

Reading Time Flex Study Report of COVID-19 Antigen Rapid Test

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Reading Time Flex Study Report of COVID-19 Antigen Rapid Test

1. Purpose

Reading Time Flex Study for COVID-19 Antigen Rapid Test .

2. Material

ICOV-502 Lot1: COV20060001-T
 Lot2: COV20060002-T
 Lot3: COV20060003-T

SARS-COV-2 Antigen weak positive
 SARS-COV-2 Antigen strong positive

3. Test methods

Negative, SARS-COV-2 Antigen weak positive, and SARS-COV-2 Antigen strong positive standards have been tested according to the directions for use in replicates of three. The test was rated as positive or negative at 3, 5, 10, 15, 20, 30minutes, 1 hour and 2 hours.

4. Acceptance Criteria

The correct results can be obtained within 15 minutes of reading

5. Result

6. Table: Reading Time Flex Study Result

Time	Lot 1: COV20060001-T								
	Negative			SARS-COV-2 Antigen weak positive			SARS-COV-2 Antigen strong positive		
3min	-	-	-	-	-	-	+	+	+
5min	-	-	-	-	-	+	+	+	+
10min	-	-	-	+	+	+	+	+	+
15min	-	-	-	+	+	+	+	+	+
20min	-	-	-	+	+	+	+	+	+

30min	-	-	-	+	+	+	+	+	+
1 h	-	-	-	+	+	+	+	+	+
2hs	-	-	-	+	+	+	+	+	+
Time	Lot 2: COV20060002-T								
	Negative			SARS-COV-2 Antigen weak positive			SARS-COV-2 Antigen strong positive		
3min	-	-	-	-	-	-	+	+	+
5min	-	-	-	-	+	+	+	+	+
10min	-	-	-	+	+	+	+	+	+
15min	-	-	-	+	+	+	+	+	+
20min	-	-	-	+	+	+	+	+	+
30min	-	-	-	+	+	+	+	+	+
1 h	-	-	-	+	+	+	+	+	+
2hs	-	-	-	+	+	+	+	+	+
Time	Lot 3: COV20060003-T								
	Negative			SARS-COV-2 Antigen weak positive			SARS-COV-2 Antigen strong positive		
3min	-	-	-	-	-	-	+	+	+
5min	-	-	-	-	+	-	+	+	+
10min	-	-	-	+	+	+	+	+	+
15min	-	-	-	+	+	+	+	+	+

20min	-	-	-	+	+	+	+	+	+
30min	-	-	-	+	+	+	+	+	+
1 h	-	-	-	+	+	+	+	+	+
2hs	-	-	-	+	+	+	+	+	+

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

As can be seen from the above table, the test results tend to be stable after 15 minutes, and remain unchanged until one hour.

7. Conclusion

This study demonstrated the ability of the assay to give correct results with the prescribed read time of 15 minutes. For the samples tested, the result remained consistent within a 1hr period.