T.C.
SAĞLIK BAKANLIĞI
ÖZEL MEDLİFE LABORATUVARI
KLİNİK KARŞILAŞTIRMA SONUÇLARI

Clinical Evaluation Report For SARS-CoV-2 Antigen Rapid Test (Immunochromatography)

E-Mail: info@medlifelab.com.tr
Tel: 0380 512 0 500 / Fax: 0380 514 3 999
Kiremit Ocağı Mh. Hacı Bilal Sok. No:3 (Eski Devlet Hastanesi Karşısı) / DÜZCE

1.Research Summary

Clinical institutions conduct clinical validation tests on products of SARS-CoV-2 Antigen Rapid Test (Hereinafter referred to as assessment reagent) which is registered for the first time. Proving the clinical performance of the assessment reagent meets the expected requirements. Medlife Laboratories from four different sites in Turkey (Istanbul, Tekirdag, Bolu and Duzce) have tested n=1720 samples for the SARS-CoV-2 virus with the Unibioscience rapid antigen test of the manufacturer Unioninvest Ltd. There were 430 samples in the case group (symptomatic n=207 and asymptomatic n= 223) Out of the 207 samples of persons with clinical signs (symptomatic cases) there were 202 samples tested as positive by the assessment reagent; Out of 223 samples of persons without any clinical signs (asymptomatic cases) , 217 samples were tested as positive by the assessment reagent). In total 419 out of 430 true positive samples (verified by PCR) were tested as positive by the assessment reagent. The control group consisted of 1290 true negative samples (verified by PCR); 1281 samples were tested as negative by the assessment reagent. Clinical diagnosis results of assessment reagents:
The sensitivity was 97.44%, the specificity was 99.30%.
The sensitivity within the group of symptomatic true positive cases was 97,58%.
The sensitivity within the group of asymptomatic true positive cases was 97,30%.

2 Basic Content

2.1 Test purpose

The intention of the laboratory tests was to validate the performance of the test product by direct comparison with PCR based test results.

2.2 Introduction

SARS- CoV-2, also known as the Covid- 19 virus, causes an acute respiratory infectious disease. Humans are generally susceptible. The main source of infection is currently people infected with the virus, including those who have an asymptomatic course.
The incubation period varies according to current epidemiological studies between 1 and 14 days, but usually between 3 and 7 days. Typical symptoms of manifestation include fever, fatigue and dry cough. Among others, rhinorrhea, sore throat, myalgia & diarrhea symptoms may occur in rare cases.

2.3 Trial design

2.3.1 Description of the overall design and plan of the test

This experiment was based on blind and control methods. The samples from confirmed patients infected with novel coronavirus, were selected for blind detection by the test reagent. The test results were compared with the PCR results, and the feasibility of application of test reagent in clinical practice was evaluated by judging the clinical sensitivity of the test reagent.

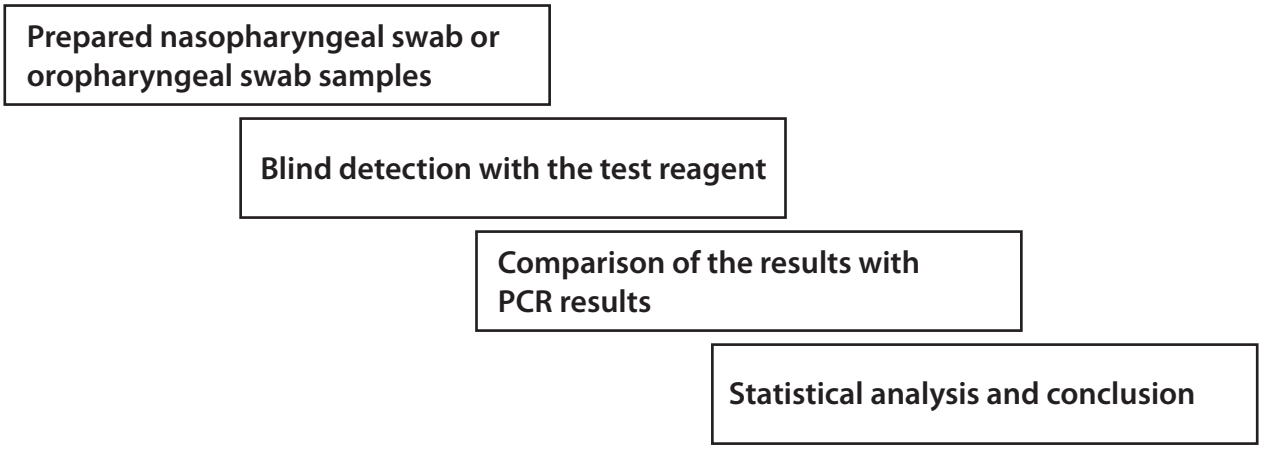
Before starting the tests, employees were familiarized with the handling of the test product in accordance with the instructions in the operating manual, in order to reduce investigator-dependent errors to a minimum.

E-Mail: info@medlifelab.com.tr
Tel: 0380 512 0 500 / Fax: 0380 514 3 999
Kiremit Ocağı Mh. Hacı Bilal Sok. No:3 (Eski Devlet Hastanesi Karşısı) / DÜZCE

2.3.1.1 The general process

(a) In a first step, nasopharyngeal or oropharyngeal swab samples were prepared in institutes.
(b) The blank test was performed with the test reagent and the test results were recorded.
(c) Each invalid result was retested. If the result was still invalid, the test was marked as invalid.
d) Finally, the results of the test reagent and PCR were statistically evaluated.

2.3.1.2 Test process flow chart



3. Test design and test method

3.1 Sample selection basis, criteria of inclusion, exclusion and elimination

3.2 Selection basis

A total of 1720 samples were tested for Sars Covid 19-2 by the clinical facilities of the Medlife laboratories using real-time polymerase chain reaction (RT-PCR). N=430 samples were Sars Covid 19-2 positive. Within the group tested positive by the RT-PCR test, n=207 samples were assigned to symptomatic individuals. N=223 samples out of a total of n=430 samples were assigned to asymptomatic persons. N=1290 cases formed the control group, consisting of only RT-PCR negative samples.

The samples selected are nasopharyngeal or oropharyngeal swab specimens from patients with suspected or confirmed novel coronavirus infection. According to the clinical information, the patients were divided into a case group and a control group. In addition, patients in the case group were divided into a symptomatic and an asymptomatic group.
Case group: samples of patients diagnosed with coronavirus infection based on the "Diagnostic and treatment plan for pneumonia caused by a new coronavirus infection", including samples of subjects without clinical symptoms.
Symptomatic group: samples from patients infected with the novel coronavirus with clinical symptoms.
Asymptomatic group: samples from patients infected with the novel coronavirus with no clinical symptoms.
Control group: samples from patients not infected with the novel coronavirus.

E-Mail: info@medlifelab.com.tr
Tel: 0380 512 0 500 / Fax: 0380 514 3 999
Kiremit Ocağı Mh. Hacı Bilal Sok. No:3 (Eski Devlet Hastanesi Karşısı) / DÜZCE

3.2.1 Criteria for sample inclusion

(1) Age limit;
(2) No gender limit;
(3) Complete information file, including clinical status (case (symptomatic / asymptomatic) and control), sample ID number, name, gender, age, department, PCR result, sample type and sampling date.

3.2.2 Criteria for sample exclusion

(1) Samples that have been repeatedly frozen and thawed for more than 3 times;
(2) A sample with incomplete information;
(3) A sample of duplicate cases.

3.2.3 Criteria for sample elimination

(1) Samples that fail to meet the inclusion criteria and included by mistake.
(2) Samples that meet the inclusion criteria but fail to meet the test plan due to contamination during sample preservation or insufficient sample size caused by human error after inclusion.

4. Establishment of Reference Methods

The clinical evaluations were compared with the PCR results, that is, the diagnosis or exclusion of infection divided into symptomatic groups and asymptomatic groups according to the PCR results, and the clinical sensitivity and specificity of the assessment reagents were evaluated.

4.1. Product Information for clinical evaluations assessment reagent

Reagent name: SARS-CoV-2 Antigen Rapid Test
Batch number: UNI200801
Expiry date: 2021.08
Storage conditions: 2 - 25°C

4.2. The information of clinical unit

Hospital: Medlife Laboratories Duzce
Address: Kiremit Ocagi Dst. Haci Bilal St. N:3, Duzce, Turkey

5. Method of quality control

In the course of the validation phase, care was taken to ensure that the tests with the assessment reagent were performed in a uniform manner. Methods and assessment standards were harmonized. The entire testing process was strictly standardized. The tester recorded the test results faithfully and carefully. All observations and findings in the clinical evaluation were reviewed to ensure the reliability of the data and that the conclusions in the clinical evaluation can be derived from the original data. Appropriate data management measures were in place during the clinical evaluation and data processing phase.

6. Statistical analysis method of clinical evaluation data

Statistical analysis was conducted to summarize the results in the form of a four-lattice table and based on this, clinical sensitivity, clinical specificity including the confidence-interval (95% CI) were calculated.

E-Mail: info@medlifelab.com.tr
Tel: 0380 512 0 500 / Fax: 0380 514 3 999
Kiremit Ocağı Mh. Hacı Bilal Sok. No:3 (Eski Devlet Hastanesi Karşısı) / DÜZCE

6.1. Modification of scheme during test

None

7. Clinical evaluation results and analysis

7.1 Statistics of test reagent results and PCR results on nasopharyngeal swab samples

7.2 Statistical results

Unibioscience SARS-CoV-2 Antigen Rapid Test	Descriptive results in total		
	Case Group	Control Group	Total
Detected Positive	419	9	428
Detected Negative	11	1281	1292
Total	430	1290	1720

Unibioscience SARS-CoV-2 Antigen Rapid Test	Descriptive results assigned to symptomatic and asymptomatic samples within the case group		
	Symptomatic group	Asymptomatic group	Total
Detected Positive	202	6	208
Detected Negative	5	217	222
Total	207	223	430

7.3 Analysis of compliance rate

Overall Sensitivity of Assessment Reagent: 97,44% (95% CI: 95.47% to 98.72%)	**Sensitivity within the symptomatic group:** 97,58% (95% CI: 94.45% to 99.21%)
Overall Specificity of Assessment Reagent: 99,30% (95% CI: 98.68% to 99.68%)	**Sensitivity within the asymptomatic group:** 97,30% (95% CI: 94.24% to 99.01%)

E-Mail: info@medlifelab.com.tr
Tel: 0380 512 0 500 / Fax: 0380 514 3 999
Kiremit Ocağı Mh. Hacı Bilal Sok. No:3 (Eski Devlet Hastanesi Karşısı) / DÜZCE

8. Discussion and conclusion

The SARS-CoV-2 antigen rapid test has been validated. The testing process was carried out strictly according to the clinical evaluation plan and standard operating procedures.
In the sample group of the case group (n=430) the sensitivity for the detection of SARS-CoV-2 was 97.44%.
In the control group of samples (n=1290) the specificity for the detection of SARS-CoV-2 was 99.30%.
In the group of samples of symptomatic cases (n=207), the sensitivity to detect SARS-CoV-2 was 97.58% at an average cycle threshold (CT value) of 25.62.
In the group of asymptomatic case samples (n=223), the sensitivity to detect SARS-CoV-2 was 97.30% at an average cycle threshold (CT value) of 27.63.

The performance of the above-mentioned Sars Covid 19-2 rapid antigen test is considered satisfactory.

8.1. Description of special conditions in clinical evaluations
None.

8.2 Attachment
Statistical Table of Clinical Trial Data

Analyst Signature-Stamp

General Manager Signature-Stamp

MEDLIFE
LABORATUVAR HİZMETLERİ LİMİTED ŞİRKETİ
Kiremit Ocağı Mh. Hacı Bilal Sk. No: 3 DÜZCE
Tel: 0 380 512 0 500 Fax: 0 380 514 3 999
Düzce Ticaret Sicil No: 7064
Mersis No: 0613 0 [illegible] Ticaret Sicil No: 6652

E-Mail: info@medlifelab.com.tr
Tel: 0380 512 0 500 / Fax: 0380 514 3 999
Kiremit Ocağı Mh. Hacı Bilal Sok. No:3 (Eski Devlet Hastanesi Karşısı) / DÜZCE