

ACCELERATED STABILITY TEST REPORTS

2019-nCoV IgG/IgM Rapid Test Cassette (1-360-K025)

METHOD

Accelerated Stability of the 2019-nCoV IgG/IgM Rapid Test Cassette was evaluated using samples from 1 batch. These were placed in an incubator with the temperature calibrated at 45°C and 55°C. Relative humidity (RH) calibrated at about 60%. A series of stability tests will be performed at 0, 7, 14, 21, 28, 35, 42, 56, 77 and 84 days for 45°C. About 55°C, some performance study would be tested at 0, 7, 14, 21, 28, 35 and 42 days according to Arrhenius Plot. See Table in below. Test cassettes were assayed using negative specimen. Testing at each specific time interval consisted of 3 replicates for each specimen. The tests were performed according to the package insert. Results are presented in Table below.

Table: Time line for Accelerate Stability Study

Storage Temp	Day	Day	Day	Day	Day	Day	Day	Day	Day	Day
	0	7	14	21	28	35	42	56	77	84
45°C	x	x	x	x	x	x	x	x	x	x
55°C	x	x	x	x	x	x	x			

Table: 45°C Accelerated Stability Study Result

Day	Specimen	2019-nCoV IgG/IgM Rapid Test Cassette		
		COV20010001-R		
0	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
7	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
14	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
21	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
28	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
35	Negative			
	IgG positive			
	IgM positive			
42	Negative			
	IgG positive			
	IgM positive			
56	Negative			

	IgG positive			
	IgM positive			
77	Negative			
	IgG positive			
	IgM positive			
84	Negative			
	IgG positive			
	IgM positive			

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

Table: 55°C Accelerated Stability Study Result

Day	Specimen	2019-nCoV IgG/IgM Rapid Test Cassette		
		COV20010001-R		
0	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
7	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
14	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
21	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
28	Negative	-	-	-
	IgG positive	+	+	+
	IgM positive	+	+	+
35	Negative			
	IgG positive			
	IgM positive			
42	Negative			
	IgG positive			
	IgM positive			

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

Conclusion

2019-nCoV IgG/IgM Rapid Test Cassette is stable at 45°C for 28 days and at 55°C for 28 days, the whole study will be finished at about Middle of April 2020.