

## Specificity and Cross-Reaction Study Report

### COVID-19 Antigen Rapid Test

#### 1. Purpose:

To study the specificity and cross-reaction of Safecare COVID-19 Antigen Rapid Test it(Swab).

#### 2. Material:

2.1 Cross reactivity and potential interference was evaluated by testing the following materials at listed on the table. Each reactant were tested in triplicate in the absence or presence of recombinant COVID-19 antigen.

Cross-Reactant	Concentration	Cross-Reactant	Concentration
Adenovirus	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Influenza B	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
Human metapneumovirus (hMPV)	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Respiratory Syncytial Virus	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
Rhinovirus	1.0 x 10 <sup>5</sup> PFU/mL	Bordetella pertussis	1.0 x 10 <sup>6</sup> cells/mL
Enterovirus	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Chlamydia pneumoniae	1.0 x 10 <sup>6</sup> IFU/mL
Human coronavirus OC43	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Haemophilus influenzae	1.0 x 10 <sup>6</sup> cells/mL
Human coronavirus 229E	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Legionella pneumophila	1.0 x 10 <sup>6</sup> cells/mL
Human coronavirus NL63	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Mycoplasma pneumoniae	1.0 x 10 <sup>6</sup> U/mL
Human parainfluenza virus 1	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Streptococcus pneumoniae	1.0 x 10 <sup>6</sup> cells/mL
Human parainfluenza virus 2	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Streptococcus pyogenes	1.0 x 10 <sup>6</sup> cells/mL

Human parainfluenza virus 3	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Mycobacterium tuberculosis	1.0 x 10 <sup>6</sup> cells/mL
Human parainfluenza virus 4	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Staphylococcus aureus	1.0 x 10 <sup>6</sup> org/mL
Influenza A	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	Candida albicans	1.0 x 10 <sup>6</sup> cells/mL

### 2.3 Product used:

Product	LOT1	LOT2	LOT3
COVID-19 Antigen Rapid Test Device	COV20081001	COV20081002	COV20081003

### 3. Testing Procedure:

3.1 The total 144 samples were scrambled and numbered randomly, refer to the “*Sample blind list*”.

3.2 Test the Cross-Reaction Samples with three lots of test-strip, by three operators. The reading time is 10-15 minutes after sample addition.

3.3 Collect the data of every sample to the table followed.

#### Sample blind list

Cross-Reactant	Negative Sample (no inactivated SARS-Cov-2 virus)			Positive Sample (with inactivated SARS-Cov-2 virus)		
Adenovirus	SC140	SC005	SC129	SC029	SC041	SC142
Human metapneumovirus (hMPV)	SC149	SC180	SC169	SC123	SC033	SC135
Rhinovirus	SC134	SC001	SC148	SC066	SC095	SC077
Enterovirus	SC146	SC081	SC179	SC191	SC093	SC078
Human coronavirus OC43	SC121	SC056	SC193	SC177	SC112	SC101
Human coronavirus 229E	SC070	SC194	SC055	SC084	SC107	SC003
Human coronavirus NL63	SC040	SC144	SC087	SC062	SC098	SC076
Human parainfluenza virus 1	SC067	SC131	SC167	SC061	SC021	SC164
Human parainfluenza virus 2	SC085	SC052	SC184	SC171	SC069	SC068

Human parainfluenza virus 3	SC054	SC141	SC080	SC117	SC042	SC064
Human parainfluenza virus 4	SC132	SC059	SC111	SC017	SC012	SC186
Influenza A	SC124	SC026	SC051	SC049	SC015	SC110
Influenza B	SC086	SC151	SC160	SC138	SC198	SC030
Respiratory Syncytial Virus	SC022	SC014	SC050	SC057	SC197	SC089
Bordetella pertussis	SC105	SC173	SC053	SC092	SC018	SC008
Chlamydia pneumoniae	SC006	SC039	SC032	SC182	SC047	SC113
Haemophilus influenzae	SC172	SC063	SC195	SC072	SC175	SC023
Legionella pneumophila	SC159	SC136	SC079	SC100	SC106	SC174
Mycoplasma pneumoniae	SC162	SC058	SC011	SC183	SC127	SC188
Streptococcus pneumoniae	SC147	SC130	SC128	SC161	SC104	SC002
Streptococcus pyogenes	SC007	SC024	SC109	SC013	SC126	SC199
Mycobacterium tuberculosis	SC038	SC046	SC097	SC163	SC083	SC045
Staphylococcus aureus	SC181	SC153	SC019	SC020	SC133	SC027
Candida albicans	SC010	SC145	SC189	SC028	SC165	SC044

## 4.2 Test Result

Test the Cross-Reaction Samples with three lot of test-strip, by three operator. The reading time is 10-15 minutes after sample addition. The detailed test data is as follows.

### 4.2.1 Result for Lot1:

Sample No.	Result	Sample No.	Result
SC121	-	SC022	-
SC057	+	SC067	-

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SC066	+	SC049	+
SC007	-	SC134	-
SC146	-	SC038	-
SC100	+	SC162	-
SC072	+	SC085	-
SC149	-	SC124	-
SC086	-	SC105	-
SC123	+	SC172	-
SC020	+	SC061	+
SC182	+	SC010	-
SC054	-	SC183	+
SC138	+	SC117	+
SC084	+	SC040	-
SC070	-	SC017	+
SC177	+	SC159	-
SC147	-	SC181	-
SC013	+	SC140	-
SC163	+	SC006	-
SC028	+	SC092	+
SC029	+	SC191	+
SC161	+	SC062	+
SC171	+	SC132	-

4.2.2 Result for Lot2:

Sample No.	Result	Sample No.	Result
SC165	+	SC001	-
SC133	+	SC012	+
SC131	-	SC144	-
SC021	+	SC046	-
SC136	-	SC106	+
SC093	+	SC015	+
SC127	+	SC041	+
SC033	+	SC081	-
SC042	+	SC194	-
SC005	-	SC014	-
SC130	-	SC141	-
SC047	+	SC107	+
SC095	+	SC175	+
SC180	-	SC052	-
SC063	-	SC039	-
SC058	-	SC145	-
SC126	+	SC112	+
SC197	+	SC083	+
SC173	-	SC026	-

SC056	-	SC059	-
SC104	+	SC018	+
SC069	+	SC024	-
SC151	-	SC198	+
SC153	-	SC098	+

4.2.3 Result for Lot3:

Sample No.	Result	Sample No.	Result
SC064	+	SC019	-
SC129	-	SC055	-
SC188	+	SC195	-
SC135	+	SC101	+
SC068	+	SC077	+
SC148	-	SC097	-
SC087	-	SC008	+
SC080	-	SC003	+
SC167	-	SC164	+
SC169	-	SC079	-
SC110	+	SC050	-
SC189	-	SC113	+
SC193	-	SC076	+

SC078	+	SC053	-
SC089	+	SC186	+
SC179	-	SC011	-
SC160	-	SC128	-
SC002	+	SC142	+
SC199	+	SC111	-
SC109	-	SC174	+
SC044	+	SC051	-
SC184	-	SC030	+
SC045	+	SC027	+
SC023	+	SC032	-

## 5. Conclusion:

Test the cross-reaction specimens, there are no cross-reactivity or interference was found.

Coronavirus, CoV
Adenovirus
Enterovirus
paraFluV
measles virus
Mumps virus
Anti-Flu A (IgG and IgM)
Anti-Flu B (IgG and IgM)
ANA
anti-respiratory syncytial virus (IgG and IgM)
anti-rhinovirus (IgG and IgM)
Cytomegalovirus IgG antibody
Rubella virus IgG antibody
IgM antibody to rubella virus
IgG antibody to varicella zoster virus

IgG antibody to Chlamydia pneumoniae
IgG antibody to herpes simplex virus type 1 + 2
SARS virus antibody (total antibody or IgG)
anti-HCV (IgG and IgM)
anti-HBV (IgG and IgM)
anti-HIV (IgG and IgM)
anti-haemophilus influenzae (IgG and IgM)