

№ 23 /2019 dated 15.04.2020

## ADVISORY NOTICE

### Dear colleagues!

We inform you that the company “DNA-technology” has started the production of the kit for detection of SARS-CoV-2 and SARS-CoV-like viruses using reverse transcription and real-time polymerase chain reaction (SARS-CoV-2/SARS-CoV). Kit is certified as RU-IVD, certificate # RZN 2020/9948 dated 01.04.2020 and CE-IVD, certificate # FD 9031-2020 dated 16.04.2020. The kit meets the requirements of international documents for diagnostics of the coronavirus (*Laboratory testing for coronavirus disease (COVID-19) in suspected human cases. Interim guidance. 19 March 2020. WHO*).

### ***Main advantages of the kit:***

1) The Kit employs the unique technology of simultaneous detection of three genomic targets:  
-gene E (encodes an envelope membrane protein) of Betacoronavirus SARS-CoV which is confirmed to cause atypical pneumonia of 2002 and fragments  
-two genes of SARS-CoV-2 which is confirmed to cause the new coronavirus infection COVID-19 – gene E (the genomic region common with SARS-CoV isolate) and gene N (encodes the SARS-CoV-2 - specific ribonucleocapsid protein или nucleocapsid phosphoprotein).

The developed solution does not have analogs in Russia and allows complementary detection of genomic targets of SARS-CoV isolates. Moreover, the kit possess improved reliability of diagnostics due to inclusion of additional SARS-CoV-2 – specific target, which allows to consider the possible accumulation of mutations in viral genome and lower the risk of false negative results.

2) The kit possess high analytical sensitivity (500 copies of nucleic acid / ml of initial sample or 10 copies of viral genome for an amplification tube\*). Thus, the Kit allows detecting coronavirus RNA in low-target biological samples.

Diagnostic sensitivity (95% confidence interval) – 100% (95,6 – 100%);

Diagnostic specificity (95% CI) – 100% (96,7 – 100%)

- 3) The kit includes RNA control, which must be added in each test tube and negative control sample in order to estimate the quality of RNA extraction and reverse transcription.
- 4) The kit includes DNA-plasmid with viral-specific insert which must be ran in parallel to assure the performance of PCR
- 5) One-step RT-PCR allows to optimize the workflow and save the time.
- 6) The full range of biological samples approved by WHO can be used for analysis: swabs from nasopharyngeal cavity, oropharyngeal cavity, bronchoalveolar lavage, endotracheal and nasopharyngeal aspirate, phlegm.

The kit is validated for the following instruments “DT” line (“DTlite” and “DTprime” produced by “DNA-technology”) and for QIAGEN and Rotor-Gene Q (QIAGEN, Germany).

**Attention!**

*While ordering SARS-CoV-2/SARS-CoV kit, please, specify the model of your Real-time instrument!*

*For instruments DT line it is recommended to use strips format (8 x 0,2 ml) ref # R3-P436-S3/9EU*

*For Rotor-Gene (Qiagen) only tubes format 0,2 ml is allowed! ) ref # R3-P436-23/9EU*

Software for instruments DT line automatically forms report with the conclusion and interpretation of the results.

Time of analysis from sample preparation to getting the blank with results is about 3 hours.

Shelf life of the kit is 12 months.

If you have any questions, please do not hesitate contact "DNA-Technology" team:

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\*in case of usage kit “PREP-NA” (“DNA-technology”)

