Variability Study Report of COVID-19 Antigen Rapid Test

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1. Purpose

The study was designed to determine the precision (intra- and inter-assay variability), the reproducibility (day-to-day variability) of the COVID-19 Rapid Test.

2. Material

ICOV-502 Lot1: COV20060001-T

Lot2: COV20060002-T Lot3: COV20060003-T

3. Test methods

Negative, SARS-COV-2 Antigen Weak Positive, SARS-COV-2 Antigen Strong Positive were tested according to the package inset. Ten replicates of each level were tested each day for 3 consecutive days using all the 3 lots. Read the results at 15 minutes. Results were presented in Table below.

4. Acceptance Criteria

There is no difference among the three lot of COVID-19 Rapid Test at ten days. When a positive sample is tested, the result is positive; When a nagative sample is tested, the result is nagative.

5. Result

Table: Variability Study Results

Negative (Dilution)

Day	Lot#:	1	2	3	4	5	6	7	8	9	10
	COV20060001-T	-	-	-	-	-	-	=	-	-	-
Day 1	COV20060002-T	-	-	-	-	-	-	-	-	-	-
	COV20060003-T	-	-	-	-	-	-	-	-	-	-
	COV20060001-T	-	-	-	-	-	-	-	-	-	1-
Day 2	COV20060002-T	-	-	-	-	-	-	-	-	-	-
	COV20060003-T	-	-	-	-	-	-	-	-	-	-
Day 3	COV20060001-T	-	-	-	-	-	-	-	-	-	-
	COV20060002-T		*	-		-	-	-	-	-	14
	COV20060003-T	-	-	-	-	-	-	-	-	-	-

SARS-COV-2 Antigen Weak Positive

Day	Lot#:	1	2	3	4	5	6	7	8	9	10
Day 1	COV20060001-T	+	+	+	+	+	+	+	+	+	+
	COV20060002-T	+	+	+	+	+	+	+	+	+	+
	COV20060003-T	+	+	+	+	+	+	+	+	+	+
Day 2	COV20060001-T	+	+	+	+	+	+	+	+	+	+
	COV20060002-T	+	+	+	+	+	+	+	+	+	+

	COV20060003-T	+	+	+	+	+	+	+	+	+	+
Day 3	COV20060001-T	+	+	+	+	+	+	+	+	+	+
	COV20060002-T	+	+	+	+	+	+	+	+	+	+
	COV20060003-T	+	+	+	+	+	+	+	+	+	+
SARS-CO	OV-2 Antigen Strong	Positi	ive								
Day	Lot#:	1	2	3	4	5	6	7	8	9	10
	COV20060001-T	+	+	+	+	+	+	+	+	+	+
Day 1	COV20060002-T	+	+	+	+	+	+	+	+	+	+
	COV20060003-T	+	+	+	+	+	+	+	+	+	+
Day 2	COV20060001-T	+	+	+	+	+	+	+	+	+	+
	COV20060002-T	+	+	+	+	+	+	+	+	+	+
	COV20060003-T	+	+	+	+	+	+	+	+	+	+
Day 3	COV20060001-T	+	+	+	+	+	+	+	+	+	+
	COV20060002-T	+	+	+	+	+	+	+	+	+	+
	COV20060003-T	+	+	+	+	+	+	+	+	+	+

Note: "-" mean negative result, "+" mean positive result

As can be seen from the above table, the test results of three batches of different reagents in three consecutive days showed no difference. The negative samples show negative result and the positive samples show positive result.

6. Conclusion

Test results showed that there were consistent between the 3 lots of test.