REDCELL COVID 19 Antigen Test Performance Evaluation Report

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Evaluation Report

Istanbul, April 9 , 2022

1.0 Objective

The aim of this study is to determine the performance evaluation using clinical samples of the COVID 19 Antigen Test Kit.

2.0 Clinical Sample Performance Evaluation Study

The performance evaluation study of COVID 19 Antigen Test was based on the parameters below.

3. 0 Materials and Method

Clinical sample performance study

COVID 19 Antigen Test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in nasal swab specimens either directly collected from individuals.

Nasal swabs require a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is added to the sample well of the test device to initiate the test. When the swab sample migrates in the test strip, SARS-CoV-2 viral antigens bind to anti-SARS-CoV-2 antibodies conjugated to indicator and capture particles in the test strip forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip.

Total 582 specimens were analyzed, including 164 positive cases and 418 negative cases. 104 of the samples were taken from the hospitalized patients unrelated to COVID-19. All samples were collected during the epidemic of the new coronavirus SARS-CoV-2 and a blind control test was used during this study.

Studies were conducted by Sağlık Bilimleri University Teknopol Campus COVID-19 Laboratory. Separate nasopharyngeal swab samples for RT-qPCR test and nasal swab samples for antigen test were taken simultaneously from patients.

The age range of 582 samples was 12-66. Gender distribution; 336 men (57.7 %), 246 women (43.3 %)
Test samples were obtained from the following units. Positive and negative samples from Istanbul Sabiha Gokcen Airport Pre-Flight Test Center and Saglik Bilimleri University Technopol Campus Covid 19 Lab, hospitalized patients from Umraniye Education and Research Hospital. Positive samples were collected from patients with a suspicion of COVID-19 infection within 7 days of onset of symptoms.

REDCELL Direct SARS-CoV-2 RT-qPCR Test Kit Test was selected as the reference reagent on the same clinical samples of the nasal swabs. Clinical equivalence between the test reagents was investigated.

Coincidence rates and kappa values of test reagents were evaluated as follows:

Test Reagent	Reference Reagent		Total
	Positive	Negative	
Positive	a	b	a+b
Negative	c	d	c+d
Total	a+c/b+d		

Positive coincidence rate: a/(a+c) x %100
Negative coincidence rate: d/(b+d) x %100
Total coincidence rate: (a+d)/(a+b+c+d) x %100

The study was performed by using COVID 19 Antigen Test (Lot : COVAG0622, COVAG0122) kit and REDCELL Direct SARS-CoV-2 RT-qPCR Test Kit(Lot: COR20522, COR20222).

Of the 164 positive samples tested with RT-qPCR test, 158 of them were detected as positive by COVID Antigen Test. Of 418 Negative samples tested with NAT 416 were detected as negative with the COVID Antigen Test.

Samples detected as Positive by NAT testing were further investigated for the Delta and Omicron variant with Diagnovital SARS-CoV-2 L452R Mutation Detection Kit and Diagnovital SARS-CoV-2 T547K Mutation Detection Kit(Lot: AK124R2222) . Of the 164 positive samples, 17 were detected as Delta variant and 33 as Omicron variant. All variant positive samples were detected positive with COVID-19 Antigen test.

Covid 19 Antigen test	**Direct SARS-CoV-2 RT-qPCR Test**		Total
	Positive Samples	Negative Samples	
Positive	158	2	160
Negative	6	416	422
Total	164	418	582

Clinical sensitivity (%) = [158 / (158 + 6)] ×100% = 96.3 %
Clinical specificity (%) = [416/ (416+2)] ×100% = 99,5 %

In relation to the above evaluations, a sensitivity of 96.3 % (95% CI: 90.40%-98,2%) and a specificity of 99,5 % (95% CI: 97,3%-100 %) are found.

4.0 Result

When the PCR test is accepted as a reference test as a result of clinical samples performance studies with nasopharyngeal swabs, The sensitivity of the COVID 19 Antigen Test Test was 96.3%, and the specificity was 99.5%.

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