REDCELL

Covid-19 Antigen Test performance study

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Evaluation Report

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1.0 Objectives

The aim of this study is to determine the analytical sensitivity, inactivated virus sensitivity and the performance evaluation using clinical samples of the REDCELL COVID-19 Antigen Test Kit.

In this study, recombinant antigens of the SARS Cov2 virus, inactivated virus and clinical samples were used.

2.0 Description of the Performance Evaluation Study

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

a) Analytical sensitivity
b) Inactivated virus sensitivity
c) Clinical sample performance study
d) Cross Reactivity
e) Interference substances

3. 0 Materials and Methods

a) Analytical sensitivity :

Analytical sensitivity study was carried out with commercially available recombinant antigens of SARS Cov 2 virus with known values. Nucleoprotein recombinant antigen belonging to the virus were used in this study. Analytical sensitivity obtained as a result of testing with the specified antigens is given below.
Nucleoprotein : 100 piccogram.

b) Inactivated virus sensitivity:

In the dilution study with 10^9 pfu / ml inactivated SARS Cov 2 virus, it was determined that it reacted at 1/20.000 dilution and the sensitivity of inactive virus was 50.000 pfu /ml.

c) Clinical sample performance study

REDCELL COVID-19 Antigen test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein and RBD antigens specific to SARS-CoV-2 in nasopharyngeal swab specimens either directly collected or collected in universal transport media from individuals.

Nasopharyngeal 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.

The specimens were collected via nasopharengeal and throat swabs and placed in VTM or rNAT Transfer Tubes. Total 380 specimens were analyzed, including 122 positive cases and 258 negative cases. All samples were collected during the epidemic of the new coronavirus SARS-CoV-2 and a blind control test was used during this study.

The age range of 380 samples was 18-79. Gender distribution; 221 men (58.2), 159 women (41.8%)

REDCELL Direct SARS-CoV-2 RT-qPCR Test Kit Test was selected as the reference reagent on the same clinical samples of the nasopharengeal and throat 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: b/(b+d) x %100
Total coincidence rate: (a+d)/(a+b+c+d) x %100
Kappa consistency analysis was carried out for the mentioned data. For example kappa coefficient > 0.75 is highly consistent. The two reagents are considered to be equivalent.

This study was performed by using REDCELL Covid-19 Antigen Test (Lot : COVAG1121) kit.
380 samples were tested on two different kits. REDCELL Covid-19 Antigen Test kit (Lot : COVAG1121) and REDCELL Direct SARS-CoV-2 RT-qPCR Test Kit

It was found positive by 122 qPCR tests out of 380 samples. Of the samples that gave positive results with the PCR test, 116 were detected as positive by the Covid 19 antigen test.

Although 258 samples were detected as negative by the PCR test, 261 samples were detected as negative with the Covid 19 antigen test.

REDCELL Covid-19 Antigen Test	Direct SARS-CoV-2 RT-qPCR Test		Total
	Positive	Negative	
Positive	116	0	116
Negative	6	258	264
Total	122	258	380

Clinical sensitivity (%) = [116 / (116 + 6)] ×100% = 95.08 %

Clinical specificity (%) = [261/ (3 + 258)] ×100% = 98.8 %

Total agreement rate (%) = [(122+258) / (116 + 6+ 3 + 258)] ×100% = 99.2 %

d) Cross Reactivity

The cross reactivity of REDCELL COVID-19 Antigen Test was evaluated with a total of 6 bacteria, 10 viruses. Bacteria were evaluated at a concentration over 106 CFU/ml. Viruses were evaluated at a concentration of over 104 TCID50 /ml. None of the microorganisms tested in the following table gave a positive result.

Bacteria panel	**Cross Reactivity (Y/N)**
Escherichia coli	N
Staphylococcus aureus	N
Staphylococcus epidermidis	N
Streptococcus pneumoniae	N
Haemophilus influenzae	N
Pseudomonas aeruginosa	N
Viral panel	
Corona virus (HCoV-OC43)	N
Corona virus (HCoV-NL63)	N
Corona virus (HCoV-229E)	N
Adeno virus type 7	N
Respiratory syncytial virus (18537)	N
Rhinovirus	N
Human parainfluenza virus Type 1-4	N
Influenza A virus (A/TW/344/19 (H1N1))	N
Enterovirus Type 71	N
Influenza B virus (B/TW/2129/19)	N

e) Interference substances :

Exogenous and endogenous substances were evaluated and did not interfere with REDCELL COVID-19 Antigen Test at the levels tested below.

Interfering Substances	**Concentration**
Aspirin	20 mg/ml
Oxymetazoline HCl	10 mg/ml
Saline nasal sprays	10%
Whole blood	5%
Hemoglobin	20 mg/ml
Mucin	4.00%
Phenylephrine HCl	100 mg/ml
Dextromethorphan	10 mg/ml
Diphenhydramine HCl	5 mg/ml
Ibuprofen	20 mg/ml

4.0 Results

Performance study with recombinant antigen, analytical sensitivity of REDCELL Covid-19 Antigen Test was determined as follows.

Nucleoprotein : 100 piccogram ,

Test sensitivity obtained at the end of dilution with inactivated virus was determined as 50.000 pfu/ml.

When the PCR test is accepted as a reference test as a result of clinical samples performance studies with nasopharyngeal and throat swabs, The sensitivity of the REDCELL Covid-19 Antigen Test was 95.08 %, and the specificity was 98.8 %.

In the cross reactivity test, it did not cross-reactivity with the tested microorganisms.

In the Interference test, it did not interfere with exogenous and endogenous substances.

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