Clinical Effectiveness

Revision History

Revision	Date	Description of changes
00	2020. 03. 10	Established the Clinical Effectiveness

Written by	Reviewed by	Approved by
		
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Associate Manager of RA	Manager of RA/MSL	Vise President

1. PURPOSE AND SCOPE

1) Purpose

To evaluate the effectiveness with clinical samples on STANDARD™ Q COVID-19 Ag Test.

2) Scope

STANDARD™ Q COVID-19 Ag Test.

2. OVERVIEW

1) Device description

STANDARD COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to COVID-19 present in human nasopharynx and oropharynx. This test is for in vitro professional diagnostic use and intended as an aid to early diagnosis of COVID-19 infection in patient with clinical symptoms with COVID-19 infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of COVID-19 infection.

2) Testing Condition

Testing Date	March, 09. 2020.
Testing Site	Department of Laboratory medicine, Seoul National University Bundang Hospital
Testing Environment	Temperature: 20-24°C, Humidity: below 70%
Testing Representative	Jeong Su Park | Professor (M.D., Ph.D), Department of Laboratory medicine, Seoul National University Bundang Hospital
Reagent System	STANDARD™ Q COVID-19 Ag Test LOT: QCO302001 (MFG: 2020.03.02 /EXP: 2022.03.01)

3) Sample Condition

The residual samples from the subjects who met all of the following criteria were included.
Anonymized residual nasopharyngeal swab specimens in Universal Transport Media (Noble Bioscience.,Inc, Korea) which had been retained for the purpose of destruction following the ordered COVID-19 tests in Laboratory Medicine, the Seoul National University Bundang Hospital
(1) Positive samples (n=5)
a. As to COVID-19 positive ones of samples undergoing COVID-19 tests as requested in Laboratory Medicine, the Seoul National University Bundang Hospital, 5 residual samples retained, which showed positive results in tests using a Real-time PCR (PowerChek™ 2019-nCoV Real-time PCR kit, Emergency Use Approved).

(2) Negative samples (n=2)
a. As COVID-19 negative ones of samples undergoing COVID-19 tests as requested in Laboratory Medicine, the Seoul National University Bundang Hospital, 2 residual samples retained, which showed negative results in tests using a Real-time PCR (PowerChek™ 2019-nCoV Real-time PCR kit, Emergency Use Approved)

(3) Detailed specimen information (Real-time PCR result)

No.	Symptom espression	Confirmation date	Real-time PCR date	Target		Interpretation
				ORF1ab(RdRp)	E	
13	30/01/2020	02/02/2020	14/02/2020	ND	36.6	Negative
14	30/01/2020	02/02/2020	17/02/2020	ND	ND	Negative
15	18/02/2020	21/02/2020	24/02/2020	22.2	18.2	Positive
16	18/02/2020	21/02/2020	26/02/2020	19.8	19.5	Positive
18	21/02/2020	22/02/2020	25/02/2020	16.5	16.6	Positive
19	21/02/2020	22/02/2020	27/02/2020	18.5	18.1	Positive
20	21/02/2020	22/02/2020	29/02/2020	23.2	23.0	Positive

3. TEST PROCEDURE

All tests have been performed according to the Instructions for use.

(1) Mix the buffer and specimen in a 1:1 ratio.

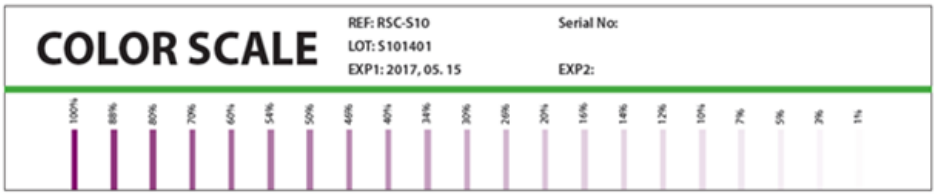
(2) Apply 4 drops of extracted specimen to the specimen well of the test device

(3) Read the test result in 30 minutes.

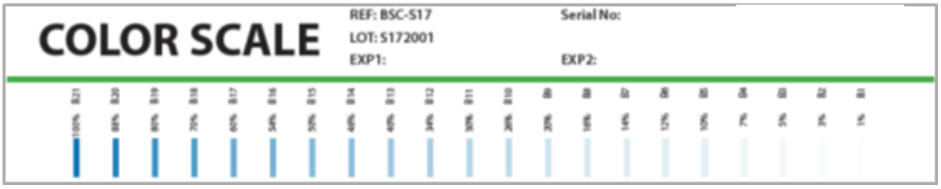
4. RESULT RECORDING CRITERIA

1) The overall intensity of the test line and control line are scored as follows:
   (1) Strong Positive Intensity: 3+ (CS ≥ 26%)
   (2) Medium Positive Intensity: 2+ (26% > CS ≥ 12%)
   (3) Weak Positive Intensity: 1+ (12% > CS > 1%)
   (4) Very Weak Positive Intensity: w+ (≒ 1%)
   (5) Negative Intensity: - (CS < 1%)

For Control Line



For Test Line



2) Clearance of background is scored as follows:
   (1) Perfect clear: Perfect
   (2) Good clear: Good
   (3) Normal clear: Normal
   (4) Bad clear: Bad
   (5) Not determined: N/D

3) Flow rating at 30 minutes was scored as follows:
   (1) Flow Complete: Com

(2) Flow Incomplete: Not

4) Acceptance Criteria

(1) Control line, background and flow rate are satisfied with the acceptance criteria

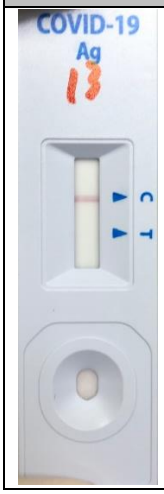
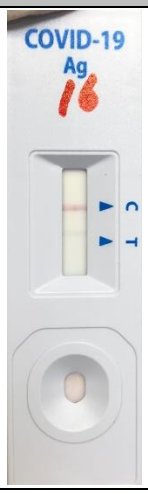
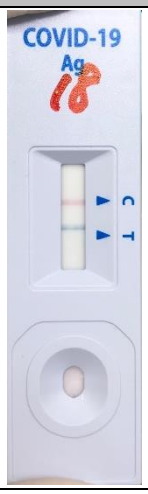
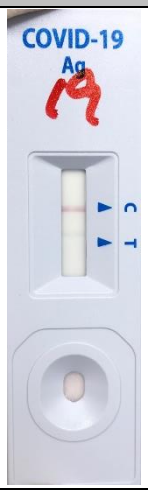
C line	Background	Flow rate
>2+	Perfect cleare or Good	Complete

(2) The result of the investigational device should be matched with the result of the confirmatory test.

5. TEST RESULTS

Specimen No	Confirmatory Method	COVID-19 Ag					Remark
		B.G	F.L	C Line	T-Line	Result	
13	Negative	Perfect	Com	3+	-	Negative	Accepted
14	Negative	Perfect	Com	3+	-	Negative	Accepted
15	Positive	Perfect	Com	3+	2+	Positive	Accepted
16	Positive	Perfect	Com	3+	1+	Positive	Accepted
18	Positive	Perfect	Com	3+	3+	Positive	Accepted
19	Positive	Perfect	Com	3+	1+	Positive	Accepted
20	Positive	Perfect	Com	3+	-	Negative	Not Accepted

6. ATTACHMENT OF RESULT PHOTO

No. 13	No. 14	No. 15	No. 16	No. 18	No. 19	No. 20
						

7. CONCLUSION

Although this test was performed using the small number of specimens, STANDARD Q COIVD-19 Ag Test showed 80% of sensitivity and 100% of specificity.