interval

Klikatauscan QR code untukinformasilengkapmanufaktur:
https://bit.ly/RapidTestCovidAccuTell

Scan to discover !

AccuBioTech Co.,Ltd

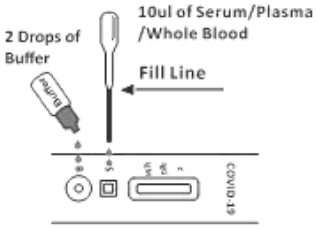
## Distributor & ImportirResmi:

**PT ISOTEKINDO INTERTAMA**
Jl. Raya Kebayoran Lama 309C , Jakarta Selatan 12210, DKI Jakarta, Indonesia
**P :** (021) 5305073-74 | **F :** (021) 5304939 | **E :** info@isotekindo.co.id | **M :** 0811.171.0055 (*Call & Whatsapp*)
**W :** www.isotekindo.co.id

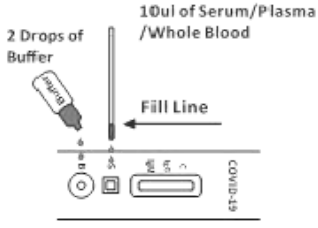
## TEST PROCEDURE

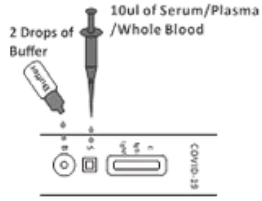
Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1) Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2) Place the test cassette on a clean and level surface. For Serum or Plasma or Whole Blood Specimens




**To use a dropper:** Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 10µl), and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. Avoid trapping air bubbles in the specimen well.




**To use a micropipette (recommended):**
Pipette and dispense 10µl of specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer.

3) Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.

## MATERIALS

**Materials provided**

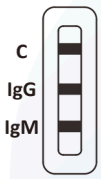
- Test cassettes
- Droppers/Capillary
- Buffer
- Package insert

**Materials required but not provided**

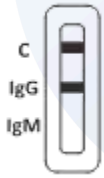
- Specimen collection containers
- Centrifuge (for plasma only)
- Micropipette
- Timer
- Lancets (for fingerstickwhole blood only)

## INTERPRETATION OF RESULTS

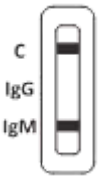
**(Please refer to the illustrations)**




**IgG and IgM** POSITIVE:* Three lines appear. One colored line should be in the control line region (C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies.



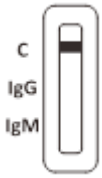

**IgG POSITIVE:*** Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG.




**IgM POSITIVE:*** Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies

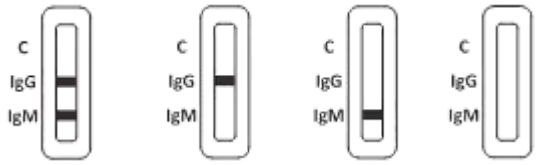
***NOTE:**

The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.




**NEGATIVE:** One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).

**INVALID:** Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.




AccuBioTech Co., Ltd.
Building 10, No. 28 Yu Hua Road, Beijing, China

EC REP
Medical Device Safety Service GmbH
Schiffgraben 41，30175 Hannover，Germany