Performance Evaluation Report of

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

Document No.: PER-B352-BT(MC42)/02
Version No.: 02

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For and on behalf of ACCUBIOTECH CO., LTD.
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Summary

Background

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.

ACCU-TELL® 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.

Purpose

Evaluate the performance through sample correlation, cross-reactivity, etc for ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma), to ensure that the performance of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/ Plasma) is consistent with the claimed intended use.

Principles

ACCU-TELL® 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.

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® 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.

PERFORMANCE CHARACTERISTICS

1. Sample correlation

Purpose：

Evaluate the diagnostic value in SARS-COV-2 infection (COVID-19) with ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)

Material:

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

REF.: ABT-IDT-B352

Lot No.: 2020030601

Samples Information:

For Site A:

The study is testing 100 samples from patient infections SARS-COV-2(COVID-19) and

150 samples from the excluded cases.

For Site B:

The study is testing 70 samples from confirmed infected patients, and 10 samples from the excluded cases.

Comment:

- **Site A** indicate Jiangsu Provincial Center for Disease Control and prevention
- **Site B** indicate Hubei Center for Disease Control and Prevention
- Clinical agreement sample size reference ***In Vitro Diagnostics EUA*** **from FDA (U.S. FOOD & DRUG) Website**

Method:

Read the entire manual and bring the test and specimens to reach room temperature (15-30℃) before use.

Remove from the test cassette from the sealed pouch and use it within 1 hour.

1) Place the test cassette on a clean and level surface, hold the dropper vertically, draw the specimen up to the fill line (approximately 10µl), and transfer the specimen to the sample(S) of the test cassette, then add 2 drops of buffer (approximately 80µl) the buffer.

2) The colored line(s)to appear, the test result should be read at 10 minutes, do not interpret the result after 20 minutes

Result:

Relative Sensitivity

Relative Sensitivity of ACCU-TELL® 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.

Relative Specificity

Relative Specificity of ACCU-TELL® 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.

- 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	1	85
	IgM+ and IgG-	9	3	12

	IgM- and IgG+	2	0	2
	IgM- and IgG-	5	146	151
Site B	IgG+ and IgM+	58	0	58
	IgM+ and IgG-	5	0	5
	IgM- and IgG+	1	0	1
	IgM- and IgG-	6	10	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%)

Relative Sensitivity: (95+64)/(100+70) =93.5%(95%CI:88.7%-96.7%)
Relative Specificity: (146+10)/(150+10) =97.5%(95%CI:93.7%-99.3%)
Accuracy: (95+64+146+10)/(100+70+150+10)=95.5%(95%CI:93.7%-99.3%)
CI means confidence interval

Summary for Clinical study data from site A and site B

Method		**Confirmed Cases (PCR Positive)**	**PCR Negative Excluded Cases**	**Total**
ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)	Positive	159	4	163
	Negative	11	156	167
Total		170	160	330

Positive Percent Agreement (PPA): 159/ (159+11) =93.53% (95%CI*: 88.7%~96.7%);
Negative Percent Agreement (NPA): 156/(156+4) =97.50% (95%CI*:93.7%~99.3%);
Total Percent Agreement (TPA): (159+156)/(159+11+156+4) =95.50% (95%CI*:92.6%~97.4%)
CI means confidence interval

Conclusion:

The results show that the Relative Sensitivity of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) is 93.5%, the Relative Specificity is 97.5% and the Accuracy is 95.5%.

2. Seroconversion Study

Material:

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

REF.: ABT-IDT-B352

Lot No.: COV2003001-T

Method:

Living in Zhejiang Province during the 2020 COVID-19 pandemic.

The sensitivity and specificity of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) was evaluated on samples from individuals residing in Zhejiang (China) by State Key Laboratory for Diagnosis and Treatment of Infectious Disease. The lot number is COV2003001-T. The sensitivity was evaluated on 104 samples from 30 hospitalized patients at The First Affiliated Hospital, College of Medicine, Zhejiang University.

All the studied cases are confirmed by RT-PCR positive for SARS-CoV-2 infection. Of these objectives, seven were both IgM and IgG positive at the first sample test.

Twenty seroconverted during observation and three subjects never seroconverted. The sensitivity was 90% (27/30) for the subjects tested.

Result:

Case (Patient) ID No.	Sample ID No.	nCoV-2 RT-PCR Results	Days Between Symptoms Onset and Blood Collection	IgM	IgG	IgM (+) and/or IgG (+)
CJG-2000004116	CJG-2000004116-01	+	7	-	-	-
	CJG-2000004116-02	N/A	10	-	-	-
	CJG-2000004116-03	+	18	+	+	+
CSC-2000004214	CSC-2000004214-01	+	10	+	+	+
	CSC-2000004214-02	N/A	13	+	+	+
	CSC-2000004214-03	N/A	18	+	+	+
	CSC-2000004214-04	-	32	+	+	+
CZ-05148433	CZ-05148433-01	+	7	-	-	-
	CZ-05148433-02	-	8	+	+	+
	CZ-05148433-03	+	22	+	+	+
GJ-03013432	GJ-03013432-01	+	1	+	+	+
	GJ-03013432-02	+	2	+	+	+
	GJ-03013432-03	-	9	+	+	+
GXM-05143619	GXM-05143619-01	+	4	-	-	-
	GXM-05143619-02	N/A	6	+	-	+
	GXM-05143619-03	+	9	-	+	+
HHZ-05150218	HHZ-05150218-01	+	11	+	+	+
	HHZ-05150218-02	+	13	+	+	+
	HHZ-05150218-03	+	22	+	+	+

	HHZ-05150218-04	N/A	24	+	+	+
HSJ-03886796	HSJ-03886796-01	+	2	-	-	-
	HSJ-03886796-02	+	5	-	-	-
	HSJ-03886796-03	+	7	+	-	+
	HSJ-03886796-05	N/A	11	+	+	+
	HSJ-03886796-04	+	20	+	+	+
JXJ-2000004055	JXJ-2000004055-01	+	8	-	-	-
	JXJ-2000004055-04	-	14	+	-	+
	JXJ-2000004055-03	+	20	+	+	+
	JXJ-2000004055-02	N/A	24	+	+	+
LE-01613279	LE-01613279-01	-	7	-	-	-
	LE-01613279-02	+	14	-	-	-
	LE-01613279-03	-	33	+	+	+
LH-05079034	LH-05079034-01	+	6	-	-	-
	LH-05079034-02	+	7	+	+	+
	LH-05079034-03	+	20	+	+	+
LMX-05148953	LMX-05148953-06	N/A	7	-	-	-
	LMX-05148953-01	+	8	-	-	-
	LMX-05148953-02	+	10	-	-	-
	LMX-05148953-03	+	11	+	-	+
	LMX-05148953-07	N/A	13	+	+	+
	LMX-05148953-04	N/A	16	+	+	+
	LMX-05148953-05	N/A	24	+	+	+
	LMX-05148953-08	-	33	+	+	+
MRG-2000004008	MRG-2000004008-01	+	4	-	-	-
	MRG-2000004008-02	+	21	+	+	+
	MRG-2000004008-03	N/A	26	+	+	+
MXR-2000004129	MXR-2000004129-01	+	11	+	+	+
	MXR-2000004129-02	N/A	22	+	+	+
	MXR-2000004129-03	+	25	+	+	+
SBZ-2000004184	SBZ-2000004184-01	+	7	-	-	-
	SBZ-2000004184-02	N/A	8	-	-	-
	SBZ-2000004184-03	+	10	-	-	-
SGH-2000004035	SGH-2000004035-01	+	5	-	-	-
	SGH-2000004035-02	+	19	+	+	+
	SGH-2000004035-03	+	24	+	+	+
SWD-2000004137	SWD-2000004137-01	+	15	+	+	+
	SWD-2000004137-02	N/A	19	+	+	+
	SWD-2000004137-03	+	23	+	+	+
	SWD-2000004137-04	-	68	+	+	+
WCD-2000004024	WCD-2000004024-01	+	2	-	-	-
	WCD-2000004024-02	N/A	14	-	-	-

	WCD-2000004024-03	+	22	-	-	-
WCJ-05151120	WCJ-05151120-01	+	6	+	+	+
	WCJ-05151120-02	+	15	+	+	+
	WCJ-05151120-03	N/A	21	+	+	+
	WCJ-05151120-04	+	27	+	+	+
WH-2000004159	WH-2000004159-01	+	7	-	-	-
	WH-2000004159-02	+	10	-	-	-
	WH-2000004159-03	+	14	+	-	+
	WH-2000004159-04	-	29	+	+	+
WJQ-05149865	WJQ-05149865-01, WJQ-05149865-04	+	0	-	-	-
	WJQ-05149865-02	+	1	-	-	-
	WJQ-05149865-03	+	2	+	-	+
	WJQ-05149865-05	N/A	15	+	+	+
WMM-05148912	WMM-05148912-01	+	2	-	-	-
	WMM-05148912-02	+	18	+	+	+
	WMM-05148912-03	+	20	+	+	+
WYC-2000004016	WYC-2000004016-01	+	35	+	-	+
	WYC-2000004016-02	+	41	+	+	+
	WYC-2000004016-03	-	55	+	+	+
XYS-00987017	XYS-00987017-01	+	11	-	-	-
	XYS-00987017-02	+	21	+	+	+
	XYS-00987017-03	+	23	+	+	+
XZC-2000004086	XZC-2000004086-01	+	9	-	-	-
	XZC-2000004086-02	+	25	+	-	+
	XZC-2000004086-03	-	35	-	+	+
YYQ-05148957	YYQ-05148957-01	N/A	3	+	-	+
	YYQ-05148957-02	+	7	+	+	+
	YYQ-05148957-03	+	42	+	+	+
YYX-2000004130	YYX-2000004130-01	+	4	-	-	-
	YYX-2000004130-02	N/A	6	-	-	-
	YYX-2000004130-03	+	15	+	+	+
YZM-2000004131	YZM-2000004131-01	+	4	-	-	-
	YZM-2000004131-02	+	8	+	+	+
	YZM-2000004131-03	N/A	16	+	+	+
ZFS-2000004005	ZFS-2000004005-01	+	13	+	+	+
	ZFS-2000004005-02	+	16	+	+	+
	ZFS-2000004005-03	N/A	17	+	+	+
ZJH-00823994	ZJH-00823994-01	+	3	-	-	-
	ZJH-00823994-02	-	7	-	-	-
	ZJH-00823994-03	N/A	11	-	-	-

ZLQ-05150650	ZLQ-05150650-03	+	7	-	-	-
	ZLQ-05150650-01	+	19	+	-	+
	ZLQ-05150650-02	+	22	+	-	+

Conclusion:
Of these objectives, seven were both IgM and IgG positive at the first sample test. Twenty seroconverted during observation and three subjects never seroconverted. The sensitivity was 90% (27/30) for the subjects tested.

3.Interfering Substances

Purpose
Investigate the influence of the interfering substance in positive samples via spiking the positive samples into the interfering samples.

Material
Product information
ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)
Lot No.: COV2003001-T

Sample Information

Interfering substance

Analytes	Concentration	Lot No.	Dilution Solution
Acetaminophen	20 mg/dL	20200214-01	Negative Serum
Caffeine	20 mg/dL	20200214-02	Negative Serum
Albumin	2 g/dL	20200214-03	Negative Serum
Acetylsalicylic Acid	20 mg/dL	20200214-04	Negative Serum
Gentisic Acid	20 mg/dL	20200214-05	Negative Serum
Ethanol	1%	20200214-06	Negative Serum
Ascorbic Acid	2g/dL	20200214-07	Negative Serum
Creatine	200mg/d	20200214-08	Negative Serum
Bilirubin	1g/dL	20200214-09	Negative Serum
Hemoglobin	1000mg/dl	20200214-10	Negative Serum
Oxalic Acid	60mg/dL	20200214-11	Negative Serum
Uric acid	20mg/ml	20200214-12	Negative Serum

COVID-19 IgG and IgM positive control (PGM-01) Lot No.:20200318-01
Negative serum Lot No.: VVSP200116-08

Method
Treatment on interfering substance

Analytes	Concentration	PGM-01	Mixture	Re-number
98ul Acetaminophen	20 mg/dL	2ul	100ul MIX	I1
98ul Caffeine	20 mg/dL	2ul	100ul MIX	I2
98ul Albumin	2 g/dL	2ul	100ul MIX	I3
98ul Acetylsalicylic Acid	20 mg/dL	2ul	100ul MIX	I4

98ul Gentisic Acid	20 mg/dL	2ul	100ul MIX	I5
98ul Ethanol	1%	2ul	100ul MIX	I6
98ul Ascorbic Acid	2g/dL	2ul	100ul MIX	I7
98ul Creatine	200mg/d	2ul	100ul MIX	I8
98ul Bilirubin	1g/dL	2ul	100ul MIX	I9
98ul Hemoglobin	1000mg/dl	2ul	100ul MIX	I10
98ul Oxalic Acid	60mg/dL	2ul	100ul MIX	I11
98ul Uric acid	20mg/ml	2ul	100ul MIX	I12

Comment: the small-sized positive sample (2ul) is negligible to the interfering substances (98ul).

Treatment on the positive with negative serum similar ratio above

Sample	**PGM-01**	**Mixture**	**Re-number**
98ul Negative Serum	2ul	100ul MIX	PGM-02

Perform the test according to the Package Insert.

Results

Result on Interfering Substances

Region	**Before Treatment**					**After Treatment**			
	Analytes	Concentration	Result			Spiked sample	Result		
IgG line	Negative Serum	/	-	-	-	PGM-02	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Acetaminophen	20 mg/dL	-	-	-	I1	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Caffeine	20 mg/dL	-	-	-	I2	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Albumin	2 g/dL	-	-	-	I3	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Acetylsalicylic Acid	20 mg/dL	-	-	-	I4	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Gentisic Acid	20 mg/dL	-	-	-	I5	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Ethanol	1%	-	-	-	I6	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Ascorbic Acid	2g/dL	-	-	-	I7	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Creatine	200mg/d	-	-	-	I8	+	+	+
IgM line			-	-	-		+	+	+

IgG line	Bilirubin	1g/dL	-	-	-	I9	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Hemoglobin	1000mg/dl	-	-	-	I10	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Oxalic Acid	60mg/dL	-	-	-	I11	+	+	+
IgM line			-	-	-		+	+	+
IgG line	Uric acid	20mg/ml	-	-	-	I12	+	+	+
IgM line			-	-	-		+	+	+

Comment: - means negative result and + means positive results.

Conclusion:

No substances showed any interference with the test. There were no differences observed between the results at 10 minutes.

4. Cross Reactivity

Material:
ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)
Lot1:COV2002001-T
Lot2:COV2002001-T
Lot3:COV2002001-T

Method:
ACCU-TELL® 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-SARS-COV, HAMA and rheumatoid factor positive specimens. Visual interpretations were recorded at 10 minutes after specimen application. Results are presented in Table below.

Result:

Table: Cross Reactivity Study

COVID-19 IgG/IgM / Specimens	COV2002001-T			COV2002002-T			COV2002003-T		
	Neg. Serum			Neg. Serum			Neg. Serum		
3 anti-influenza A virus	-	-	-	-	-	-	-	-	-
3 anti-influenza B virus	-	-	-	-	-	-	-	-	-
3 anti-RSV	-	-	-	-	-	-	-	-	-
3 anti-Adenovirus	-	-	-	-	-	-	-	-	-
3 HBsAg	-	-	-	-	-	-	-	-	-
3 anti-Syphilis	-	-	-	-	-	-	-	-	-
3 anti-H. Pylori	-	-	-	-	-	-	-	-	-
3 anti-HIV	-	-	-	-	-	-	-	-	-
3 anti-HCV	-	-	-	-	-	-	-	-	-
1 anti-SARS-COV	+			+			+		
10 HAMA	10 -			10 -			10 -		
30 RF	28-, 2+*			28-, 2+*			28-, 2+*		

Comment: - means negative result and + means positive result.

* means 2 false positive result for IgM with the Rheumatoid Factor (Conc.>600 U/ml) and they are all weak positive result.

Conclusion:
There was no cross-reaction with anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV and HAMA positive

specimens at 10minutes. Some cross reactivity was observed with samples positive for SARS-CoV antibody and Rheumatoid Factor.

➢ Supplemental Study on Cross-Reactivity (Hospital)

Testing Purpose

Validation on some cross-reactive samples with ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma).

Testing Material

Product Information：

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

Product Lot No.： COV20030112

Specimen Information：

Sample information will be output in the table bellow.

Direction for Use：

Add 10ul samples into the sample well (Marked S) and add 2 drops of buffer into the buffer well (Marked B). Start the timer and read the results at 20 min.

Testing Result

Item No.	Information on Cross-reactive Samples				Testing Result of ACCU-TELL's test	
	Sample No.	Corresponding pathogen or sample name	Type of Sample	Confirmed test or method	IgG	IgM
1	FZM-05128018	H1N1	Serum	RNA Test	-	-
2	ZHY-02964970	H1N1	Serum	RNA Test	-	-
3	QGG-03872800	H1N1	Serum	RNA Test	-	-
4	WXX-02223351	H3N2	Serum	RNA Test	-	-
5	HYD-04811395	H3N2	Serum	RNA Test	-	-
6	YWA-04792285	H3N2	Serum	RNA Test	-	-
7	LMJ-02129632	H7N9	Serum	RNA Test	-	-
8	ZYF-02121964	H7N9	Serum	RNA Test	-	-
9	ZWZ-01726727	H7N9	Serum	RNA Test	-	-
10	GYZ-04688766	Anti-Flu A	Serum	RNA Test	-	-
11	MLM-04429899	Anti-Flu A	Serum	RNA Test	-	-
12	XZE-01035284	Anti-Fu A	Serum	RNA Test	-	-
13	CHQ-05098579	Anti-Flu B	Serum	RNA Test	-	-
14	FMJ-05012223	Anti-Flu B	Serum	RNA Test	-	-
15	CXJ-03507807	Anti-Flu B	Serum	RNA Test	-	-
16	XZY-03153939	Anti-RSV	Serum	RNA Test	-	-
17	WCH-05108868	Anti-RSV	Serum	RNA Test	-	-
18	ZGQ-03428864	Anti-RSV	Serum	RNA Test	-	-
19	LAL-04337830	Anti-HBV	Serum	ELISA	-	-

20	LAM-04875892	Anti-HBV	Serum	ELISA	-	-
21	SJQ-05119331	Anti-HBV	Serum	ELISA	-	-
Item No.	**Information on Cross-reactive Samples**				**Testing Result of ACCU-TELL's test**	
	Sample No.	**Corresponding pathogen or sample name**	**Type of Sample**	**Confirmed test or method**	**IgG**	**IgM**
22	ZJQ-05161070	Anti-HBV	Serum	CLIA	-	-
23	HXY-04416796	Anti-HBV	Serum	CLIA	-	-
24	LWY-05165262	Anti-HBV	Serum	CLIA	-	-
25	LYB-04909505	Antinuclear antibody(ANA)	Serum	ELISA	-	-
26	WJD-04869683	Antinuclear antibody(ANA)	Serum	ELISA	-	-
27	WS-05080121	Antinuclear antibody(ANA)	Serum	ELISA	-	-
28	ZY-03450526	Antinuclear antibody(ANA)	Serum	ELISA	-	-
29	HHX-04589677	Antinuclear antibody(ANA)	Serum	ELISA	-	-
30	PZ-05120936	Anti-HIV	Serum	qPCR	-	-
31	LZW-04514918	Anti-HIV	Serum	qPCR	-	-
32	WFL-04945527	Anti-HIV	Serum	qPCR	-	-
33	TQN-04948588	Anti-HCV	Serum	ELISA	-	-
34	ZXH-00563804	Anti-HCV	Serum	ELISA	-	-
35	YQZ-00652804	Anti-HCV	Serum	ELISA	-	-
36	LYB-04909505	HAMA	Serum	ELISA	-	-
37	JZK-05157440	HAMA	Serum	ELISA	-	-
38	XXY-00843205	HAMA	Serum	ELISA	-	-
39	JGF-04424782	RF	Serum	ELISA	-	-
40	JMX-01125772	RF	Serum	ELISA	-	-
41	DLD-01004848	RF	Serum	ELISA	-	-
42	XYR-05130967	Haemophilus influenzae	Serum	Cell Culture	-	-
43	YZX-03870593	Haemophilus influenzae	Serum	Cell Culture	-	-
44	XYH-03070099	Haemophilus influenzae	Serum	Cell Culture	-	-
45	XYH-03050109	Haemophilus influenzae	Serum	Cell Culture	-	-
46	WFJ-03892159	Haemophilus influenzae	Serum	Cell Culture	-	-
47	JJF-04908426	Anti-EBV	Serum	ELISA	-	-
48	XJF-02736877	Anti-EBV	Serum	ELISA	-	-
49	WCH-05108868	Anti-EBV	Serum	ELISA	-	-

Comment：- means negative result.

Remark:

Additional specificity testing included the symptomatic and convalescent sera from six

individuals known to be infected with other strains of coronavirus, specifically 229E, NL63, OC43 or HKU1. No sample evaluated to date has generated a false positive result by ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) (LOT#: COV20030084). 31 Anti-Rhinovirus samples were evaluated in the USA and were all negative for ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma).

Conclusion:

There was no cross-reaction with the samples above.

➢ Supplemental Study on Cross-Reactivity (In-House)

Testing Purpose

Validation on some cross-reactive samples with ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma).

Testing Material

Product Information：

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

Product Lot No.： COV20030112

Specimen Information：

Sample information will be output in the table bellow

Direction for Use：

Add 10ul samples into the sample well (Marked S) and add 2 drops of buffer into the buffer well (Marked B). Start the timer and read the results at 20 min.

Testing Result

Item No.	Information on Cross-reactive Samples				**Testing Result of ACCU-TELL's test**		Comment
	Sample No.	Corresponding pathogen or sample name	Type of Sample	Confirmed Test or method	IgG	IgM	
1	205046	Anti-Flu A(+)	Serum	IFA	-	-	N/A
2	203023	Anti-Flu A(+), Anti-Flu B(+)	Serum	IFA	-	-	N/A
3	206044*	Anti-Flu A(+), Anti-Flu B(+), Anti-RSV(+),Anti-Adenovirus(+)	Serum	IFA	-	-	N/A
4	205012*	Anti-Flu A(+), Anti-Flu B(+)	Serum	IFA	-	-	N/A
5	201078*	Anti-Flu A(+), Anti-Flu B(+), Anti-Adenovirus(+)	Serum	IFA	-	-	N/A
6	208056*	Anti-Flu A(+), Anti-Flu B(+)	Serum	IFA	-	-	N/A
7	207057	Anti-Flu A(+), Anti-Flu B(+)	Serum	IFA	-	-	N/A
8	207104	Anti-Flu B(+)	Serum	IFA	-	-	N/A
9	208138	Anti-RSV(+)	Serum	IFA	-	-	N/A
10	204122	Anti-RSV(+)	Serum	IFA	-	-	N/A
11	203146	Anti-RSV(+)	Serum	IFA	-	-	N/A
12	202169	Anti-RSV(+)	Serum	IFA	-	-	N/A
13	201121	Anti-RSV(+)	Serum	IFA	-	-	N/A
14	204223	Anti-RSV(+)	Serum	IFA	-	-	N/A
15	208124	Anti-RSV(+)	Serum	IFA	-	-	N/A
16	209156*	Anti-Flu B(+)	Serum	IFA	-	-	N/A
17	207328	Anti-Flu B(+)	Serum	IFA	-	-	N/A
18	207531	Anti-Flu B(+)	Serum	IFA	-	-	N/A
19	203105	Anti-Flu B(+)	Serum	IFA	-	-	N/A

Item No.	Information on Cross-reactive Samples				Testing Result of ACCU-TELL's test		Comment
	Sample No.	Corresponding pathogen or sample name	Type of Sample	Confirmed test or method	IgG	IgM	
20	205142*	Anti-Flu B(+)	Serum	IFA	-	-	N/A
21	205184*	Anti-Flu B(+), Anti-RSV(+)	Serum	IFA	-	-	N/A
22	FCG-140699	Influenza A-IgM Positive(+)	Serum	IFA	-	-	N/A
23	FCG-119413	Influenza A-IgM Positive(+)	Serum	IFA	-	-	N/A
24	FCG-136875	Influenza B-IgM Positive(+)	Serum	IFA	-	-	N/A
25	FCG-133093	Influenza B-IgM Positive(+)	Serum	IFA	-	-	N/A
26	FCG-119244	Influenza A-IgM Positive(+) Influenza B-IgM Positive(+)	Serum	IFA	-	-	N/A

Comment: - means negative result.

* means these sample are all positive antibody against para-infuenza virus.

Conclusion:

There was no cross-reaction with the samples above.

5. Anticoagulant study

Material:

ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)
Lot#COV2002001-T

Method:

To test the samples collected from 10 volunteers with ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) respectively. From each healthy volunteer, 6 kinds anticoagulant are used to collect whole blood samples. Namely K_2EDTA treated plasma, Sodium/Potassium citrate treated plasma, Sodium/Lithium heparin treated plasma and Sodium oxalate treated plasma was collected respectively. One test was run for each sample, and read the result at 10minutes.

***Direction for testing:**

For Whole blood/serum/plasma: 10μl of Whole blood/Serum/Plasma+2drops (approximately 80ul) of buffer.
Read the results at 10 min.

Results:

Lot#COV2002001-T

Item	Time	Serum		K_2EDTA				Sodium citrate				Potassium citrate				Sodium heparin				Lithium heparin				Sodium oxalate			
				Plasma		WB		Plasma		WB		Plasma		WB		Plasma		WB		Plasma		WB		Plasma		WB	
		IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
1	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
2	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
3	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
4	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
5	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
6	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
7	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
8	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
9	**10mins**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
10	**10mins**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			

Comment: - means negative result.

Conclusion:

The result showed no difference among different anticoagulant tube to collect Whole blood/serum/plasma samples in this study

➢ Supplemental Sample Type/Anticoagulant Study (Hospital)

Purpose

Investigate the influence on anticoagulant with ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma).

Material

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

Lot No.: COV20030112

Clinical samples from the first affiliated hospital of Zhejiang university.

Method

To test the samples collected from 30 volunteers with ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) respectively. 3 kinds anticoagulant are used to collect whole blood samples. Citrate treated plasma, EDTA treated plasma and heparin treated plasma was collected respectively. One test was run for each sample.

*Direction for testing:

For Whole blood/serum/plasma:

10μl Whole blood/serum/Plasma+2drops (approximately 80ul) of buffer.

Read the results at 10 min.

Results:

Lot#COV20030112

Item No.	Serum			Plasma		Venous Whole blood		
	Sample No.	Result		Result		Anti-coagulant	Result	
		IgG	IgM	IgG	IgM		IgG	IgM
1	GJ-03013432-2	++	+	++	+	EDTA	++	+
2	SWD-2000004137-4	++	+	++	+	EDTA	++	+
3	SCF-03673322	-	+	-	+	EDTA	-	+
4	XJ-00997715	++	+	++	+	EDTA	++	+
5	WH-2000004159-3	+	++	+	++	EDTA	+	++
6	ZJL-2000004028	++	-	++	-	EDTA	++	-
7	CSC-2000004214-4	+	+	+	+	EDTA	+	+

8	LMX-05148953-03	++	-	++	-	EDTA	++	-
9	MXD-2000004129-04	+	-	+	-	EDTA	+	-
10	ZJL-2000004028	++	-	++	-	EDTA	++	-
11	YY-05148953	++	+	++	+	Heparin	++	+
12	HQH-03166520	+	++	+	++	Heparin	+	++
13	LE-01613279	++	+	++	+	Heparin	++	+
14	HSJ-03886796-6	++	+	++	+	Heparin	++	+
15	WMM-05148912-2	+++	+	+++	+	Heparin	+++	+
16	LH-05079034	++	+	++	+	Heparin	++	+
17	YYQ-05148957-2	++	+	++	+	Heparin	++	+
18	WYC-2000004016-2	++	+	++	+	Heparin	++	+
19	WJQ-05149865-5	+++	++	+++	++	Heparin	+++	++
20	CZ-05148433	+++	++	+++	++	Heparin	+++	++
21	CB-2000004087	+++	+	+++	+	Citrate	+++	+
22	HHZ-05150218-03	+	++	+	++	Citrate	+	++
23	JXJ-2000004055-02	+	+	+	+	Citrate	+	+
Item	**Serum**			**Plasma**		**Venous Whole blood**		
	Sample No.	**Result**		**Result**		**Anti-coagulant**	**Result**	
24	LE-1613279-03	+++	++	+++	++	Citrate	+++	++
25	MRG-2000004008-03	+++	+	+++	+	Citrate	+++	+
26	SGH-2000004035-02	+++	+	+++	+	Citrate	+++	+
27	SWD-200004137-04	+++	+	+++	+	Citrate	+++	+
28	WCJ-05151120-01	+++	++	+++	++	Citrate	+++	++
29	WH-2000004159-04	+++	++	+++	++	Citrate	+++	++
30	YZM-2000004131-02	+++	+	+++	+	Citrate	+++	+

Comment: “+” means weak positive results，
“++” medium positive results，
“+++”means strong positive result，
“-” means negative results.

Conclusion:

The result showed no difference among different anticoagulant tube above to collect Whole blood/serum/plasma samples in this study.

6. Temperature Flex

Materials:
ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)
Lot 1: COV2002001-T;
Lot 2: COV2002002-T;
Lot 3: COV2002003-T;

Method:
10 negative serum samples will be tested with ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) product stored at -20℃, 2~8℃,RT, 37℃ and 45℃. The results have been read at the prescribed read time.

Results:

Treatment temperature(℃)	COV2002001-T									
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
-20	-	-	-	-	-	-	-	-	-	-
2~8	-	-	-	-	-	-	-	-	-	-
RT	-	-	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-	-	-
Treatment temperature(℃)	COV2002002-T									
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N1
-20	-	-	-	-	-	-	-	-	-	-
2~8	-	-	-	-	-	-	-	-	-	-
RT	-	-	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-	-	-
Treatment temperature(℃)	COV2002003-T									
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N1
-20	-	-	-	-	-	-	-	-	-	-
2~8	-	-	-	-	-	-	-	-	-	-
RT	-	-	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-	-	-

Comment: - means negative result.

Conclusion:
The data showed that ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) product can yield correct results when tested from -20ºC to 45ºC at 30 minutes with the samples for serum samples. But the sensitive of product will influence significantly at -20℃ and 2~8℃. Performing the test at RT will be better.

7. Variation Study

Materials:

ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)
Lot 1: COV2002001-T;
Lot 2: COV2002002-T;
Lot 3: COV2002003-T;

Method:

Negative and positive (P1) specimens were run in replicates of 10 in three separate lots of products. Results were read as positive or negative at 10 minutes after specimen application.

Results:

	Lot1#: COV2002001-T			Lot2#: COV2002002-T			Lot3#: COV2002003-T		
Times	Neg	IgG Pos	IgM Pos	Neg	IgG Pos	IgM Pos	Neg	IgG Pos	IgM Pos
	10min	10min	10min	10min	10min	10min	10min	10min	10min
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+

Conclusion:

100% of actual results were consistent with expected results. No distinct difference was detected in intra lots and inter-lot.

8. Detection Level Determination

Material

Product Information:

ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)
Lot No.1: COV2002001-T
Lot No.2: COV2002002-T
Lot No.3: COV2002003-T

Sample Information:

COV-IgG-IgM positive (P1) 20200302-01

Method:

A COV-IgG-IgM positive (P1) specimen was diluted to the following concentrations: 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1:128, 1:256 and 1:512, with the same negative serum. Different diluted positive specimens were tested by ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma). The diluted positive samples were randomized and run blind-coded in replicates of 3. Interpret the results at 10 minutes.

Results:

COV-IgG-IgM positive (P1) for IgM test									
Specimen Dilution	COV2002001-T			COV2002002-T			COV2002003-T		
	10min	10min	10min	10min	10min	10min	10min	10min	10min
original	+	+	+	+	+	+	+	+	+
1:2	+	+	+	+	+	+	+	+	+
1:4	+	+	+	+	+	+	+	+	+
1:8	+	+	+	+	+	+	+	+	+
1:16	+	+	+	+	+	+	+	+	+
1:32	+	+	+	+	+	+	+	+	+
1:64	+	+	+	+	+	+	+	+	+
1:128	+	+	+	+	+	+	+	+	+
1:256	+	+	+	+	+	+	+	+	+
1:512	-	-	-	-	-	-	-	-	-
COV-IgG-IgM positive (P1) for IgG test									
Specimen Dilution	COV2002001-T			COV2002002-T			COV2002003-T		
	10min	10min	10min	10min	10min	10min	10min	10min	10min
original	+	+	+	+	+	+	+	+	+
1:2	+	+	+	+	+	+	+	+	+
1:4	+	+	+	+	+	+	+	+	+
1:8	+	+	+	+	+	+	+	+	+
1:16	+	+	+	+	+	+	+	+	+
1:32	+	+	+	+	+	+	+	+	+
1:64	+	+	+	+	+	+	+	+	+

1:128	-	-	-	-	-	-	-	-	-
1:256	-	-	-	-	-	-	-	-	-

Comment: - means negative result and + means positive result.

Conclusion:

From the above study results, the detection level of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) is 1:256 for COVID-19 IgM positive specimen and 1:64 for COVID-19 IgG positive specimen with the COV-IgG-IgM positive (P1).

➢ Supplement Study Report on Whole blood

Purpose:

The positive whole blood on COVID-19 couldn't be collected at this special moment. The simulated study was performed via spiking the positive plasma on COVID-19 into the negative whole blood.

Material:

Product information:

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

Lot No.: COV2003001-T

Positive plasma on COVID-19:

Sample No.	Lot No.	Sample No.	Lot No.
P1	20200312-28	P10	20200318-01
P2	20200312-35	P11	20200324-01
P3	20200312-43	P12	20200324-02
P4	20200312-51	P13	20200324-03
P5	20200313-01	P14	20200324-04
P6	20200313-02	P15	20200324-05
P7	20200313-03	P16	20200324-06
P8	20200313-04	P17	20200324-07
P9	20200313-05	N/A	N/A

Negative whole blood:

17 negative finger-stick whole blood (FWB): WB20200330-01~17

17 negative venous whole blood (VWB): WB20200325-01~17

All the samples are clinical samples.

Method:

Treatment on finger-stick whole blood:

10ul positive plasma plus 10ul fresh finger-stick whole blood, then test the mixed sample immediately.

Positive plasma	Finger WB	Finger WB+	Comment
10ul P1	10ul FWB1	20ul FWB1+	No anti-coagulation in the samples, the mixed sample should
10ul P2	10ul FWB2	20ul FWB2+	
10ul P3	10ul FWB3	20ul FWB3+	
10ul P4	10ul FWB4	20ul FWB4+	
10ul P5	10ul FWB5	20ul FWB5+	

10ul P6	10ul FWB6	20ul FWB6+	be used immediately.
10ul P7	10ul FWB7	20ul FWB7+	
10ul P8	10ul FWB8	20ul FWB8+	
10ul P9	10ul FWB9	20ul FWB9+	
10ul P10	10ul FWB10	20ul FWB10+	
10ul P11	10ul FWB11	20ul FWB11+	
10ul P12	10ul FWB12	20ul FWB12+	
10ul P13	10ul FWB13	20ul FWB13+	
10ul P14	10ul FWB14	20ul FWB14+	
10ul P15	10ul FWB15	20ul FWB15+	
10ul P16	10ul FWB16	20ul FWB16+	
10ul P17	10ul FWB17	20ul FWB17+	

Treatment on venous whole blood:

10ul positive plasma plus 10ul red blood cell from the venous whole blood, then test the mixed sample immediately.

Positive plasma	Venous WB	Venous WB+	Comment
10ul P1	10ul VWB1	20ul VWB1+	If the red blood cell is not separated from the whole blood, centrifuge the whole blood for 15 mins.
10ul P2	10ul VWB2	20ul VWB2+	
10ul P3	10ul VWB3	20ul VWB3+	
10ul P4	10ul VWB4	20ul VWB4+	
10ul P5	10ul VWB5	20ul VWB5+	
10ul P6	10ul VWB6	20ul VWB6+	
10ul P7	10ul VWB7	20ul VWB7+	
10ul P8	10ul VWB8	20ul VWB8+	
10ul P9	10ul VWB9	20ul VWB9+	
10ul P10	10ul VWB10	20ul VWB10+	
10ul P11	10ul VWB11	20ul VWB11+	
10ul P12	10ul VWB12	20ul VWB12+	
10ul P13	10ul VWB13	20ul VWB13+	
10ul P14	10ul VWB14	20ul VWB14+	
10ul P15	10ul VWB15	20ul VWB15+	
10ul P16	10ul VWB16	20ul VWB16+	
10ul P17	10ul VWB17	20ul VWB17+	

Perform the test according to the package insert.

Result:

Item No.	Plasma	Item No.	Finger WB+	Item No.	Venous WB+
P1	IgG+,IgM+	FWB1+	IgG+,IgM+	VWB1+	IgG+,IgM+
P2	IgG+,IgM+	FWB2+	IgG+,IgM+	VWB2+	IgG+,IgM+
P3	IgG+,IgM+	FWB3+	IgG+,IgM+	VWB3+	IgG+,IgM+
P4	IgG+,IgM+	FWB4+	IgG+,IgM+	VWB4+	IgG+,IgM+
P5	IgG+,IgM+	FWB5+	IgG+,IgM+	VWB5+	IgG+,IgM+
P6	IgG+,IgM+	FWB6+	IgG+,IgM+	VWB6+	IgG+,IgM+
P7	IgG+,IgM+	FWB7+	IgG+,IgM+	VWB7+	IgG+,IgM+
P8	IgG+,IgM+	FWB8+	IgG+,IgM+	VWB8+	IgG+,IgM+
P9	IgG+,IgM+	FWB9+	IgG+,IgM+	VWB9+	IgG+,IgM+
P10	IgG+,IgM+	FWB10+	IgG+,IgM+	VWB10+	IgG+,IgM+
P11	IgG+,IgM+	FWB11+	IgG+,IgM+	VWB11+	IgG+,IgM+
P12	IgG+,IgM+	FWB12+	IgG+,IgM+	VWB12+	IgG+,IgM+
P13	IgG+,IgM+	FWB13+	IgG+,IgM+	VWB13+	IgG+,IgM+
P14	IgG+,IgM+	FWB14+	IgG+,IgM+	VWB14+	IgG+,IgM+
P15	IgG+,IgM+	FWB15+	IgG+,IgM+	VWB15+	IgG+,IgM+
P16	IgG+,IgM+	FWB16+	IgG+,IgM+	VWB16+	IgG+,IgM+
P17	IgG+,IgM+	FWB17+	IgG+,IgM+	VWB17+	IgG+,IgM+

Conclusion:

The results above indicated that the positive plasma samples spiked into the negative finger-stick whole blood samples and negative venous whole blood samples showed a very similar result. All the samples still could be tested well.

10. Accelerated Stability

Material:

Lot 1: COV2002001-T
Lot2: COV2002002-T
Lot3: COV2002003-T

Method:

Accelerated Stability of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 55℃and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 0, 7, 14, 21, 28, 35 days. ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) was assayed using negative and positive (P1) specimens. Testing at each specific time interval consisted of triplicates for each specimen. The tests were performed according to the directions for use.

Timeline for Accelerate Stability Study

Day / Temp.	0day	7days	14 days	21 days	28 days	35 days
55℃	√	√	√	√	√	√

Results:

Accelerated Stability Study Results at 55℃.

Accelerated Stability Study Results at 55℃.											
Day	Specimen		Batch No.								
			COV2002001-T			COV2002002-T			COV2002002-T		
0	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
7	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG	IgG	+	+	+	+	+	+	+	+	+

14	Positive	IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
21	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
28	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
35	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
42	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+

Note: - means negative result, + means positive result

Conclusion:

ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) is stable at 55℃ for 42days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 24 months from the date of manufacture.

11. Read Time Flex Study

Purpose:
Investigate the read time of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) via interpreting the result at different time point.

Material
Product Information:
ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)
Product Lot No.1: COV2002001-T
Product Lot No.2: COV2002002-T
Product Lot No.3: COV2002003-T
Sample information:
COVID-19 IgG and IgM positive specimen (P1),
COVID-19 IgG positive specimen (P2),

Method
Negative, IgG positive (P2) and IgG/IgM dual positive (P1) standard has been tested according to the directions for use. The test was rated as positive or negative at 1, 3, 5, 10, 15, 20 , 30minutes, 1 hour, 2 hours, 8 hours, and 24 hours. 10ul sample +2 drops of buffer.

Results:

Time		Lot 1:COV2002001-T			Lot 2: COV2002002-T			Lot3: COV2002003-T		
		Neg.	P1	P2	Neg.	P1	P2	Neg.	P1	P2
1min	IgG	-	+	+	-	+	+	-	+	+
	IgM	-	+	-	-	+	-	-	+	-
3min	IgG	-	+	+	-	+	+	-	+	+
	IgM	-	+	-	-	+	-	-	+	-
5min	IgG	-	+	+	-	+	+	-	+	+
	IgM	-	+	-	-	+	-	-	+	-
10min	IgG	-	+	+	-	+	+	-	+	+
	IgM	-	+	-	-	+	-	-	+	-
15min	IgG	-	+	+	-	+	+	-	+	+
	IgM	-	+	-	-	+	-	-	+	-
20min	IgG	-	+	+	-	+	+	-	+	+
	IgM	-	+	-	-	+	-	-	+	-
30min	IgG	-	+	+	-	+	+	-	+	+
	IgM	-	+	-	-	+	-	-	+	-
1 h	IgG	-	+	+	-	+	+	-	+	+
	IgM	-	+	-	-	+	-	-	+	-
2hs	IgG	-	+	+	-	+	+	-	+	+
	IgM	-	+	-	-	+	-	-	+	-
8hs	IgG	-	+	+	-	+	+	-	+	+
	IgM	WM	+	WM	-	+	-	-	+	-

24hs	IgG	WM	WM	+	-	+	+	-	+	+
	IgM	WM	+	WM	-	+	-	-	+	-

Comment: + means positive results and – means negative result.
WM means water marker.

Conclusion:

1~5 mins, the results above is acceptable, but the background is not clear. If the results were interpreted after 30mins, the time is too long. In a word, this study demonstrated the ability of the assay to give correct results and clear background with the prescribed read time of 10-20 minutes. Don't consider the background of the test, the results could be shown up at 1 min after sample application. For the samples tested, the result remained consistent over a 2-hrs period.

12. Dose Hook Effect

Purpose:

Investigate the dose hook effect of the ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma). Investigate the influence of high dose samples on ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma).

Material:

Product Information:

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

Lot No.1: COV2003001-T

Sample Information:	
COV- IgM positive1 (MP1)	20200319-12
COV-IgM positive2 (MP2)	20200319-16
COV-IgG positive1 (GP1)	20200319-9
COV-IgG-IgM positive1 (GMP1)	20200319-19

Method:

A COV-IgM positive1 (MP1), COV-IgM positive2 (MP2), COV-IgG positive1 (GP1) and COV-IgG-IgM positive1 (GMP1) specimen was diluted to the following concentrations: 1:10, 1:20, 1:30, 1:36, 1:48, 1:72, 1:80 and 1:92, with the same negative serum. Different diluted positive specimens were tested by ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma). Interpret the results at 10 minutes.

Results:

COV- IgM positive (P1)	
Specimen	COV2003001-T
Dilution	10min
original	10
1:10	9
1:20	8
1:30	7
1:36	5.5
1:48	5
1:72	4
1:80	3.5
1:92	1
COV- IgM positive (P2)	
Specimen	COV2003001-T
Dilution	10min
original	9.5
1:10	8.5

1:20	7
1:30	6
1:36	5
1:48	4
1:72	3.5
1:80	3
1:92	1

Comment: 1~<3 means negative result and 3~10 means positive result.

COV- IgG positive (GP1)	
Specimen	COV2003001-T
Dilution	10min
original	10
1:10	9.5
1:20	7
1:30	4
1:36	1
1:48	1

Comment: 1~<3 means negative result and 3~10 means positive result.

COV- IgG-IgM positive (GMP1)		
Specimen Dilution	COV2003001-T	
	10min	
	IgG	IgM
original	8.5	9
1:20	5	7.5

Comment: 1~<3 means negative result and 3~10 means positive result.

Conclusion:

Results show there is no dose hook effect for ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma).

For and on behalf of ACCUBIOTECH CO., LTD.

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