

Комунальне некомерційне підприємство
«Київська міська клінічна лікарня №4»
виконавчого органу київської міської ради
(Київської міської державної адміністрації)
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Clinical Evaluation Report

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CHAPTER 1. Introduction and description of the analysis

Coronavirus (CoV) belongs to the order Nidovirales under the Coronaviridae family with 4 genera: α , β , γ and δ . The α and β genera are only pathogenic to mammals, while γ and δ genera mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence supporting fecal-oral transmission

7 kinds of human coronaviruses (HCoV) that cause human respiratory diseases have been identified so far, including: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and SARS-CoV-2. SARS-CoV-2 is one of the most contagious viral pathogens that causes human respiratory tract infections (RTI). Currently, the main source of infection are patients infected with the new coronavirus; asymptomatic infected people can also be a source of infection. According to the current epidemiological study, the incubation period is 1 to 14 days, mostly 3 to 7 days.

Thus, a rapid antigen test makes it possible to effectively conduct screening studies to increase the chances of detecting patients with coronavirus.

The institution that conducted the study

The studies were carried out on the basis of the communal non-profit enterprise Kyiv City Clinical Hospital No. 4, which was completely redesigned for the treatment of COVID-19 patients during the COVID-19 pandemic.

Laboratory qualification: Certificate of recognition of measuring capabilities from 24.12.2020. № PT-517/20 issued by the State Enterprise "Ukrmetrteststandard" valid until 23.12.2022.

Study period

January-March 2021

CHAPTER 2. Subject of study

A clinical study of Medomics tests - SARS-CoV-2 LFIA antigen detection kit and Abbott - Panbio COVID-19 Ag rapid tests in comparison with the reference method - real-time PCR was performed.

Table 1. Medomics Test Information - SARS-CoV-2 LFI antigen detection kit

Manufacturer's name	Jiangsu Medomics Medical Technology Co., Ltd
Product name	SARS-CoV-2 LFIA antigen detection kit
Lot №	20201218, type I, date of manufacture 08.12.20
Packaging	20 tests/kit
Kit content	test cassette, lysis buffer, sampling tubes, pipettes, sampling probe, operating manual
Additional materials required (not included in the kit)	personal protective equipment, timer, waste container
Storage temperature	2-30°C
Shelf life	24 months
Country of manufacture	China

Table 2. Abbott test information - COVID-19 Ag Panbio rapid tests

Manufacturer's name	Abbott Rapid Diagnostics
Product name	Panbio COVID-19 Ag
Lot №	41ADF426A, date of manufacture 11.12.2020
Packaging	25 tests/kit
Kit content	test cassette, lysis buffer, sampling tubes, pipettes, sampling probe, operating manual
Additional materials required (not included in the kit)	personal protective equipment, timer, waste container
Storage temperature	2-30°C
Shelf life	12 months
Country of manufacture	South Korea

Table 3. Information on PCR reagents for detection

Manufacturer's name	Sansure Biotech Inc.
Product name	Reagent kit for detecting RNA of coronaviruses 2019-nCoV by real-time PCR
Kit content	2019-nCoV-PCR Mix, 2019-nCoV-PCR-Enzyme Mix, 2019-nCoV-PCR-positive control, 2019-nCoV-PCR-negative control
Shelf life	12 months
Country of manufacture	China
RNA extraction	automated nucleic acid extraction system NATCH CS
Amplifier	amplifier for quantitative real-time PCR MA-6000

CHAPTER 3. Sample preparation

A total of 100 positive samples were tested, of which 80 positive samples and 20 negative samples previously tested by real-time PCR. All samples from the throat were collected, processed and tested by specialists of the clinical laboratory of the communal non-profit enterprise "Kyiv City Clinical Hospital No. 4".

Samples without amplification can be considered negative. As positive samples, we used samples with a threshold cycle Ct value less than 35. Ct positivity is an indirect indicator of viral load.

Samples for testing were prepared as follows: one swab is collected from one person and inserted into one tube with 500 µl saline solution. RT-PCR test is performed firstly to confirm the test result. Divide the remaining samples equally into two tubes Medomics test cassettes SARS-CoV-2 LFIA antigen detection kit and Abbott PANBIO™ COVID-19 Ag rapid tests.

CHAPTER 4. Testing methods

4.1 Testing procedure

Name: SARS-CoV-2 antigen Test Kit (LFIA)

Manufacturer, country: Jiangsu Medomics Medical Technology Co., Ltd (China)

1. Warm materials to room temperature for 30 minutes.
2. Add 350 µl of Medomics lysis buffer to the tube and mix (resuspend 3-4 times).
3. Add 100 µl of the treated sample to the appropriate well on the test cassette.
4. Wait. The result should be noticeable within 15-20 minutes. The results, which are observed after 20 minutes, have no clinical significance.

Name: COVID-19 Ag rapid tests

Manufacturer, country: Abbott, South Korea

1. Warm the materials to room temperature for 30 minutes.
2. Add 300 µl of Abbott extraction reagent to the test tube and mix (resuspend 3-4 times).
3. Add 125 µl of the treated sample to the appropriate well on the test cassette.
4. Wait. The result should be noticeable within 15 minutes. The results, which are observed after 20 minutes, have no clinical significance.

CHAPTER 5. Study results and conclusions

5.1 Clinical verification

In total, 100 clinical samples were studied, of which 80 were positive samples, 20 were negative samples.

№	Ct value range	Number of samples, pcs	PCR test result
1	≤35	80	Positive
2	-	20	Negative

Sensitivity, specificity, positive predicted value (PPV), negative predicted value (NPV), accuracy and 95% confidence interval (CI) of the test kit were analyzed compared to RT-PCR results. Confidence intervals for sensitivity, specificity, PPV, NPV and accuracy are calculated by the statistical method described in CLSI EP12-A2 (2008). Sensitivity, specificity, PPV, NPV, accuracy: range from 0% to 100%, the closer the value to 100%, the higher the degree of compliance with the clinical diagnosis.

5.2 Analysis of results

The test results are given below, and the clinical results are described in detail in Annex I Table of study results.

Table 5: 2×2 Contingency Table Analysis RT-PCR and SARS-CoV-2 LFIA Antigen Detection Kit (Medomics)

	RT-PCR		
Medomics COVID-19 Ag test	Positive	Negative	Total
Positive	50	0	50
Negative	30	20	50
Total	80	20	100
Sensitivity: 62,5 %			
Specificity: 100 %			
PPV: 100.00%			
NPV: 40 %			
Accuracy: 70 %			

Table 6. 2×2 Contingency Table Analysis of RT-PCR and Panbio COVID-19 antigen (Abbott) Rapid test

	RT-PCR		
Abbott COVID-19 Ag test	Positive	Negative	Total
Positive	47	1	48
Negative	33	19	52
Total	80	20	100
Sensitivity: 58.75%			
Specificity: 95.00%			
PPV: 97.92%			
NPV: 36.54%			
Accuracy: 66.00%			

Explanation of terms

Sensitivity = True Positives / (True Positives + False Negatives)

Specificity = True Negatives / (True Negatives + False Positives)

PPV (Positive Predictive Value) = True Positives / (True Positives + False Positives)

NPV (Negative Predictive Value) = True Negatives / (True Negatives + False Negatives)

Accuracy = (True Negatives + True Positives) / Total Samples

Table 7. Performance comparison of Medomics of the test kit SARS-CoV-2 LFIA antigen detection kit (Medomics) and Panbio COVID-19 antigen rapid test (Abbott)

	Sensitivity	Specificity	PPV	NPV	Accuracy
Medomics	62,5 %	100,00 %	100.00 %	40,00 %	70 %
Abbott	58.75 %	95.00 %	97.92 %	36.54 %	66.00 %

Table 8. Test results comparison according to different viral load (CT value)

Ct value	≤25	Sensitivity	26-30	Sensitivity	>30	Sensitivity
Medomics	25	93%	24	53%	1	13%
Abbott	24	89%	21	47%	2	25%

The performance of Medomics COVID-19 Antigen Test Kit (LFIA) is established with 100 samples collected from clinical patients. For samples of which Ct is no more than 25, the sensitivity of Medomics SARS-CoV-2 Ag test kit is 93%, which is better than 89% of Abbott test kit. For samples of which Ct is in the range of 26-30, the sensitivity of Medomics SARS-CoV-2 Ag test kit is 53%, which is better than 47% of Abbott test kit. For most of positive samples (CT value ≤30, 90%), the performance of Medomics, SARS-CoV-2 LFIA antigen detection kit is better than Abbott tests Panbio COVID-19 antigen test. The lower detection rate may be due to sample dilution and incorrect buffer. For negative samples, the specificity of the Medomics test kit is 100%, which is a better indicator than the specificity of the Abbott tests (95%).

CHAPTER 6. Conclusions

In the course of the study, the results of 100 clinical samples show that the Medomics Antigen Test Kit LFIA SARS-CoV-2 Antigen detection Kit is better than tests Panbio COVID-19 antigen rapid test and may be relevant to its intended clinical use. The test was performed without following the exact protocol of the set, but adapted to the available samples (smears are in saline), which may reduce its sensitivity. And lower detection rate may be due to dilution of samples and improper buffer.

ANNEX I Table of study results

The results of positive samples

*Notes: '-' means negative, '+' means positive, '+-' means weak positive.

Sample ID	Medomics results	Abbott results	PCR results (Ct value)
1796	negative	negative	27
1811	<i>weak positive</i>	<i>weak positive</i>	26
1822	negative	negative	30
1823	negative	negative	27
1831	positive	negative	26
1863	positive	positive	27
1871	positive	positive	25
1899	positive	positive	24
1927	positive	positive	30
1944	negative	negative	29
2066	negative	negative	35
2110	negative	negative	25
2133	positive	positive	27
2137	negative	positive	25
2140	negative	positive	30
2155	positive	negative	24
2222	negative	negative	30
2237	<i>weak positive</i>	negative	28
2262	negative	negative	27
2263	negative	negative	34
1923	positive	<i>weak positive</i>	28
1924	positive	negative	28
2012	<i>weak positive</i>	negative	27
2015	positive	positive	26
2021	positive	positive	24

2034	negative	negative	34
2058	<i>weak positive</i>	<i>weak positive</i>	27
2059	negative	negative	27
2281	negative	<i>weak positive</i>	29
2282	<i>weak positive</i>	<i>weak positive</i>	26
1299	negative	positive	25
1304	positive	<i>weak positive</i>	26
1369	negative	negative	33
1377	negative	negative	32
1379	<i>weak positive</i>	positive	28
1388	positive	positive	25
1393	positive	positive	24
1703	positive	positive	23
1707	positive	positive	32
1752	negative	negative	27
3588	negative	<i>weak positive</i>	30
3631	<i>weak positive</i>	negative	26
3637	negative	negative	27
3648	positive	positive	25
3675	positive	positive	27
3681	negative	negative	27
3690	<i>weak positive</i>	negative	28
3694	positive	positive	25
3699	negative	negative	32
3709	positive	positive	27
3919	positive	<i>weak positive</i>	22
3927	positive	<i>weak positive</i>	24
3953	negative	negative	27
3956	<i>weak positive</i>	positive	26
4007	<i>weak positive</i>	negative	30
4008	positive	positive	23
4011	positive	positive	21
4023	negative	negative	29

4030	positive	positive	24
4029	positive	positive	19
4032	positive	positive	30
4052	<i>weak positive</i>	<i>weak positive</i>	25
4094	positive	positive	27
4098	negative	positive	30
4138	negative	negative	30
4152	negative	negative	28
4185	<i>weak positive</i>	positive	23
4190	negative	negative	26
4193	positive	<i>weak positive</i>	23
4235	positive	positive	25
4275	positive	positive	25
4295	positive	positive	22
4326	negative	negative	29
4327	<i>weak positive</i>	positive	27
4356	positive	positive	23
4357	positive	positive	22
4358	negative	negative	26
4434	<i>weak positive</i>	positive	27
4486	positive	positive	23
4506	positive	positive	22

The results of negative samples:

Notes: '-' means negative, '+' means positive, '+-' means weak positive.

Sample ID	Medomics results	Abbott results	PCR results (Ct value)
5574	negative	negative	-
5575	negative	negative	-
5576	negative	negative	-
5579	negative	negative	-
5580	negative	negative	-
5581	negative	positive	-

5582	negative	negative	-
5583	negative	negative	-
5584	negative	negative	-
5585	negative	negative	-
5611	negative	negative	-
5612	negative	negative	-
5613	negative	negative	-
5614	negative	negative	-
5692	negative	negative	-
5693	negative	negative	-
5694	negative	negative	-
5695	negative	negative	-
5696	negative	negative	-
5697	negative	negative	-

The head of the department –
bacteriologist of the highest category

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