

Simulated Shipping Study Protocol of COVID-19 Antigen Rapid Test

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Simulated Shipping Study Protocol of COVID-19 Antigen Rapid Test

1. Purpose

Evaluate Simulated Shipping for COVID-19 Antigen Rapid Test .

2. Material

ICOV-502 Lot1:
 Lot2:
 Lot3:

3. Test methods

a. 3XFT/25 °C:

Perform 3 freeze (-20 °C ± 10 °C)/thaw (15 °C -30 °C) cycles and at the last thaw, perform the QC testing.

b. 2 Days @ 55 °C /25 °C:

Place test cassette in a 55 °C oven for 2 days and then perform the QC testing.

Following table illustrates the time points when the stability tests will be performed.

Temperature	Days										Months					
	0*	7	14	21	28	35	42	56	77	84	3	4	5	6		
3FT/25 °C	X	X			X			X							X**	
2 Days @ 55 °C /25 °C	X	X			X			X							X**	

* DAY 0: Run 10 tests with each controls.

** Continue testing every 3 months until to 27th Month.

c. Humidity study:

Place the pouched devices in the 30%, 60% and >=80% relative humidity environments for 48 hours. After 48 hours, perform QC testing on the devices exposed under the 3 different relative humidity conditions.

d. Atmospheric pressure study:

Place the pouched devices in the 1.01*10⁵Pa and 0.88*10⁵Pa atmospheric pressure environments for 48 hours. After 48 hours, perform QC testing on the devices exposed under the 2 different Atmospheric pressure conditions.

4. Standard

The test complies with the standard of EN 23640

5. Acceptance Criteria

Under different conditions, such as specified temperature, humidity and atmospheric pressure, the performance does not change. When a positive sample is tested, the result is positive; When a negative sample is tested, the result is negative.

6. Result

Table 1: COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) Results for Simulated shipping study of 3XFT/25°C

Day/ month	Specimen	Lot		
		Lot1	Lot2	Lot3
0 Day	Negative			
	Positive			
7 Days	Negative			
	Positive			
28 Days	Negative			
	Positive			
56 Days	Negative			
	Positive			
6 months	Negative			
	Positive			
9 months	Negative			
	Positive			
12 months	Negative			
	Positive			
15 months	Negative			
	Positive			

18 months	Negative			
	Positive			
21 months	Negative			
	Positive			
24 months	Negative			
	Positive			
27 months	Negative			
	Positive			

Table 2: COVID-19 Rapid Test (Nasopharyngeal Swab) Results for

Simulated shipping study of 2 Days @55°C /25°C

Day/ month	Specimen	Lot		
		Lot1	Lot2	Lot3
0 Day	Negative			
	Positive			
7 Days	Negative			
	Positive			
28 Days	Negative			
	Positive			
56 Days	Negative			

	Positive			
6 months	Negative			
	Positive			
9 months	Negative			
	Positive			
12 months	Negative			
	Positive			
15 months	Negative			
	Positive			
18 months	Negative			
	Positive			
21 months	Negative			
	Positive			
24 months	Negative			
	Positive			
27 months	Negative			
	Positive			

Table 3: COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) Results for Humidity study of 30%

Specimen	Lot
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	Lot1	Lot2	Lot3
Negative			
Positive			

Table 4: COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) Results for Humidity study of 60%

Specimen	Lot		
	Lot1	Lot2	Lot3
Negative			
Positive			

Table 5: COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) Results for Humidity study of $\geq 80\%$

Specimen	Lot		
	Lot1	Lot2	Lot3
Negative			
Positive			

Table 6: COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) Results for Atmospheric pressure study of $1.01 \times 10^5 \text{Pa}$

Specimen	Lot		
	Lot1	Lot2	Lot3

Negative			
Positive			

Table 6: COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) Results for Atmospheric pressure study of $0.88 \times 10^5 \text{Pa}$

Specimen	Lot		
	Lot1	Lot2	Lot3
Negative			
Positive			

7. Conclusion