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# **COVID-19 Antigen Rapid Test ( Latex )**

## **Validation Report**

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**Reviewed By: Qian XU Date: 02/09/2020**

**Approval By: Zhong WANG Date: 03/09/2020**

**1. Review overall product performance vs. targeted performance goals**

Condition		Accepted standards
Limit of Detection		Positive detection rate $\geq 95\%$
Positive coincidence rate		no negative results
Negative coincidence rate		no positive results
Cross-reactivity		no Cross-reactivity
Interference		no differences
Precision	Intra assay	No distinct difference was detected in intra lots
	Inter assay	No significant differences were detected between batches

**2. Limit of Detection**

**2.1 Materials:**

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

**2.2 Method:**

Recombinant SARS-CoV-2 Spike glycoprotein was diluted in assay sample buffer at concentrations of 4ng/mL, 2ng/mL, 1ng/mL, 0.5ng/mL, 0.25ng/mL, 0ng/mL. The resultant dilutions were tested in replicates of 20 in the COVID-19 Antigen Rapid Test (Latex) assay. LOD was estimated from the lowest dilution that gave a positive result in the assay.

**2.3 Results:**

As per the standard assay protocol, the results were read in 15 minutes for all the dilutions prepared.

The results are as follows and a 20/20 indicates that all 20 samples were positive whilst a 0/20 indicates that no positivity was detected.

Saliva	LCOVADEV001			LCOVADEV002			LCOVADEV003			
	Repeat Times	1	2	3	1	2	3	1	2	3
4ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
2ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
1ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
0.5ng/mL	20/20	20/20	20/20	19/20	20/20	20/20	20/20	19/20	20/20	20/20
0.25ng/mL	11/20	7/20	9/20	12/20	10/20	9/20	10/20	8/20	11/20	11/20
0 ng/mL	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20

Sputum	LCOVADEV001			LCOVADEV002			LCOVADEV003			
	Repeat Times	1	2	3	1	2	3	1	2	3
4ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
2ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
1ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
0.5ng/mL	20/20	20/20	19/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
0.25ng/mL	9/20	8/20	12/20	8/20	12/20	10/20	13/20	12/20	7/20	7/20
0 ng/mL	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20

Stool	LCOVADEV001			LCOVADEV002			LCOVADEV003			
	Repeat Times	1	2	3	1	2	3	1	2	3
4ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
2ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
1ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
0.5ng/mL	20/20	20/20	19/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
0.25ng/mL	10/20	9/20	7/20	13/20	9/20	10/20	11/20	8/20	12/20	12/20
0 ng/mL	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20

#### 2.4 Conclusion:

From the above it was concluded that the limit of detection (LOD) of COVID-19 Antigen Rapid Test (Latex) is 0.5ng/mL SARS-COV-2 spike glycoprotein.

### 3. Positive coincidence rate

#### 3.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

#### 3.2 Method

The positive coincidence rate was calculated by testing different concentrations of recombinant S protein; P1 at 1000ng/ml, P2 at 250ng/ml, P3 at 62.5ng/ml, P4 at 10ng/ml and P5 at 5ng/ml in 3 lots of the COVID-19 Antigen Rapid Test (Latex).

#### 3.3 Results:

As per the standard assay protocol, the results were read after 15 minutes.

The results are as follows ("+" indicates a positive result, "-" indicates a negative result):

Positiv control	Lot 1			Lot 2			Lot 3		
	Saliva	Sputum	Stool	Saliva	Sputum	Stool	Saliva	Sputum	Stool
P1	+	+	+	+	+	+	+	+	+
P2	+	+	+	+	+	+	+	+	+
P3	+	+	+	+	+	+	+	+	+
P4	+	+	+	+	+	+	+	+	+
P5	+	+	+	+	+	+	+	+	+

#### 3.4 Conclusion

From the above it was concluded that all levels of the recombinant S protein were correctly detected, and the positive compliance rate meets the acceptable criteria.

#### 4. Negative coincidence rate

##### 4.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

##### 4.2 Method

The negative coincidence rate was calculated by testing 9 samples (N1-N9) in duplicate from healthy individuals in 3 lots of the COVID-19 Antigen Rapid Test (Latex) assay

##### 4.3 Results:

According to the standard assay protocol the results are read in 15 minutes and the results were as follows:

Negative control	Lot 1			Lot 2			Lot 3		
	Saliva	Sputum	Stool	Saliva	Sputum	Stool	Saliva	Sputum	Stool
N1	-	-	-	-	-	-	-	-	-
N2	-	-	-	-	-	-	-	-	-
N3	-	-	-	-	-	-	-	-	-
N4	-	-	-	-	-	-	-	-	-
N5	-	-	-	-	-	-	-	-	-
N6	-	-	-	-	-	-	-	-	-
N7	-	-	-	-	-	-	-	-	-
N8	-	-	-	-	-	-	-	-	-
N9	-	-	-	-	-	-	-	-	-

##### 4.4 Conclusion

From the above it was concluded that all negative samples were correctly identified in three kit lots, and the negative compliance rate meets the acceptable criteria.

## 5. Cross-reactivity

### 5.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

### 5.2 Method

Cross reactivity and potential interference of the COVID-19 Antigen Rapid Test (Latex) was evaluated by testing 10 pathogenic microorganisms (recombinant proteins) that may be present in the clinical specimen and could potentially cross-react with the assay. The interference testing was performed at 6 different concentrations of each pathogen in 3 lots of the COVID-19 Antigen Rapid Test (Latex) assay.

Concentration of Recombinant Proteins( $\mu\text{g/ml}$ )
SARS-CoV-2 S1 Protein
SARS-CoV-2 S1 Protein(D614G)
SARS-CoV S1 Protein
HCoV-NL63 S1 Protein
HCoV-229E S1 Protein
HCoV-HKU1 S1 Protein
MERS-CoV S1 Protein
Human RSV (B1) G Protein
Influenza A H1N1 HA Protein
Influenza B HA Protein

### 5.3 Results:

As per the standard assay protocol the results were read in 15 minutes and the results were as follows

("+" indicates a positive result, "-" indicates a negative result):

LCOVADEV001 Saliva

Concentration of Recombinant Proteins( $\mu\text{g/ml}$ )	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	+	+	+
SARS-CoV-2 S1 Protein(D614G)	-	+	+	+	+	+
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-

Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

LCOVADEV001 Sputum

Concentration of Recombinant Proteins( $\mu\text{g/ml}$ )	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	+	+	+
SARS-CoV-2 S1 Protein(D614G)	-	+	+	+	+	+
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-
Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

LCOVADEV001 Stool

Concentration of Recombinant Proteins( $\mu\text{g/ml}$ )	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	+	+	+
SARS-CoV-2 S1 Protein(D614G)	-	+	+	+	+	+
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-
Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

LCOVADEV002 Saliva

Concentration of Recombinant Proteins( $\mu\text{g/ml}$ )	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	+	+	+
SARS-CoV-2 S1 Protein(D614G)	-	+	+	+	+	+
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-

Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

#### LCOVADEV002 Sputum

Concentration of Recombinant Proteins( $\mu\text{g/ml}$ )	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	+	+	+
SARS-CoV-2 S1 Protein(D614G)	-	+	+	+	+	+
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-
Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

#### LCOVADEV002 Stool

Concentration of Recombinant Proteins( $\mu\text{g/ml}$ )	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	+	+	+
SARS-CoV-2 S1 Protein(D614G)	-	+	+	+	+	+
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-
Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

#### LCOVADEV003 Saliva

Concentration of Recombinant Proteins( $\mu\text{g/ml}$ )	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	+	+	+
SARS-CoV-2 S1 Protein(D614G)	-	+	+	+	+	+
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-



Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

LCOVADEV003 Sputum

Concentration of Recombinant Proteins( $\mu\text{g/ml}$ )	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	+	+	+
SARS-CoV-2 S1 Protein(D614G)	-	+	+	+	+	+
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-
Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

LCOVADEV003 Stool

Concentration of Recombinant Proteins( $\mu\text{g/ml}$ )	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	+	+	+
SARS-CoV-2 S1 Protein(D614G)	-	+	+	+	+	+
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-
Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

#### 5.4 Conclusion

The results show specific response to the S protein of SARS-CoV-2, and a related mutation D614G) but no cross-reactivity with other viruses.

## 6. Interference test

### 6.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

### 6.2 Method:

The interference study was performed by preparing recombinant SARS-CoV-2 positive and negative controls with the following interference substances, which may be present in human saliva, stool and sputum, in triplicate in 3 lot numbers of the COVID-19 Antigen Rapid Test (Latex). The qualitative assessment of the positive and negative samples was used to verify the impact of the interfering substances at the concentration listed below.

substance	concentration
Triglyceride	50mg/dl
Hemoglobin	1000mg/dl
Ascorbic Acid	20mg/dl
Bilirubin	60mg/dl

### 6.3 Results

As per the standard assay protocol, the results were read in 15 minutes. The results are as follows ("+" indicates a positive result, "-" indicates a negative result):

Saliva	Lot 1					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+
Sputum	Lot 1					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+
Stool	Lot 1					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+
Saliva	Lot 2					
	Negative			positive		
Triglyceride	-	-	-	+	+	+

Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+
Sputum	Lot 2					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+
Stool	Lot 2					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+

Saliva	Lot 3					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+
Sputum	Lot 3					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+
Stool	Lot3					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+

#### 6.4 Conclusion

The results show that at the concentrations used the interfering substances studied had no impact on the performance of the the COVID-19 Antigen Rapid Test (Latex).

## 7. Intra assay

### 7.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

### 7.2 Method:

Intra assay precision was tested using a negative (N1), a low (P5) and a medium (P3) QC control sample made from recombinant S protein in the COVID-19 Antigen Rapid Test (Latex). Testing in replicates of 20 was performed across 3 lots over three separate days by three different operators.

### 7.3 Results:

As per the standard operating protocol the results were read after in 15 minutes. The results are as follows ("+" indicates a positive result, "-" indicates a negative result):

#### Day1 Operator 1 Saliva

No.	LCOVADEV001			LCOVADEV002			LCOVADEV003		
	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+
11	-	+	+	-	+	+	-	+	+
12	-	+	+	-	+	+	-	+	+
13	-	+	+	-	+	+	-	+	+
14	-	+	+	-	+	+	-	+	+
15	-	+	+	-	+	+	-	+	+
16	-	+	+	-	+	+	-	+	+
17	-	+	+	-	+	+	-	+	+
18	-	+	+	-	+	+	-	+	+
19	-	+	+	-	+	+	-	+	+
20	-	+	+	-	+	+	-	+	+

#### Day1 Operator 1 Sputum

No.	LCOVADEV001			LCOVADEV002			LCOVADEV003		
	Negative	Positive	Positive	Negative	Positive	Positive	Negative	Positive	Positive



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	control N1	control P3	control P5	control N1	control P3	control P5	control N1	control P3	control P5
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+
11	-	+	+	-	+	+	-	+	+
12	-	+	+	-	+	+	-	+	+
13	-	+	+	-	+	+	-	+	+
14	-	+	+	-	+	+	-	+	+
15	-	+	+	-	+	+	-	+	+
16	-	+	+	-	+	+	-	+	+
17	-	+	+	-	+	+	-	+	+
18	-	+	+	-	+	+	-	+	+
19	-	+	+	-	+	+	-	+	+
20	-	+	+	-	+	+	-	+	+

Day1 Operator 1 Stool

No.	LCOVADEV001			LCOVADEV002			LCOVADEV003		
	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+
11	-	+	+	-	+	+	-	+	+
12	-	+	+	-	+	+	-	+	+
13	-	+	+	-	+	+	-	+	+
14	-	+	+	-	+	+	-	+	+
15	-	+	+	-	+	+	-	+	+
16	-	+	+	-	+	+	-	+	+
17	-	+	+	-	+	+	-	+	+
18	-	+	+	-	+	+	-	+	+



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19	-	+	+	-	+	+	-	+	+
20	-	+	+	-	+	+	-	+	+

Day3 Operator 2 Saliva

No.	LCOVADEV001			LCOVADEV002			LCOVADEV003		
	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+
11	-	+	+	-	+	+	-	+	+
12	-	+	+	-	+	+	-	+	+
13	-	+	+	-	+	+	-	+	+
14	-	+	+	-	+	+	-	+	+
15	-	+	+	-	+	+	-	+	+
16	-	+	+	-	+	+	-	+	+
17	-	+	+	-	+	+	-	+	+
18	-	+	+	-	+	+	-	+	+
19	-	+	+	-	+	+	-	+	+
20	-	+	+	-	+	+	-	+	+

Day3 Operator 2 Sputum

No.	LCOVADEV001			LCOVADEV002			LCOVADEV003		
	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+
11	-	+	+	-	+	+	-	+	+



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12	-	+	+	-	+	+	-	+	+
13	-	+	+	-	+	+	-	+	+
14	-	+	+	-	+	+	-	+	+
15	-	+	+	-	+	+	-	+	+
16	-	+	+	-	+	+	-	+	+
17	-	+	+	-	+	+	-	+	+
18	-	+	+	-	+	+	-	+	+
19	-	+	+	-	+	+	-	+	+
20	-	+	+	-	+	+	-	+	+

Day3 Operator 2 Stool

No.	LCOVADEV001			LCOVADEV002			LCOVADEV003		
	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+
11	-	+	+	-	+	+	-	+	+
12	-	+	+	-	+	+	-	+	+
13	-	+	+	-	+	+	-	+	+
14	-	+	+	-	+	+	-	+	+
15	-	+	+	-	+	+	-	+	+
16	-	+	+	-	+	+	-	+	+
17	-	+	+	-	+	+	-	+	+
18	-	+	+	-	+	+	-	+	+
19	-	+	+	-	+	+	-	+	+
20	-	+	+	-	+	+	-	+	+

Day5 Operator 3 Saliva

No.	LCOVADEV001			LCOVADEV002			LCOVADEV003		
	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+



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5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+
11	-	+	+	-	+	+	-	+	+
12	-	+	+	-	+	+	-	+	+
13	-	+	+	-	+	+	-	+	+
14	-	+	+	-	+	+	-	+	+
15	-	+	+	-	+	+	-	+	+
16	-	+	+	-	+	+	-	+	+
17	-	+	+	-	+	+	-	+	+
18	-	+	+	-	+	+	-	+	+
19	-	+	+	-	+	+	-	+	+
20	-	+	+	-	+	+	-	+	+

Day5 Operator 3 Sputum

No.	LCOVADEV001			LCOVADEV002			LCOVADEV003		
	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+
11	-	+	+	-	+	+	-	+	+
12	-	+	+	-	+	+	-	+	+
13	-	+	+	-	+	+	-	+	+
14	-	+	+	-	+	+	-	+	+
15	-	+	+	-	+	+	-	+	+
16	-	+	+	-	+	+	-	+	+
17	-	+	+	-	+	+	-	+	+
18	-	+	+	-	+	+	-	+	+
19	-	+	+	-	+	+	-	+	+
20	-	+	+	-	+	+	-	+	+

Day5 Operator 3 Stool

No.	LCOVADEV001	LCOVADEV002	LCOVADEV003
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	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5	Negative control N1	Positive control P3	Positive control P5
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+
11	-	+	+	-	+	+	-	+	+
12	-	+	+	-	+	+	-	+	+
13	-	+	+	-	+	+	-	+	+
14	-	+	+	-	+	+	-	+	+
15	-	+	+	-	+	+	-	+	+
16	-	+	+	-	+	+	-	+	+
17	-	+	+	-	+	+	-	+	+
18	-	+	+	-	+	+	-	+	+
19	-	+	+	-	+	+	-	+	+
20	-	+	+	-	+	+	-	+	+

#### 7.4 Conclusion

The results show that the intrassay precision in the 3 lots of kits tested was acceptable and no unexplained results were observed.

## 8. Inter assay

### 8.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

### 8.2 Method:

Intra assay precision was tested using a negative (N1), a low (P5) and a medium (P3) QC control sample made from recombinant S protein in the COVID-19 Antigen Rapid Test (Latex). Testing in replicates of 20 was performed across 3 lots by the same operator.

### 8.3 Results

As per the standard operating protocol the results were read after in 15 minutes. The results are as follows ("+" indicates a positive result, "-" indicates a negative result):

#### Saliva

No.	N1			P3			P5		
	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3
1	-	-	-	+	+	+	+	+	+
2	-	-	-	+	+	+	+	+	+
3	-	-	-	+	+	+	+	+	+
4	-	-	-	+	+	+	+	+	+
5	-	-	-	+	+	+	+	+	+
6	-	-	-	+	+	+	+	+	+
7	-	-	-	+	+	+	+	+	+
8	-	-	-	+	+	+	+	+	+
9	-	-	-	+	+	+	+	+	+
10	-	-	-	+	+	+	+	+	+
11	-	-	-	+	+	+	+	+	+
12	-	-	-	+	+	+	+	+	+
13	-	-	-	+	+	+	+	+	+
14	-	-	-	+	+	+	+	+	+
15	-	-	-	+	+	+	+	+	+
16	-	-	-	+	+	+	+	+	+
17	-	-	-	+	+	+	+	+	+
18	-	-	-	+	+	+	+	+	+
19	-	-	-	+	+	+	+	+	+
20	-	-	-	+	+	+	+	+	+

#### Sputum

No.	N1			P3			P5		
	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3
1	-	-	-	+	+	+	+	+	+
2	-	-	-	+	+	+	+	+	+
3	-	-	-	+	+	+	+	+	+
4	-	-	-	+	+	+	+	+	+

5	-	-	-	+	+	+	+	+	+
6	-	-	-	+	+	+	+	+	+
7	-	-	-	+	+	+	+	+	+
8	-	-	-	+	+	+	+	+	+
9	-	-	-	+	+	+	+	+	+
10	-	-	-	+	+	+	+	+	+
11	-	-	-	+	+	+	+	+	+
12	-	-	-	+	+	+	+	+	+
13	-	-	-	+	+	+	+	+	+
14	-	-	-	+	+	+	+	+	+
15	-	-	-	+	+	+	+	+	+
16	-	-	-	+	+	+	+	+	+
17	-	-	-	+	+	+	+	+	+
18	-	-	-	+	+	+	+	+	+
19	-	-	-	+	+	+	+	+	+
20	-	-	-	+	+	+	+	+	+

### Stool

No.	N1			P3			P5		
	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3
1	-	-	-	+	+	+	+	+	+
2	-	-	-	+	+	+	+	+	+
3	-	-	-	+	+	+	+	+	+
4	-	-	-	+	+	+	+	+	+
5	-	-	-	+	+	+	+	+	+
6	-	-	-	+	+	+	+	+	+
7	-	-	-	+	+	+	+	+	+
8	-	-	-	+	+	+	+	+	+
9	-	-	-	+	+	+	+	+	+
10	-	-	-	+	+	+	+	+	+
11	-	-	-	+	+	+	+	+	+
12	-	-	-	+	+	+	+	+	+
13	-	-	-	+	+	+	+	+	+
14	-	-	-	+	+	+	+	+	+
15	-	-	-	+	+	+	+	+	+
16	-	-	-	+	+	+	+	+	+
17	-	-	-	+	+	+	+	+	+
18	-	-	-	+	+	+	+	+	+
19	-	-	-	+	+	+	+	+	+
20	-	-	-	+	+	+	+	+	+

### 8.4 Conclusion

The results show that the inter assay precision in the 3 lots of kits tested was acceptable and no unexplained results were observed.

## 9. Cross-reactivity test by pathogenic microorganisms

### 9.1 Materials:

Reagent name and specifications	Lot
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	COV2008003L-T

### 9.2 Method

Cross reactivity and potential interference of the COVID-19 Antigen Rapid Test (Latex) was evaluated by testing 10 pathogenic microorganisms that may be present in the clinical specimen and could potentially cross-react with the assay.

HCoV-OC43	HCoV-NL63	HCoV-229E	MERS
Human Rhinovirus	Human Enterovirus	Human Metapneumovirus	Human RSV
Influenza A	Influenza B		

### 9.3 Results:

As per the standard assay protocol the results were read in 15 minutes and the results were as follows

("+" indicates a positive result, "-" indicates a negative result):

Pathogenic microorganisms	COV2008003L-T
HCoV-OC43	-
HCoV-NL63	-
HCoV-229E	-
MERS	-
Human Rhinovirus	-
Human Enterovirus	-
Human Metapneumovirus	-
Human RSV	-
Influenza A	-
Influenza B	-

### 9.4 Conclusion

The results show no cross-reactivity with the tested pathogenic microorganisms.