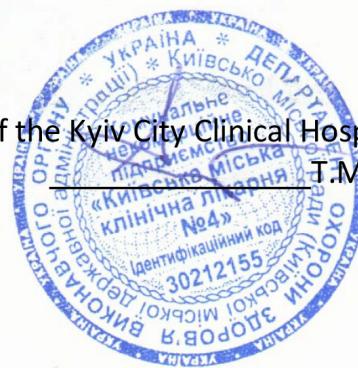




Director of the Kyiv City Clinical Hospital No.4
T.Mostepan



SARS-CoV-2 antigen Test Kit (LFIA)

Clinical Trial Report

MEDOMICS

Test Institute/Department: Kyiv City Clinical Hospital No. 4, Ukraine

Sponsor: Jiangsu Medomics Medical Technology Co., Ltd.

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1. Introduction

1.1 Background

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 cause 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 cause human respiratory tract infections (RTI). Currently, the patients infected by SARS-CoV-2 are the main source of infection. Asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The clinical manifestations include fever, fatigue, cough and other symptoms, accompanied by dyspnea, which can rapidly develop into life-threatening severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, and severe metabolic acid-base imbalance.

1.2 Intended use

SARS-CoV-2 antigen Test Kit (LFIA) is used to qualitatively detect SARS-CoV-2 in human samples in vitro.

2. Subject of study

Table1: Medomics Test Information

Manufacturer	Jiangsu Medomics Medical Technology Co., Ltd.
Product name	SARS-CoV-2 antigen Test Kit (LFIA)
Lot Number	20201218
Packaging specification	20 pcs/box
Storage temperature	2 - 30°C
Shelf-life	24 months
Country of manufacture	China

Table2: Information on PCR reagents for detection

Manufacturer	Sansure Biotech Inc.
Product name	Reagent kit for detecting RNA of coronaviruses 2019-nCoV by real-time PCR
Packaging specification	24 tests/Kit
Storage temperature	-20±5°C
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

3. Inclusion criteria and exclusion criteria

a) Inclusion criteria:

- (1) Confirmed case group: suspected patients were diagnosed as residual samples of pneumonia confirmed by SARS-CoV-2 after clinical examination and diagnosis (within 7 days after symptom onset).
- (2) Excluded case group: the remaining samples of suspected cases diagnosed by non New Coronavirus infection after clinical examination and diagnosis were suspected.
- (3) The collection and processing of samples meet the requirements of standard laboratory operation and product instructions.

b) exclusion criteria:

- (1) The time of sample collection is not clear or the clinical information is missing;
- (2) The samples with microbial pollution and obvious deterioration in appearance;
- (3) Samples that do not meet the requirements of sample collection and processing;
- (4) Samples not kept or transported as required.

4. Clinical Sample

4.1 Basic information

Test institute/department: Kyiv City Clinical Hospital No. 4

Sample types: Anterior nasal secretion、Nasopharyngeal secretion、Throat secretion

Sampling period: Within 7 days after the onset of symptoms

Sampling sites: Hospital

4.2 Sample requirements

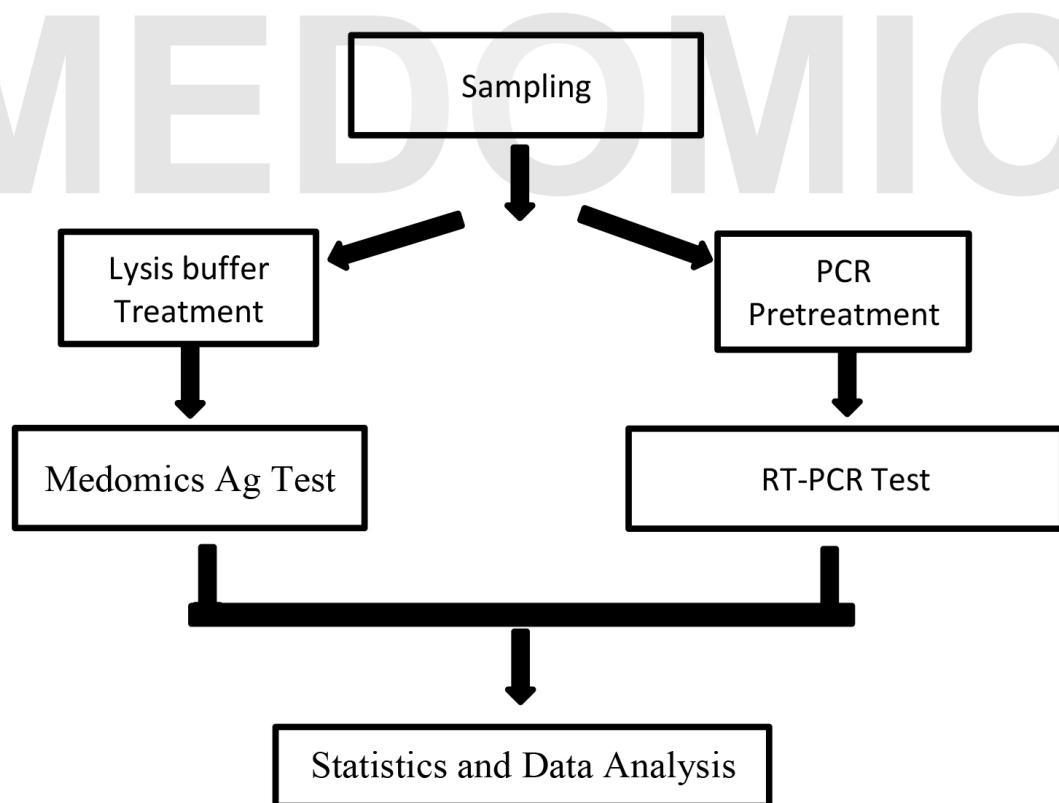
Samples should be collected from patients with COVID-19 symptoms within seven days after onset of symptoms.

One of three sample types (Anterior nasal secretion, Nasopharyngeal secretion, Throat secretion) should be selected to collect in one study. Two swabs should be collected from one patient. One swab should be tested directly using Medomics Ag Test card according to product instructions and the other swab can be eluted in viral transport media (VTM) or saline solution to perform PCR testing. Particularly, number of positive cases should be more than 100 and negative samples should be over 100 cases.

4.3 Evaluation Method

In this study, based on the real-time Polymerase Chain Reaction (RT-PCR) assay as comparator method, clinical application study of SARS-CoV-2 Antigen Test Kit (LFIA) was performed to verify the safety and effectiveness.

5. Clinical Trial Process



6. Results And Analysis

6.1 Test procedure

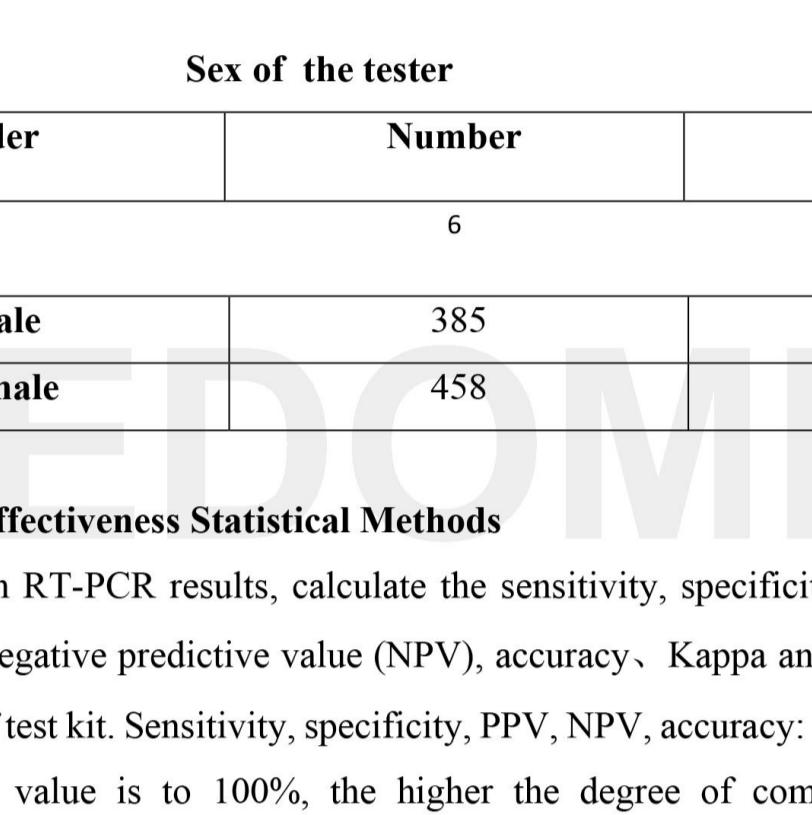
Throughout the evaluation, all samples should be tested with the SARS-CoV-2 Antigen Test Kit (LFIA) according to the 'Test procedure' described in the Instruction for Use supplied with test kit.

Briefly, Open the aluminum foil pouch, take out the test cassette and lay it on a clean flat surface, then mark the cassette with the patient ID or sample number and add 100 μ L processed sample extract into the sample well. Observe the result within 15-20 minutes. Results observed after 20 minutes are invalid.

6.2 Display of Results

- Negative result: If only the quality control C line appears and the detection T line is not visible, the sample contains no SARS-CoV-2 antigens or the SARS-CoV-2 antigens concentration is lower than the limit of detection and the result is negative.
- Positive result: If both the quality control C line and the detection T line appear, then the SARS-CoV-2 antigens have been detected and the result is positive.
- Invalid result: If the C line does not appear, the result is invalid and a new test must be performed.

Note: The color intensity of the T line is related to the concentration of SARS-CoV-2 antigens contained in the sample, and the result should be determined by whether the T line is colored or not regardless of the color intensity.



6.3 Comparative Analysis of Results

6.3.1 Tester's Information

Age distribution of the tester

Age group	Number	% of total
≤ 20	79	9.37%
21~60	637	75.56%
61~80	119	14.12%
≥ 81	8	0.95%

Sex of the tester

Gender	Number	% of total
6		
Male	385	45.67%
Female	458	54.33%

6.3.2 Major Effectiveness Statistical Methods

Compared with RT-PCR results, calculate the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy、Kappa and the 95% confidence interval (CI) of test kit. Sensitivity, specificity, PPV, NPV, accuracy: range from 0%~100%, the closer the value is to 100%, the higher the degree of compliance with clinical diagnosis.Kappa value (k) was determined as $k > 0.75$, showing good consistency. $0.40 \leq k \leq 0.75$, good consistency; $K < 0.40$, poor consistency.

6.4 Data analysis

Test results are shown as Table 1~4, and clinical results are detailed in Annex I ~II Clinical verification data list.

6.4.1 Calculation of coincidence rate

Table 1:Medomics Results from Patients and PCR (Nasopharyngeal secretion, Throat secretion)

Medomics COVID-19 Ag test	RT-PCR		
	Positive	Negative	Total
Positive	215	2	217
Negative	5	405	410
Total	220	407	627

Sensitivity: $215 / (215+5) \times 100\% = 97.73\%$,
95%CI: $p \pm 1.96 \times [p(1-p)/n]^{1/2} = [94.78\%-99.26\%]$

Specificity: $405 / (2+405) \times 100\% = 99.51\%$,
95%CI: $p \pm 1.96 \times [p(1-p)/n]^{1/2} = [98.24\%-99.94\%]$

PPV: $215 / (215+2) \times 100\% = 99.08\%$,
95%CI: $p \pm 1.96 \times [p(1-p)/n]^{1/2} = [96.71\%-99.89\%]$

NPV: $405 / (405+5) \times 100\% = 98.78\%$,
95%CI: $p \pm 1.96 \times [p(1-p)/n]^{1/2} = [97.18\%-99.60\%]$

Accuracy: $(215+405) / 627 \times 100\% = 98.88\%$,
95%CI: $p \pm 1.96 \times [p(1-p)/n]^{1/2} = [97.71\%-99.55\%]$

$Kappa=0.951(K > 0.75)$, It can be considered that the Medomics Kit and clinical

7

diagnosis results are consistent.

Table2:Medomics Results from Patients and PCR (Anterior nasal secretion)

Medomics COVID-19 Ag test	RT-PCR		
	Positive	Negative	Total
Positive	107	1	108
Negative	5	103	108
Total	112	104	216

Sensitivity: $107 / (107+5) \times 100\% = 95.54\%$,
95%CI: $p \pm 1.96 \times [p(1-p)/n]^{1/2} = [89.89\%-98.53\%]$

Specificity: $103 / (1+103) \times 100\% = 99.04\%$,
95%CI: $p \pm 1.96 \times [p(1-p)/n]^{1/2} = [94.76\%-99.98\%]$

PPV: $107 / (107+1) \times 100\% = 99.07\%$,
95%CI: $p \pm 1.96 \times [p(1-p)/n]^{1/2} = [94.95\%-99.98\%]$

NPV: $103 / (103+5) \times 100\% = 95.37\%$,
95%CI: $p \pm 1.96 \times [p(1-p)/n]^{1/2} = [89.53\%-98.48\%]$

Accuracy: $(107+103) / 216 \times 100\% = 97.22\%$,
95%CI: $p \pm 1.96 \times [p(1-p)/n]^{1/2} = [94.05\%-98.97\%]$

$Kappa=0.893(K > 0.75)$, It can be considered that the Medomics Kit and clinical diagnosis results are consistent.

Table3 Sensitivity by CT values (Nasopharyngeal secretion, Throat secretion)

CT value	N	Positive	% Positive
$Ct \leq 25$	131	130	99.24%
$25 < Ct \leq 30$	86	84	97.67%
$30 < Ct \leq 33$	3	1	33.33%
Total	220	215	97.73%

Table4 Sensitivity by CT values (Anterior nasal secretion)

CT value	N	Positive	% Positive
$Ct \leq 25$	64	63	98.44%
$25 < Ct \leq 30$	43	42	97.67%
$30 < Ct \leq 33$	5	2	40%
Total	112	107	95.54%

7. Conclusions

A total of 843 testers' Nasopharyngeal , Throat and Anterior nasal swab were collected in this clinical trial.

Nasopharyngeal , Throat swab: Medomics Kit were tested 215 positive out of 220 PCR positive, 405 negative out of 407 PCR negative. the clinical sensitivity of Medomics Kit was 97.73%, the clinical specificity of Medomics Kit was 99.51%, $Kappa=0.951$;

Anterior nasal swab:Medomics Kit were tested 107 positive out of 112 PCR positive,103 negative out of 104 PCR negative. the clinical sensitivity of Medomics Kit was 95.54%, the clinical specificity of Medomics Kit was 99.04%, $Kappa=0.893$;

SARS-CoV-2 antigen Test Kit (LFIA) produced by Jiangsu Medomics Medical Technology Co., Ltd. showed no statistically significant difference between Medomics Kit test results tested by patients and the clinical diagnosis results, which were highly consistent.

Annex I Clinical Verification Data List

e.g. Supplement Table 1

Sample type: Nasopharyngeal secretion, Throat secretion

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

No.	Sample type	Date of testing	Sex	Age	Days after onset of symptoms	CT value of PCR	PCR Result	Medomics results (P/N)
01	Nasopharyngeal	2021.01.25	Female	58	1	22.53	+	+
02	Nasopharyngeal	2021.01.25	Male	52	2	22.53	+	+
03	Nasopharyngeal	2021.01.25	Male	24	2	22.91	+	+
04	Nasopharyngeal	2021.01.25	Female	24	6	NA	-	-
05	Nasopharyngeal	2021.01.24	Female	25	5	NA	-	-
06	Nasopharyngeal	2021.01.24	Female	27	3	22.93	+	+
07	Throat	2021.01.24	Female	35	NA	NA	-	-
08	Nasopharyngeal	2021.01.24	Male	36	0	24.13	+	+
09	Nasopharyngeal	2021.01.24	Female	44	5	NA	-	-
10	Nasopharyngeal	2021.01.24	Female	62	5	NA	-	-
11	Nasopharyngeal	2021.01.24	Female	25	5	23.63	+	+
12	Nasopharyngeal	2021.01.20	Male	48	4	NA	-	-
13	Nasopharyngeal	2021.01.20	Female	41	4	29.90	+	+
14	Nasopharyngeal	2021.01.20	Female	40	NA	NA	-	-

1

15	Throat	2021.01.20	Male	43	NA	NA	-	-
16	Throat	2021.01.20	Male	70	NA	NA	-	-
17	Throat	2021.01.20	Female	45	3	NA	-	-
18	Throat	2021.01.20	Female	35	3	NA	-	-
19	Throat	2021.01.20	Female	36	2	NA	-	-
20	Throat	2021.01.28	Male	38	2	NA	-	-
21	Throat	2021.01.28	Male	42	0	26.05	+	+
22	Throat	2021.01.28	Female	36	0	21.02	+	-
23	Throat	2021.01.20	Male	55	1	28.75	+	+
24	Throat	2021.01.20	Female	66	NA	NA	-	-
25	Throat	2021.01.20	Male	28	3	26.35	+	+
26	Throat	2021.01.20	Female	24	NA	NA	-	-
27	Throat	2021.01.20	Male	35	NA	NA	-	-
28	Throat	2021.01.20	Female	29	NA	NA	-	-
29	Throat	2021.01.27	Male	46	7	NA	-	+
30	Throat	2021.01.27	Female	43	5	NA	-	-
31	Throat	2021.01.27	Male	27	5	NA	-	-
32	Nasopharyngeal	2021.01.27	Female	26	5	21.48	+	+
33	Nasopharyngeal	2021.01.27	Male	65	4	24.02	+	+
34	Nasopharyngeal	2021.01.29	Male	41	4	21.61	+	+
35	Nasopharyngeal	2021.01.29	Female	49	6	24.62	+	+
36	Nasopharyngeal	2021.01.29	Female	47	6	23.92	+	+

1

37	Nasopharyngeal	2021.01.29	Female	53	4	21.40	+	+
38	Nasopharyngeal	2021.01.29	Male	55	5	22.47	+	+
39	Nasopharyngeal	2021.01.29	Female	61	2	24.80	+	+
40	Nasopharyngeal	2021.01.29	Female	50	3	26.94	+	+
41	Nasopharyngeal	2021.01.29	Male	63	4	NA	-	-
42	Nasopharyngeal	2021.01.29	Female	20	6	NA	-	-
43	Nasopharyngeal	2021.01.29	Female	21	7	NA	-	-
44	Throat	2021.01.29	Male	23	2	NA	-	-
45	Throat	2021.01.29	Female	78	1	27.51	+	+
46	Throat	2021.01.29	Female	32	5	31.39	+	-
47	Throat	2021.01.29	Male	35	4	28.05	+	+
48	Throat	2021.01.29	Female	41	3	27.95	+	+
49	Throat	2021.01.29	Male	23	2	26.84	+	+
50	Throat	2021.01.29	Female	42	5	NA	-	-
51	Throat	2021.01.29	Female	22	4	22.99	+	+
52	Throat	2021.01.29	Male	41	7	22.20	+	+
53	Throat	2021.01.29	Female	20	2	23.00	+	+
54	Throat	2021.01.29	Female	15	3	24.00	+	+
55	Throat	2021.01.29	Male	48	4	24.38	+	+
56	Throat	2021.01.29	Female	41	NA	NA	-	-
57	Throat	2021.02.04	Male	23	5	21.05	+	+
58	Throat	2021.02.04	Female	68	4	26.48	+	-

1

59	Throat	2021.02.04	Female	35	4	27.85	+	+
60	Throat	2021.02.04	Male	36	5	27.09	+	+
61	Throat	2021.02.04	Male	32	3	26.71	+	+
62	Throat	2021.02.04	Male	30	NA	NA	-	-
63	Throat	2021.02.04	Male	21	NA	NA	-	-
64	Throat	2021.02.04	Male	45	6	26.62	+	+
65	Throat	2021.02.04	Male	12	0	26.26	+	+
66	Throat	2021.02.04	Male	8	NA	NA	-	-
67	Throat	2021.02.04	Male	28	NA	NA	-	-
68	Throat	2021.02.04	Female	29	NA	NA	-	-
69	Nasopharyngeal	2021.02.04	Female	45	NA	NA	-	-
70	Nasopharyngeal	2021.02.04	Female	52	NA	NA	-	-
71	Nasopharyngeal	2021.02.04	Male	54	NA	NA	-	-
72	Nasopharyngeal	2021.02.04	Male	68	4	24.91	+	+
73	Nasopharyngeal	2021.02.04	Male	64	5	24.44	+	+
74	Nasopharyngeal	2021.02.04	Female	40	NA	NA	-	-
75	Nasopharyngeal	2021.02.02	Female	39	4	22.41	+	+
76	Nasopharyngeal	2021.02.02	Female	38	2	23.83	+	+
77	Nasopharyngeal	2021.02.02	Female	30	NA	NA	-	-
78	Nasopharyngeal	2021.02.02	Female	32	NA	NA	-	-
79	Nasopharyngeal	2021.02.02	Female	31	0	22.88	+	+
80	Nasopharyngeal	2021.02.02	Female	30	NA	NA	-	-

1

81	Throat	2021.02.02	Male	45	4	22.84	+	+
82	Throat	2021.02.02	Female	43	NA	NA	-	-
83	Throat	2021.02.02	Male	44	5</td			

235	Nasopharyngaea	2021.02.07	Female	50	0	28.57	+	+
236	Nasopharyngaea	2021.02.08	Male	63	NA	NA	-	-
237	Nasopharyngaea	2021.02.08	Male	40	NA	NA	-	-
238	Nasopharyngaea	2021.02.08	Male	36	NA	NA	-	-
239	Nasopharyngaea	2021.02.08	Male	56	0	23.46	+	+
240	Nasopharyngaea	2021.02.08	Female	47	5	24.08	+	+
241	Nasopharyngaea	2021.02.07	Male	46	6	23.78	+	+
242	Nasopharyngaea	2021.02.07	Male	59	NA	NA	-	-
243	Nasopharyngaea	2021.02.07	Male	38	NA	NA	-	-
244	Nasopharyngaea	2021.02.07	Male	33	NA	NA	-	-
245	Nasopharyngaea	2021.02.07	Female	49	2	21.09	+	+
246	Nasopharyngaea	2021.02.07	Male	50	NA	NA	-	-
247	Nasopharyngaea	2021.02.05	Male	63	NA	NA	-	-
248	Nasopharyngaea	2021.02.08	Male	40	NA	NA	-	-
249	Nasopharyngaea	2021.02.08	Male	33	3	27.23	+	+
250	Throat	2021.02.08	Female	16	NA	NA	-	-
251	Throat	2021.02.08	Female	54	NA	NA	-	-
252	Throat	2021.02.08	Female	32	NA	NA	-	-
253	Throat	2021.02.08	Female	50	NA	NA	-	-
254	Throat	2021.02.08	Female	59	0	25.96	+	+
255	Nasopharyngaea	2021.02.05	Female	33	NA	NA	-	-
256	Nasopharyngaea	2021.02.05	Female	33	NA	NA	-	-

2

257	Throat	2021.02.06	Male	59	5	28.62	+	+
258	Nasopharyngaea	2021.02.06	Female	56	6	28.37	+	+
259	Nasopharyngaea	2021.02.06	Female	29	4	22.28	+	+
260	Throat	2021.02.06	Female	19	5	24.79	+	+
261	Throat	2021.02.06	Female	17	7	25.32	+	+
262	Throat	2021.02.06	Female	69	NA	NA	-	-
263	Throat	2021.02.06	Male	52	NA	NA	-	-
264	Throat	2021.02.06	Female	50	NA	NA	-	-
265	Throat	2021.02.06	Female	59	NA	NA	-	-
266	Nasopharyngaea	2021.02.06	Female	20	NA	NA	-	-
267	Throat	2021.02.02	Female	52	2	28.63	+	+
268	Throat	2021.02.02	Female	45	NA	NA	-	-
269	Nasopharyngaea	2021.02.02	Male	31	NA	NA	-	-
270	Nasopharyngaea	2021.02.06	Male	45	1	26.21	+	+
271	Nasopharyngaea	2021.02.06	Male	58	2	25.33	+	+
272	Throat	2021.02.06	Male	43	2	23.70	+	+
273	Throat	2021.02.06	Male	33	NA	NA	-	-
274	Throat	2021.02.06	Male	59	NA	NA	-	-
275	Throat	2021.02.06	Male	56	NA	NA	-	-
276	Throat	2021.02.06	Male	25	NA	NA	-	-
277	Throat	2021.02.06	Male	22	NA	NA	-	-
278	Throat	2021.02.02	Male	23	NA	NA	-	-

2

279	Nasopharyngaea	2021.02.02	Female	42	4	26.01	+	+
280	Nasopharyngaea	2021.02.02	Female	64	5	29.43	+	+
281	Nasopharyngaea	2021.02.02	Female	40	5	26.88	+	+
282	Nasopharyngaea	2021.02.02	Female	52	NA	NA	-	-
283	Nasopharyngaea	2021.02.02	Female	45	NA	NA	-	-
284	Nasopharyngaea	2021.02.05	Female	38	4	22.93	+	+
285	Nasopharyngaea	2021.02.07	Male	37	2	22.30	+	+
286	Nasopharyngaea	2021.02.02	Male	60	2	21.85	+	+
287	Nasopharyngaea	2021.02.02	Male	39	0	21.00	+	+
288	Nasopharyngaea	2021.02.02	Male	36	NA	NA	-	-
289	Nasopharyngaea	2021.02.02	Male	36	NA	NA	-	-
290	Nasopharyngaea	2021.02.02	Male	47	6	24.91	+	+
291	Nasopharyngaea	2021.02.02	Female	59	5	24.22	+	+
292	Nasopharyngaea	2021.02.02	Female	54	4	23.81	+	+
293	Nasopharyngaea	2021.02.02	Male	54	1	23.47	+	+
294	Throat	2021.02.02	Male	17	NA	NA	-	-
295	Throat	2021.02.02	Male	47	NA	NA	-	-
296	Throat	2021.02.02	Male	59	NA	NA	-	-
297	Throat	2021.02.07	Male	54	NA	NA	-	-
298	Throat	2021.02.07	Female	54	NA	NA	-	-
299	Throat	2021.02.07	Female	62	NA	NA	-	-
300	Nasopharyngaea	2021.02.07	Female	41	NA	NA	-	-

2

301	Nasopharyngaea	2021.02.09	Male	71	2	22.30	+	+
302	Nasopharyngaea	2021.02.09	Male	65	3	21.85	+	+
303	Throat	2021.02.09	Male	52	7	23.91	+	+
304	Throat	2021.02.09	Male	42	4	24.30	+	+
305	Throat	2021.02.09	Male	55	NA	NA	-	-
306	Nasopharyngaea	2021.02.09	Male	45	NA	NA	-	-
307	Nasopharyngaea	2021.02.09	Male	55	NA	NA	-	-
308	Throat	2021.02.09	Male	49	NA	NA	-	-
309	Throat	2021.02.09	Male	51	NA	NA	-	-
310	Throat	2021.02.09	Male	52	NA	NA	-	-
311	Nasopharyngaea	2021.02.09	Male	26	0	21.92	+	+
312	Nasopharyngaea	2021.02.09	Female	33	5	20.21	+	+
313	Throat	2021.02.09	Male	43	NA	NA	-	-
314	Throat	2021.01.28	Female	26	NA	NA	-	-
315	Throat	2021.01.24	Male	36	NA	NA	-	-
316	Nasopharyngaea	2021.01.28	Female	35	NA	NA	-	-
317	Nasopharyngaea	2021.01.28	Male	32	NA	NA	-	-
318	Nasopharyngaea	2021.01.28	Female	68	NA	NA	-	-
319	Nasopharyngaea	2021.01.28	Female	72	NA	NA	-	-
320	Nasopharyngaea	2021.01.28	Female	80	NA	NA	-	-
321	Nasopharyngaea	2021.01.28	Female	66	NA	NA	-	-
322	Nasopharyngaea	2021.01.28	Female	68	7	28.12	+	+

2

323	Throat

477	Throat	2021.01.27	Male	41	NA	NA	-	-
478	Nasopharyngea	2021.01.27	Male	37	NA	NA	-	-
479	Nasopharyngea	2021.01.27	Female	45	NA	NA	-	-
480	Nasopharyngea	2021.01.27	Female	26	NA	NA	-	-
481	Throat	2021.01.25	Female	47	4	28.53	+	+
482	Nasopharyngea	2021.02.11	Female	34	NA	NA	-	-
483	Nasopharyngea	2021.02.11	Female	51	4	22.13	+	+
484	Nasopharyngea	2021.02.11	Female	54	NA	NA	-	-
485	Throat	2021.02.11	Female	49	2	22.54	+	+
486	Throat	2021.02.11	Female	34	NA	NA	-	-
487	Throat	2021.02.08	Male	27	5	28.78	+	+
488	Throat	2021.02.08	Female	16	NA	NA	-	-
489	Throat	2021.02.08	Female	53	3	21.20	+	+
490	Throat	2021.02.08	Female	22	NA	NA	-	-
491	Nasopharyngea	2021.02.08	Female	49	5	22.47	+	+
492	Nasopharyngea	2021.02.08	Female	46	NA	NA	-	-
493	Nasopharyngea	2021.02.08	Male	30	2	26.82	+	+
494	Nasopharyngea	2021.02.08	Male	34	2	26.80	+	+
495	Nasopharyngea	2021.01.25	Male	36	NA	NA	-	-
496	Nasopharyngea	2021.01.25	Female	69	NA	NA	-	-
497	Nasopharyngea	2021.01.25	Female	34	7	22.87	+	+
498	Nasopharyngea	2021.01.25	Female	35	NA	NA	-	-

3

499	Nasopharyngea	2021.01.25	Female	30	NA	NA	-	-
500	Nasopharyngea	2021.01.25	Female	52	NA	NA	-	-
501	Nasopharyngea	2021.01.25	Female	50	NA	NA	-	-
502	Nasopharyngea	2021.01.25	Female	23	NA	NA	-	-
503	Nasopharyngea	2021.01.25	Male	39	NA	NA	-	-
504	Nasopharyngea	2021.02.02	Female	30	NA	NA	-	-
505	Nasopharyngea	2021.02.02	Male	40	5	22.83	+	+
506	Nasopharyngea	2021.02.02	Female	26	NA	NA	-	-
507	Nasopharyngea	2021.02.02	Female	55	NA	NA	-	-
508	Throat	2021.02.02	Female	64	6	24.23	+	+
509	Throat	2021.02.02	Female	31	NA	NA	-	-
510	Nasopharyngea	2021.02.02	Male	33	NA	NA	-	-
511	Throat	2021.02.02	Male	43	5	21.32	+	+
512	Throat	2021.02.02	Male	25	NA	NA	-	-
513	Nasopharyngea	2021.02.07	Male	15	7	26.85	+	+
514	Throat	2021.02.07	Male	33	0	28.09	+	+
515	Throat	2021.02.02	Male	63	NA	NA	-	-
516	Nasopharyngea	2021.02.07	Female	71	NA	NA	-	-
517	Throat	2021.02.07	Male	45	NA	NA	-	-
518	Throat	2021.02.07	Male	24	0	24.12	+	+
519	Throat	2021.02.07	Female	33	6	23.54	+	+
520	Nasopharyngea	2021.02.07	Female	36	NA	NA	-	-

3

521	Throat	2021.02.07	Female	21	NA	NA	-	-
522	Throat	2021.02.07	Female	18	NA	NA	-	-
523	Nasopharyngea	2021.02.07	Female	24	NA	NA	-	-
524	Throat	2021.02.07	Female	53	NA	NA	-	-
525	Nasopharyngea	2021.02.07	Female	33	NA	NA	-	-
526	Nasopharyngea	2021.02.07	Female	48	NA	NA	-	-
527	Throat	2021.02.07	Male	58	4	26.96	+	+
528	Throat	2021.02.10	Male	47	NA	NA	-	-
529	Nasopharyngea	2021.02.10	Female	54	NA	NA	-	-
530	Throat	2021.02.10	Female	37	NA	NA	-	-
531	Throat	2021.02.10	Female	51	NA	NA	-	-
532	Nasopharyngea	2021.02.10	Female	24	NA	NA	-	-
533	Nasopharyngea	2021.02.10	Female	50	3	24.57	+	+
534	Nasopharyngea	2021.02.10	Male	60	NA	NA	-	-
535	Nasopharyngea	2021.02.10	Male	56	7	21.36	+	+
536	Nasopharyngea	2021.02.10	Male	36	5	24.52	+	+
537	Nasopharyngea	2021.02.08	Male	63	0	22.74	+	+
538	Nasopharyngea	2021.02.08	Male	28	NA	NA	-	-
539	Nasopharyngea	2021.02.08	Male	32	NA	NA	-	-
540	Nasopharyngea	2021.02.10	Female	44	NA	NA	-	-
541	Nasopharyngea	2021.02.10	Male	15	NA	NA	-	-
542	Nasopharyngea	2021.02.10	Male	63	NA	NA	-	-

3

543	Nasopharyngea	2021.02.10	Male	22	NA	NA	-	-
544	Nasopharyngea	2021.02.10	Male	37	NA	NA	-	-
545	Nasopharyngea	2021.02.10	Female	57	NA	NA	-	-
546	Nasopharyngea	2021.02.10	Female	40	NA	NA	-	-
547	Nasopharyngea	2021.02.10	Female	25	7	21.39	+	+
548	Throat	2021.02.10	Female	42	NA	NA	-	-
549	Throat	2021.02.08	Female	17	5	26.15	+	+
550	Nasopharyngea	2021.02.08	Male	41	NA	NA	-	-
551	Throat	2021.02.08	Male	41	NA	NA	-	-
552	Throat	2021.02.08	Male	23	NA	NA	-	-
553	Nasopharyngea	2021.02.08	Female	36	NA	NA	-	-
554	Throat	2021.02.08	Female	63	5	25.90	+	+
555	Throat	2021.02.08	Female	29	NA	NA	-	-
556	Throat	2021.02.08	Female	60	4	22.58	+	+
557	Throat	2021.02.12	Male	63	5	22.54	+	+
558	Throat	2021.02.12	Male	57	NA	NA	-	-
559	Nasopharyngea	2021.02.12	Male	34	NA	NA	-	-
560	Nasopharyngea	2021.02.12	Male	50	NA	NA	-	-
561	Nasopharyngea	2021.02.12	Male	46	6	25.23	+	+
562	Nasopharyngea	2021.02.12	Female	17	NA	NA	-	-
563	Nasopharyngea	2021.02.12	Female	39	NA	NA	-	-
564	Nasopharyngea	2021.02.12	Female	29	NA	NA	-	-

3

565	Nasopharyngea	2021.02.12	Female	48	NA	NA	-	-
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38	Anterior nasal secretion	2021.01.29	Male	55	5	29.47	+	+
39	Anterior nasal secretion	2021.01.29	Female	61	2	27.80	+	+
40	Anterior nasal secretion	2021.01.29	Female	50	3	26.94	+	+
41	Anterior nasal secretion	2021.01.29	Male	63	4	NA	-	-
42	Anterior nasal secretion	2021.01.29	Female	20	6	NA	-	-
43	Anterior nasal secretion	2021.01.29	Female	21	7	NA	-	-
44	Anterior nasal secretion	2021.01.29	Male	23	2	NA	-	-
45	Anterior nasal secretion	2021.01.29	Female	78	1	27.51	+	+
46	Anterior nasal secretion	2021.01.29	Female	32	5	29.39	+	+
47	Anterior nasal secretion	2021.01.29	Male	35	4	31.05	+	-
48	Anterior nasal secretion	2021.01.22	Female	41	3	27.95	+	+
49	Anterior nasal secretion	2021.01.22	Male	23	2	31.84	+	+
50	Anterior nasal secretion	2021.01.22	Female	42	5	NA	-	-
51	Anterior nasal secretion	2021.01.22	Female	22	4	22.99	+	+
52	Anterior nasal secretion	2021.01.22	Male	41	7	22.20	+	+
53	Anterior nasal secretion	2021.02.12	Female	20	2	23.00	+	+
54	Anterior nasal secretion	2021.02.12	Female	15	3	24.00	+	+
55	Anterior nasal secretion	2021.02.12	Male	48	4	24.38	+	+
56	Anterior nasal secretion	2021.02.12	Female	41	NA	NA	-	-
57	Anterior nasal secretion	2021.02.12	Male	23	5	21.05	+	+
58	Anterior nasal secretion	2021.02.12	Female	68	4	29.48	+	-
59	Anterior nasal secretion	2021.02.12	Female	35	4	27.85	+	+

41

60	Anterior nasal secretion	2021.02.12	Male	36	5	27.09	+	+
61	Anterior nasal secretion	2021.02.09	Female	32	3	26.71	+	+
62	Anterior nasal secretion	2021.02.09	Female	30	NA	NA	-	-
63	Anterior nasal secretion	2021.02.09	Female	21	NA	NA	-	-
64	Anterior nasal secretion	2021.02.07	Female	45	6	26.62	+	+
65	Anterior nasal secretion	2021.02.07	Male	12	0	26.26	+	+
66	Anterior nasal secretion	2021.02.04	Male	8	NA	NA	-	-
67	Anterior nasal secretion	2021.02.04	Male	28	NA	NA	-	-
68	Anterior nasal secretion	2021.02.04	Female	29	NA	NA	-	-
69	Anterior nasal secretion	2021.02.04	Female	45	NA	NA	-	-
70	Anterior nasal secretion	2021.02.04	Female	52	NA	NA	-	-
71	Anterior nasal secretion	2021.02.04	Male	54	NA	NA	-	-
72	Anterior nasal secretion	2021.02.04	Male	68	4	24.91	+	+
73	Anterior nasal secretion	2021.02.04	Male	64	5	24.44	+	+
74	Anterior nasal secretion	2021.02.04	Female	40	NA	NA	-	-
75	Anterior nasal secretion	2021.02.02	Female	39	4	22.41	+	+
76	Anterior nasal secretion	2021.01.22	Female	38	2	23.83	+	+
77	Anterior nasal secretion	2021.01.22	Female	30	NA	NA	-	-
78	Anterior nasal secretion	2021.01.22	Female	32	NA	NA	-	-
79	Anterior nasal secretion	2021.02.02	Female	31	0	22.88	+	+
80	Anterior nasal secretion	2021.02.02	Female	30	NA	NA	-	-
81	Anterior nasal secretion	2021.02.02	Male	45	4	26.84	+	+

42

82	Anterior nasal secretion	2021.02.02	Female	43	NA	NA	-	-
83	Anterior nasal secretion	2021.02.02	Male	44	5	29.33	+	+
84	Anterior nasal secretion	2021.02.02	Female	41	5	25.43	+	+
85	Anterior nasal secretion	2021.02.02	Male	10	2	27.22	+	+
86	Anterior nasal secretion	2021.02.02	Male	25	2	29.75	+	+
87	Anterior nasal secretion	2021.02.02	Female	25	NA	NA	-	-
88	Anterior nasal secretion	2021.02.02	Male	20	0	25.04	+	+
89	Anterior nasal secretion	2021.02.08	Female	21	4	26.94	+	+
90	Anterior nasal secretion	2021.01.28	Female	28	3	26.84	+	+
91	Anterior nasal secretion	2021.01.28	Female	29	3	27.67	+	+
92	Anterior nasal secretion	2021.01.28	Female	56	3	29.33	+	+
93	Anterior nasal secretion	2021.01.28	Female	34	6	NA	-	-
94	Anterior nasal secretion	2021.01.28	Female	45	6	27.22	+	+
95	Anterior nasal secretion	2021.02.02	Female	71	7	29.95	+	+
96	Anterior nasal secretion	2021.02.02	Male	52	NA	NA	-	-
97	Anterior nasal secretion	2021.02.08	Male	46	5	28.95	+	+
98	Anterior nasal secretion	2021.02.02	Male	44	NA	NA	-	-
99	Anterior nasal secretion	2021.02.02	Male	47	NA	NA	-	-
100	Anterior nasal secretion	2021.02.02	Female	64	3	27.15	+	+
101	Anterior nasal secretion	2021.02.02	Female	62	4	26.13	+	+
102	Anterior nasal secretion	2021.02.02	Female	65	NA	NA	-	-
103	Anterior nasal secretion	2021.02.02	Male	61	1	22.81	+	+

43

104	Anterior nasal secretion	2021.02.02	Male	78	NA	NA	-	-
105	Anterior nasal secretion	2021.02.02	Male	67	NA	NA	-	-
106	Anterior nasal secretion	2021.02.02	Male	64	NA	NA	-	-
107	Anterior nasal secretion	2021.02.02	Male	15	NA	NA	-	-
108	Anterior nasal secretion	2021.02.08	Male	16	NA	NA	-	-
109	Anterior nasal secretion	2021.02.08	Male	52	NA	NA	-	-
110	Anterior nasal secretion	2021.02.08	Male	28	NA	NA	-	-
111	Anterior nasal secretion	2021.02.08	Male	68	0	22.28	+	+
112	Anterior nasal secretion	2021.02.08	Male	70	NA	NA	-	-
113	Anterior nasal secretion	2021.01.26	Male	14	NA	NA	-	-
114	Anterior nasal secretion	2021.01.26	Female	55	NA	NA	-	-
115	Anterior nasal secretion	2021.01.25	Female	20	NA	NA	-	-
116	Anterior nasal secretion	2021.01.25	Female	29	4	25.61	+	+
117	Anterior nasal secretion	2021.01.25	Male	54	4	29.13	+	+
118	Anterior nasal secretion	2021.01.25	Male	68	NA	NA	-	-
119	Anterior nasal secretion	2021.01.25	Male	50	NA	NA	-	-
120	Anterior nasal secretion	2021.01.26	Male	52	4	26.98	+	+
121	Anterior nasal secretion	2021.01.26	Male	66	5	29.22	+	+
122	Anterior nasal secretion	2021.01.26	Female	40	NA	NA	-	-
123	Anterior nasal secretion	2021.01.26	Male	77	NA	NA	-	-
124	Anterior nasal secretion	2021.01.26	Male	35	NA	NA	-	-
125	Anterior nasal secretion	2021.01.25	Female	38	7	27.64	+	+

44

126	Anterior nasal secretion	2021.01.26	Female	37	2	26.06	+	+

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Curriculum vitae

Bondarchuk Olga Leonidivna

Date of birth: November 13, 1974

City: Kyiv

Citizenship: Ukrainian

Phone: 066-130-50-37

Email: origa@ukr.net

Education: full higher.

- 2004 - Bogomolets National Medical University, specialty - "Medical and preventive care".
- 2004-2005 - Shupyk National Medical Academy of Postgraduate Education, the internship in the specialty "Microbiology and Virology".
- 2006 - workshop training on laboratory diagnosis of cholera on the basis of the Laboratory for Especially Dangerous Infectious Diseases of the city SES;
- 2009 - pre-certification cycle in bacteriology at the Shupyk National Medical Academy of Postgraduate Education;
- 2010 - the second category in the specialty "Bacteriology";
- 2012 - workshop training on laboratory diagnosis of cholera on the basis of the Laboratory for Especially Dangerous Infectious Diseases of the city SES;
- 2012 - pre-certification cycle in bacteriology at the Shupyk National Medical Academy of Postgraduate Education;
- 2012 - the first category in the specialty "Bacteriology";
- 2013 - advanced training "Polymerase chain reaction in laboratory diagnosis of infectious diseases" at the Shupyk National Medical Academy of Postgraduate Education;
- 2014 - pre-certification cycle in bacteriology at the Shupyk National Medical Academy of Postgraduate Education;

- 2015 - advanced training "Laboratory diagnosis of HIV infection, viral hepatitis B, C, D, herpesvirus infections" at the Shupyk National Medical Academy of Postgraduate Education;
- 2017 - advanced training "Application of PCR and ELISA methods in laboratory diagnosis of infectious diseases" at the Ukrainian Military Medical Academy;
- 2019 - advanced training "Modern problems of TORCH-infections" (with elements of distance learning) at the Shupyk National Medical Academy of Postgraduate Education;

Work experience: since 2005 worked at the Kyiv City Clinical Hospital № 4 as a bacteriologist. In 2011-2013 - worked in the bacteriological laboratory of the sanitary-epidemiological station of Solomyansky district. At the same time, remained in KCCH № 4 as a part-time employee (bacteriologist). Since 2013 and until now - the bacteriologist of the clinical diagnostic laboratory KCCH № 4, Solomyansky district.

During the whole period, 10 articles were published in scientific medical periodicals:

1. «CHOICE OF RATIONAL ANTIBACTERIAL THERAPY IN THE SURGICAL TREATMENT OF PATIENTS WITH ACUTE DESTRUCTIVE APPENDICITIS», Ukrainian Journal of Surgery, № 1 (10), 2011.
2. «Colonic dysbiosis in the pathogenesis of acute appendicitis and its complications», SURGERY OF UKRAINE, № 2, 2011.
3. «FORMATION OF BIOFILMS BY SOFT TISSUE PHLEGMON PATHOGENS», SURGERY OF UKRAINE, №1, 2016.
4. «CLINICAL EXPERIENCE OF THE USE OF THE TEST-SYSTEM STOMATOFLOR FOR THE EVALUATION OF MICROBIOTA OF PERIODONTAL POCKET WITH A PCR METHOD IN A REAL-TIME», IMPLANTOLOGY, PERIODONTOLOGY, OSTEОLOGY, № 2 (42), 2016.
5. «Application of dermal equivalent based on allogeneic cultured adipose-derived multipotent mesenchymal stromal cells and fibrin hydrogel for treatment of persistent nonhealing wounds», Kharkiv surgical school, № 3-4 (84-85), 2017.

6. «Clinical picture, diagnosis and treatment of VZV-vasculopathy of cerebral arteries», International Neurological Journal, № 3, 2018.
7. «Real-time PCR as a Method of Periodontal Pathogens Detection Around Zirconia and Titanium Abutments», Dentistry news, № 2 (95), 2018.
8. «The results of biofilm formation intensity on titanium abutments using real-time polymerase chain reaction and microbiological culture», Clinical dentistry, № 4, 2018.
9. «Comparative assessment of the use of abutments from zirconium oxide and titanium in prosthesis on implants», Dental Magazine, № 8, 2018.
10. «The aspects of the use of laser radiation for optimizing diagnostic techniques in the follow-up of patients with generalized periodontal disease», Modern dentistry, № 5, 2019.

Oral reports:

1. "USE OF BACTERIOPHAGS IN THE TREATMENT OF DISEASES CAUSED BY METHYCOLIN-RESISTANT STRAINES STAPHYLOCOCCUS AUREUS", scientific-practical conference with international participation "9th International Conference on Bioresources and Viruses", September 10, 2019, Kyiv.
2. "The use of bacteriophages in the treatment of surgical diseases in conditions of limited effectiveness of antibiotics", II International Congress "Rational use of antibiotics in the modern world. ANTIBIOTIC RESISTANCE STOP! ", November 14, 19, Kyiv.

Abstracts:

1. Bondarchuk OL, Poniatovskiy VA, Prystupiuk MO, Smikodub OO, Shyrobokov VP "USE OF BACTERIOPHAGS IN THE TREATMENT OF DISEASES CAUSED BY METHYCOLIN-RESISTANT STRAINES STAPHYLOCOCCUS AUREUS", a collection of materials of the scientific-practical conference "9th International Conference on Bioresources and Viruses", 2019.
2. Prystupiuk MO, Poniatovsky VA, Bondarchuk OL, Smikodub OO, Onofriychuk YA, Bezrodny BG, Shyrobokov VP, "The use of bacteriophages in the treatment of surgical diseases in conditions of limited efficiency of antibiotics "collection of materials of the II international congress" Rational use of antibiotics in the modern world. ANTIBIOTIC RESISTANCE STOP! ", 2019.

3. Shirobokov VP, Poniatoovsky VA, Prystupyuk MO, Bondarchuk OL, "The role of bacteriophages in the treatment of infections caused by antibiotic-resistant microorganisms", a collection of materials of the scientific conference dedicated to the 100th anniversary of the department of Microbiology, Virology and Immunology of the National Medical University. O.O. Bogomolets of the Ministry of Health of Ukraine, November 5, 19

Personal qualities:

Honesty, responsibility, integrity, attention to detail, discipline, punctuality, communication.

Additional Information:

Languages: English, Ukrainian, Russian.

Marital status: married.