

**Real-time stability study report of
ACCU-TELL® COVID-19 IgG/IgM Cassette
(Whole Blood/Serum/Plasma)
No. RTS-B352-BT01/05**

Purpose

Evaluate the Real Time Stability of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) in 2~8°C and 30±3°C (real time). The product catalog number is ABT-IDT-B352. And three lots will be studied

Materials:

ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)
Lot 1: COV20030051,
Lot 2: COV20050013,
Lot 3: COV20050023.

Standard Sample:

IgG Positive control:125ng/mL
IgM Positive control:4µg/mL
Negative Control

Comment:

Original supplier of positive control: Novoprotein

Method:

A real time stability study of at least three complete manufacturing lots will be run at the recommended storage temperatures to verify product stability over length of storage time. Tests were assayed according to the product package inserts at designated time points using negative, IgG positive and IgM positive specimens. Run three replicates per control and read at the product read time.

Following table illustrate the designated time points when the stability test will be performed.

Designed Time Points for Real Time Stability Study

Storage	Day	Month	Month	Month	Month	Month	Month	Month	Month	Month
Temp	0	3	6	9	12	15	18	21	24	27
2~8°C	×	×	×	×	×	×	×	×	×	×
30±3°C	×	×	×	×	×	×	×	×	×	×

*Day 0: Run 10 tests each with controls

Acceptance Criteria :

There should show positive results for IgG Positive sample and IgM Positive, and negative results for negative samples during 27 months at 2~8 °C and 30 ± 3 °C condition.



Results:

1. 2~8 °C

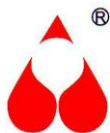
Real Time Stability Study Results at 2-8 °C.						
Month	Specimen		Batch No.			Operator/Date
			COV20030051			
0	Negative	IgG	-	-	-	Alex Wang/2020.03.21
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
3	Negative	IgG	-	-	-	Alex Wang/2020.06.12
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
6	Negative	IgG	-	-	-	Alex Wang/2020.09.03
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
9	Negative	IgG	-	-	-	Alex Wang/2020.12.04
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
12	Negative	IgG	-	-	-	Alex Wang/2021.03.05
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	



15	Negative	IgG	-	-	-	Alex Wang/2021.06.07
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
IgM		+	+	+		
18	Negative	IgG	-	-	-	Alex Wang/2021.09.13
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
IgM		+	+	+		
21	Negative	IgG	-	-	-	Alex Wang/2021.12.14
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
IgM		+	+	+		
24	Negative	IgG	-	-	-	Alex Wang/2022.03.18
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
IgM		+	+	+		
27	Negative	IgG	-	-	-	Alex Wang/2022.06.17
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
IgM		+	+	+		



Real Time Stability Study Results at 2-8°C.									
Month	Specimen		Batch No.						Operator/Date
			COV20050013			COV20050023			
0	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2020.05.21
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
3	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2020.08.21
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
6	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2020.11.27
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
9	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2021.02.18
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
12	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2021.05.14
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2021.08.11
		IgM	-	-	-	-	-	-	



15	IgG Positive	IgG	+	+	+	+	+	+	Alex Wang/ 2021.11.12	
		IgM	-	-	-	-	-	-		
	IgM Positive	IgG	-	-	-	-	-	-		
		IgM	+	+	+	+	+	+		
18	Negative	IgG	-	-	-	-	-	-		Alex Wang/ 2021.11.12
		IgM	-	-	-	-	-	-		
	IgG Positive	IgG	+	+	+	+	+	+		
		IgM	-	-	-	-	-	-		
	IgM Positive	IgG	-	-	-	-	-	-		
		IgM	+	+	+	+	+	+		
21	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2022.02.14	
		IgM	-	-	-	-	-	-		
	IgG Positive	IgG	+	+	+	+	+	+		
		IgM	-	-	-	-	-	-		
	IgM Positive	IgG	-	-	-	-	-	-		
		IgM	+	+	+	+	+	+		
24	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2022.05.12	
		IgM	-	-	-	-	-	-		
	IgG Positive	IgG	+	+	+	+	+	+		
		IgM	-	-	-	-	-	-		
	IgM Positive	IgG	-	-	-	-	-	-		
		IgM	+	+	+	+	+	+		
27	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2022.08.12	
		IgM	-	-	-	-	-	-		
	IgG Positive	IgG	+	+	+	+	+	+		
		IgM	-	-	-	-	-	-		
	IgM Positive	IgG	-	-	-	-	-	-		
		IgM	+	+	+	+	+	+		

Note: “-” mean negative result, “+” mean positive result.

2. 30±3°C

Real Time Stability Study Results at 30±3°C.					
Month	Specimen	Batch No.			Operator/Date
		COV20030051			
	Negative	IgG	-	-	-
		IgM	-	-	-
	IgG	IgG	+	+	+



0	Positive	IgM	-	-	-	Alex Wang/2020.03.21
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
3	Negative	IgG	-	-	-	Alex Wang/2020.06.12
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
6	Negative	IgG	-	-	-	Alex Wang/2020.09.03
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
9	Negative	IgG	-	-	-	Alex Wang/2020.12.04
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
12	Negative	IgG	-	-	-	Alex Wang/2021.03.05
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
15	Negative	IgG	-	-	-	Alex Wang/2021.06.07
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
	Negative	IgG	-	-	-	Alex Wang/2021.09.13
		IgM	-	-	-	
	IgG	IgG	+	+	+	



18	Positive	IgM	-	-	-	Alex Wang/2021.12.14
	IgM Positive	IgG	-	-	-	
		IgM	+	+	+	
21	Negative	IgG	-	-	-	
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
IgM		+	+	+		
24	Negative	IgG	-	-	-	Alex Wang/2022.03.18
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
IgM		+	+	+		
27	Negative	IgG	-	-	-	Alex Wang/2022.06.17
		IgM	-	-	-	
	IgG Positive	IgG	+	+	+	
		IgM	-	-	-	
	IgM Positive	IgG	-	-	-	
IgM		+	+	+		

Real Time Stability Study Results at 30±3°C.									
Month	Specimen		Batch No.						Operator/Date
			COV20050013			COV20050023			
0	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2020.05.21
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
3	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2020.08.21
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM	IgG	-	-	-	-	-	-	



	Positive	IgM	+	+	+	+	+	+	
6	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2020.11.27
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
9	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2021.02.18
		IgM	-	-	-	-	-	-	
	IgG	+	+	+	+	+	+		
	IgG Positive	IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
12	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2021.05.14
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
15	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2021.08.11
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
18	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2021.11.12
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
21	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2022.02.14
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM	IgG	-	-	-	-	-	-	
		IgM	-	-	-	-	-	-	



	Positive	IgM	+	+	+	+	+	+	
24	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2022.05.12
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	
27	Negative	IgG	-	-	-	-	-	-	Alex Wang/ 2022.08.12
		IgM	-	-	-	-	-	-	
	IgG Positive	IgG	+	+	+	+	+	+	
		IgM	-	-	-	-	-	-	
	IgM Positive	IgG	-	-	-	-	-	-	
		IgM	+	+	+	+	+	+	

Note: “-” mean negative result, “+” mean positive result.

Conclusion:

The ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) was stable at 2-8°C and 30±3°C for 27 months. These data were show that the shelf life of this product was determined to be at least 24 months.