

Open Pouch Stability Study Report of COVID-19 Antigen Rapid Test

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Prepared By	5.1.2e	5.1.2e	2020.06.03
Reviewed By	5.1.2e	5.1.2e	2020.06.03

Open Pouch Stability Study of COVID-19 Antigen Rapid Test

1. Purpose

Evaluate open pouch stability influence for COVID-19 Antigen Rapid Test .

2. Material

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

3. Procedure

COVID-19 Antigen samples including negative specimen, weak positive and middle positive were run in triplicate using the COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) which were opened pouch after 10 minutes, 20 minutes, 30 minutes, 1 hour, 1.5 hours and 2 hours at following condition. All results were read at 15 minutes after sample application.

Condition 1: Room temperature and high humidity ($\geq 90\%$)

Condition 2: 45°C and normal humidity ($\leq 60\%$)

Condition 3: 45°C and high humidity ($\geq 90\%$)

Condition 4: Room temperature and normal humidity ($\leq 60\%$)

4. Standard

The test complies with the standard of EN 23640

5. Acceptance Criteria

Open pouch have no effect on the results. When a positive sample is tested, the result is positive; when a negative sample is tested, the result is negative.

6.Result:

Table-Open Pouch Stability Study Result

Sample	Time	Condition 1								
		COV20060001-T			COV20060002-			COV20060003-T		
Negative	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
	30min	-	-	-	-	-	-	-	-	-
	60min	-	-	-	-	-	-	-	-	-
	90min	-	-	-	-	-	-	-	-	-
	120min	-	-	-	-	-	-	-	-	-
Weak Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+

Positive	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
Sample	Time	Condition4								
		COV20060001-T			COV20060002-			COV20060003-T		
Negative	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
	30min	-	-	-	-	-	-	-	-	-
	60min	-	-	-	-	-	-	-	-	-
	90min	-	-	-	-	-	-	-	-	-
	120min	-	-	-	-	-	-	-	-	-
Weak Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
Strong Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+

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

As can be seen from the above table, the test results of negative samples were still negative and positive samples were still positive at different times after open pouch. so open pouch for 10min-120min has no influence on the test result of the negative and positive sample. However, it is not recommended to open pouch for too long, because it is easy to cause the backflow of liquid. The recommended time is within 1h after bag pouch.

7. Conclusion:

Results above indicated best results of COVID-19 Antigen Rapid Test will be got within 1 hour after opening the pouch.