Summary of the
EVALUATION PROTOCOL

of Detection kit for SARS-CoV-2 RNA presence in biological material using real-time isothermal amplification *In Vitro* Diagnostic Medical Device Clinical Trials

No. 02/20 as of 18.03.2020

Trials conditions and place

Clinical trials of Detection kit for SARS-CoV-2 RNA presence in biological material using real-time isothermal amplification in different execution forms amedical device designed for *in vitro* diagnostics, manufactured by SmartLifeCare LLC, Russia, were performed by employees of Vector, the Federal Budgetary Institution of Science State Research Center for Virology and Biotechnology of Federal Service for Supervision of Consumer Rights Protection and Human Well-Being (WHO reference laboratory providing confirmatory testing for COVID-19 - *The State Research Center of Virology and Biotechnology VECTOR*) according to manufacturer's operational documentation.

Samples containing NA	Probes quantity	Detection kit for SARS-CoV-2 RNA presence in biological material using real-time isothermal amplification in different execution forms according to TU 21.20.23-001-39070608-2020, SmartLifeCare LLC				Vector-PCRrv-2019-nCoV-RG 2019-nCoV RNA detection by PCR with hybridization-fluorescence reagent kit according to TU 21.20.23-088-05664012-2020, Vector, the Federal Budgetary Institution of Science State Research Center for Virology and Biotechnology
		Lot 30018	Lot 30019	Lot 20018	Lot 20019	Series 11.03.2020
Positive samples, oropharyngeal swabs containing 2019-nCoV coronavirus	160	40	40	40	40	40
Positive samples, nasopharyngeal swabs containing 2019-nCoV coronavirus	160	40	40	40	40	40
Positive sputum samples containing 2019-nCoV coronavirus	80	20	20	20	20	20
Total positive	400	100	100	100	100	100
Influenza A	24	6	6	6	6	6
Influenza B	24	6	6	6	6	6

Parainfluenza	24	6	6	6	6	6
Adenovirus	24	6	6	6	6	6
RSV	24	6	6	6	6	6
Metapneumovirus	24	6	6	6	6	6
Rhinovirus	24	6	6	6	6	6
hCov NL63	24	6	6	6	6	6
hCov OC43	24	6	6	6	6	6
hCov 229E	24	6	6	6	6	6
hCov HKUI	24	6	6	6	6	6
Streptococcus pneumoniae	20	5	5	5	5	5
Haemophilus influenzae	20	5	5	5	5	5
Streptococcus pyogenes	20	5	5	5	5	5
Staphylococcus aureus	36	9	9	9	9	9
SARS-Cov	40	10	10	10	10	10
Total heterologous negative	200	100	100	100	100	100

Sensitivity of the Detection Kit For SARS-Cov-2 RNA Presence in Biological Material Using Real-Time Isothermal Amplification, when examining 400 samples containing 2019-nCoV (SARS-CoV-2) coronavirus strain. No. 974 with 2 lots of the kit (each of 2 execution forms) at a concentration of 1×10^4 copies/ml, **is 100% (99.2% - 100%) with a confidence level of 95%.** Intra-repetitive, inter-repetitive and inter-serial reproducibility for all positive samples is 100%.

Specificity of the Detection Kit For SARS-Cov-2 RNA Presence in Biological Material Using Real-Time Isothermal Amplification, when examining 400 samples containing 2019-nCoV (SARS-CoV-2) coronavirus strain. No. 974 with 2 lots of the kit (each of 2 execution forms) at a concentration of 1×10^4 copies/ml, **is 100 % (99,2 % – 100 %) with a confidence level of 90 %.**

Diagnostic efficacy of the Detection Kit For SARS-Cov-2 RNA Presence in Biological Material Using Real-Time Isothermal Amplification, when examining 400 negative samples, including nasopharyngeal and oropharyngeal swabs from patients with a different etiology of the disease (Influenza A and B, Parainfluenza, Adenovirus infection, respiratory syncytial infection, Metapneumovirus infection, Rhinovirus infection, and human coronavirus infection caused by hCov NL63, hCov OC43, hCov 229E, hCov HKUI, sputum samples from patients with a different etiology of the disease (Influenza, Streptococcus pneumoniae, Haemophilus influenzae, Streptococcus pyogenes, and Staphylococcus aureus, also cell culture samples Vero containing SARS-CoV-2 virus (Frankfurt 1 strain) with the kits of two lots (each of 2 execution forms), **is proven**;

- when examining 400 positive samples (100 with 2 Lots of the Kit in 2 execution forms) containing 2019-nCoV (SARS-CoV-2) coronavirus strain. No. 974 at a concentration of 1×10^4 copies/ml, positive result is obtained in 400 cases, **diagnostic sensitivity is 100% (99,2 % – 100 %) with a confidence level of 95 %.**

- when examining 400 heterologous samples (100 with 2 Lots of the Kit in 2 execution forms), including nasopharyngeal and oropharyngeal swabs samples from patients with a different etiology of the disease (Influenza A and B, Parainfluenza, Adenovirus infection, RSV, Metapneumovirus infection, Rhinovirus infection and human coronavirus infection caused by hCov NL63, hCov OC43, hCov 229E, hCov HKUI, sputum samples from patients with a different etiology of the disease (Influenza, *Streptococcus pneumoniae, Haemophilus influenzae, Streptococcus pyogenes, Staphylococcus aureus)* as well as Vero cell culture samples containing SARS-CoV-2 virus (Frankfurt 1 strain), **the diagnostic specificity is 100 % (99,2 % – 100 %) with a confidence level of 95 %.**