# Specimen Volume Flex Study Report of COVID-19 Antigen Rapid Test

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### 1. Purpose

Specimen Volume Flex Study for COVID-19 Antigen 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 spiked extraction reagent were added into the sample well of COVID-19 Antigen Rapid Test with the following operation method, read the results at 15 minutes, a suitable specimen volume should be validated in this study.

Method A- 2 drops specimen

Method B- 3 drops specimen

Method C- 4 drops specimen

Method D-5 drops specimen

# 4. Acceptance Criteria

The appropriate specimen volume is characterized by good performance, no risk of false positive or false negative, and good stability of the results.

### 5. Result

Table: Specimen Volume Flex Study Result

	Method	Α		В		С		D	
Lot	Specimen	15mi	20mi	15mi	20mi	15mi	20mi	15mi	20mi
		n	n	n	n	n	n	n	n
COV20060001-T	Negative	ı	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-
		1	-	_	2	_	<u> </u>	-	1
	SARS-COV-2	+	+	+	+	+	+	+	+
	Antigen weak	+	+	+	+	+	+	+	+
	positive	+	+	+	+	+	+	+	+
COV20060002-T	Negative	1	3	-	T.	-	-		1
		-	-	-	-	-	-	-	-
		T	=	-		-	34	1	1
00	SARS-COV-2	+	+	+	+	+	+	+	+

	Antigen weak positive	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+
COV20060003-T	Negative	-	-	-	-	-	-	-	-
		-	-	-	-	-		-	-
		-	-	-	-	120	-	( <del>-</del> )	-
	SARS-COV-2	+	+	+	+	+	+	+	+
	Antigen weak	+	+	+	+	+	+	+	+
	positive	+	+	+	+	+	+	+	+

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

As can be seen from the table above, the negative and weak positive results of the four different sample sizes were consistent, however, 5 drops of samples are prone to cause liquid to flow on the NC membrane surface, leading to flooding risk. All in all, 3 drops are better.

# 6. Conclusion

This study demonstrated the ability of the assay to give correct results with 2-5 drops specimen volume. To reduce or eliminate the risks from incorrect specimen volume, the specimen volume was determined to be 3 drops.