

# Clinical Effectiveness

## Revision History

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

| Written by                                                                                                                             | Reviewed by                                                                                                                       | Approved by                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| <br><u>Sang Kil Park</u><br>Associate Manager of RA | <br><u>SunYoung Jeong</u><br>Manager of RA/MSL | <br><u>Hae-June Park</u><br>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<br>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 expression | 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.

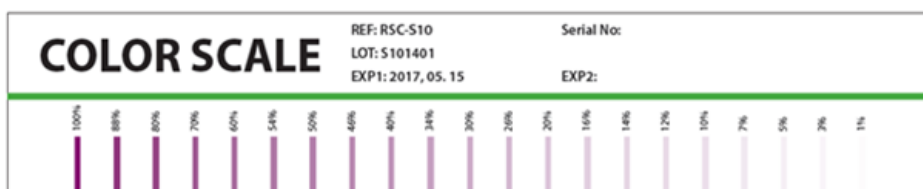
- (1) Mix the buffer and specimen in a 1:1 ratio.
- (2) Apply 4 drops of extracted specimen to the specimen well of the test device
- (3) Read the test result in 30 minutes.

### 4. RESULT RECORDING CRITERIA

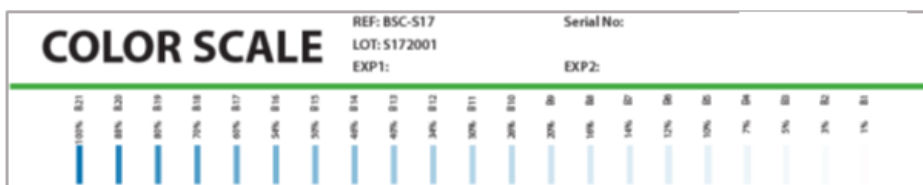
1) The overall intensity of the test line and control line are scored as follows:

- (1) Strong Positive Intensity: 3+ (CS  $\geq$  26%)
- (2) Medium Positive Intensity: 2+ (26% > CS  $\geq$  12%)
- (3) Weak Positive Intensity: 1+ (12% > CS > 1%)
- (4) Very Weak Positive Intensity: w+ ( $\approx$  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

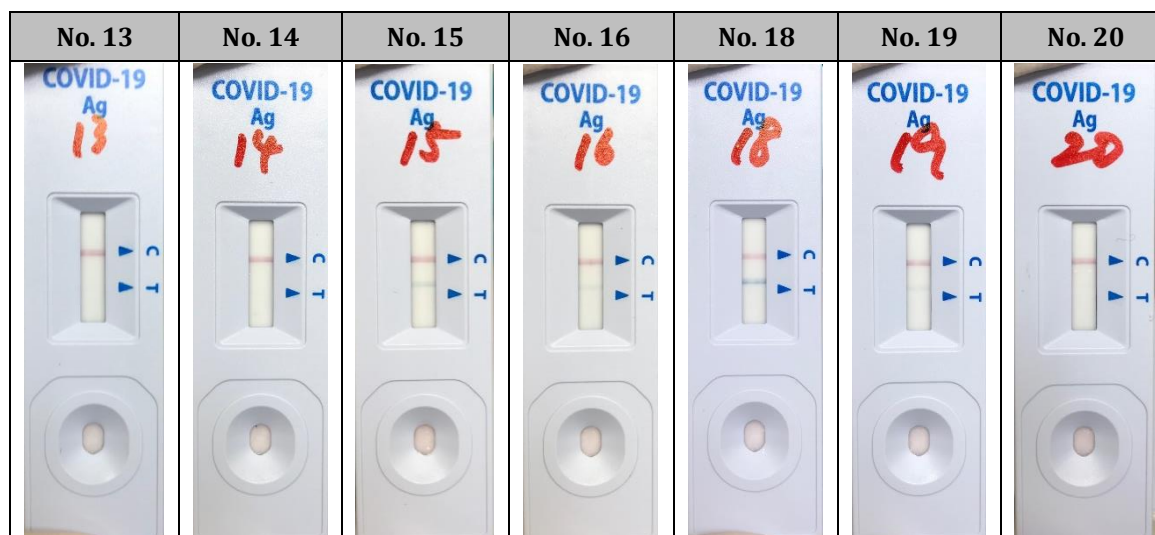
| C line | Background            | Flow rate |
|--------|-----------------------|-----------|
| >2+    | Perfect clear or Good | Complete  |

(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



### 7. CONCLUSION

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