

**ACCU-TELL<sup>®</sup>**
**COVID-19 IgG/IgM Cassette  
(Whole Blood/Serum/Plasma)**
**For in vitro diagnostic Use only**
**For Whole Blood/Serum/Plasma Samples**

This package insert is applied to the below products:

Catalog No.	Product Name
ABT-IDT-B352	COVID-19 IgG/IgM Cassette (Whole Blood/ Serum/ Plasma)

A rapid test for the qualitative detection of antibodies (IgG and IgM) to SARS-CoV-2 in whole blood, serum, or plasma.

For professional in vitro diagnostic use only.

**INTENDED USE**

ACCU-TELL<sup>®</sup> COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of SARS-COV-2 infections.

**SUMMARY**

The novel coronaviruses belong to the  $\beta$  genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

ACCU-TELL<sup>®</sup> COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of SARS-COV-2 antigen coated colored particles for the detection of IgG and IgM antibodies to SARS-COV-2 in human whole blood, serum, or plasma.

**PRINCIPLE**

ACCU-TELL<sup>®</sup> COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. IgM antibodies to SARS-CoV-2, if present in the specimen, reacts with the anti-human IgM and the SARS-CoV-2 antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region. Therefore, if the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to SARS-CoV-2, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to SARS-CoV-2, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

**REAGENTS**

The test cassette contains to specific antigen conjugated gold colloid particles and anti-human IgM, anti-human IgG coated on the membrane.

**PRECAUTIONS**

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.
- Buffer contains sodium azide as a preservative do not flush down sink/ingest

**STORAGE AND STABILITY**

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

- ACCU-TELL<sup>®</sup> COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma.
- To collect Fingerstick Whole Blood Specimens:
  - ✓ Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - ✓ Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - ✓ Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - ✓ Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - ✓ Add the Fingerstick Whole Blood specimen to the test cassette by using a dropper or micropipette measuring 10ul. The dropper provided with the test dispenses approximately 10ul in one drop even if more blood is aspirated in the dropper.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

**MATERIALS**
**Materials provided**

Test cassettes  
Droppers/Capillary  
Buffer

Package insert

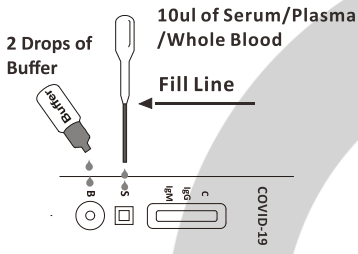
**Materials required but not provided**

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

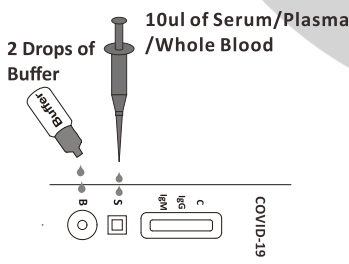
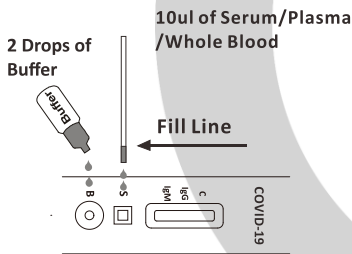
**TEST PROCEDURE**

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

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



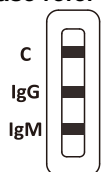
**To use a dropper:** Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 10µl), and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. Avoid trapping air bubbles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



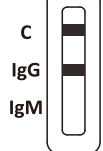
**To use a micropipette (recommended):** Pipette and dispense 10µl of specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer.

- 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.

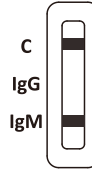
**INTERPRETATION OF RESULTS**  
(Please refer to the illustrations)



**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.

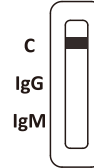


**IgG POSITIVE:\* Two lines appear.** One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG.



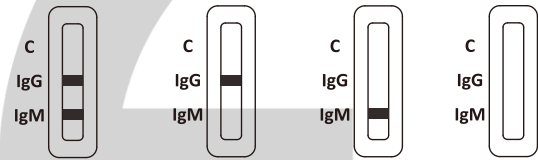
**IgM POSITIVE:\* Two lines appear.** One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies.

\*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.



**QUALITY CONTROL**

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**LIMITATIONS**

- ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.
- In the early onset of symptom, anti-SARS-COV-2 IgM concentrations may be below detectable levels.
- The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
- Results from immunosuppressed patients should be interpreted with caution.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- 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.
- 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.
- This test has not been reviewed by the FDA.
- 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.
- Not for the screening of donated blood.
- There may be false positive risk with the plasma in EDTA tube

after a period storage.

## PERFORMANCE CHARACTERISTICS

### POSITIVE AGREEMENT

Positive agreement of ACCU-TELL<sup>®</sup> COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) was evaluated using clinical samples collected from symptomatic subjects. All subjects were confirmed positive for COVID-19 by Nucleic Acid Test (RT-PCR) or clinical diagnosis.

### NEGATIVE AGREEMENT

Negative agreement of ACCU-TELL<sup>®</sup> COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) was evaluated using clinical samples collected from symptomatic subjects. Samples were collected during the COVID-19 pandemic and all were excluded for COVID-19 by Nucleic Acid Test (RT-PCR) or clinical diagnosis.

The positive and/or negative population consisted of the following subjects.

The results show that the positive agreement of ACCU-TELL<sup>®</sup> COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) is 93.5%, the negative agreement is 97.5% and the total agreement is 95.5%.

- Living in site A during the COVID-19 pandemic.
- Living in site B during the COVID-19 pandemic.

Method	PCR Positive (Confirmed Cases)	PCR Negative (Excluded Cases)	Total
Site A	IgG+ and IgM+	84	85
	IgM+ and IgG-	9	12
	IgM- and IgG+	2	2
	IgM- and IgG-	5	151
Site B	IgG+ and IgM+	58	58
	IgM+ and IgG-	5	5
	IgM- and IgG+	1	1
	IgM- and IgG-	6	16
Total	170	160	330
Agreement	(95+64)/(100+70) =93.5% (95%CI:88.7%-96.7%)	(146+10)/(150+10) =97.5% (95%CI:93.7%-99.3%)	(95+64+146+10)/(100+70+150+10)=95.5% (95%CI:93.7%-99.3%)

CI means confidence interval

### Cross-reactivity

ACCU-TELL<sup>®</sup> COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV, anti-haemophilus influenza, ANA, H1N1, H3N2, H7N9, coronavirus HKU1, NL63, OC43, 229E and HAMA positive specimens. The results showed no cross-reactivity. Some cross reactivity was observed with samples positive for SARS-CoV antibody and Rheumatoid Factor. It is possible to cross-react with samples positive for MERS-CoV antibody

### Interfering Substances









The following potentially interfering substances were added to COVID-19 negative and spiked positive specimens.

Analytes	Concentration	Result			
		Negative Specimen		Spiked with Positive Specimen	
		IgG line	IgM line	IgG line	IgM line
Acetaminophen	20 mg/dL	Negative	Negative	Positive	Positive
Caffeine	20 mg/dL	Negative	Negative	Positive	Positive
Albumin	2 g/dL	Negative	Negative	Positive	Positive
Acetylsalicylic Acid	20 mg/dL	Negative	Negative	Positive	Positive
Genistic Acid	20 mg/dL	Negative	Negative	Positive	Positive
Ethanol	1%	Negative	Negative	Positive	Positive
Ascorbic Acid	2g/dL	Negative	Negative	Positive	Positive
Creatine	200mg/dl	Negative	Negative	Positive	Positive
Bilirubin	1g/dL	Negative	Negative	Positive	Positive
Hemoglobin	1000mg/dl	Negative	Negative	Positive	Positive
Oxalic Acid	60mg/dL	Negative	Negative	Positive	Positive
Uric acid	20mg/ml	Negative	Negative	Positive	Positive

None of the substances at the concentration tested interfered in the assay.

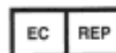
1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502.

## GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse



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



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

## BIBLIOGRAPHY