

RT-PCR-Rt KIT "OM-Screen-2019-nCoV-RT"

cat. No. OOM-132

The OM-Screen-2019-nCoV-RT kit is intended for the qualitative analysis (screening, monitoring) of coronavirus SARS-CoV-2 RNA extracted from samples obtained by taking a smear from the nose, nasopharynx and / or oropharynx, bronchial lavage water obtained by fibrobronchoscopy (bronchoalveolar lavage), as well as from (endo) tracheal, nasopharyngeal aspirate, sputum, biopsy or autopsy material of the lungs, whole blood, serum, urine.

To isolate RNA, it is recommended to use the reagent kit "M -sorb-OOM" (Cat. No. OOM-502).

Advantages of the OM-Screen-2019-nCoV-RT Reagent Kit:

1. The reagent kit takes advantage of the multiplex RT-PCR-RV, namely: the simultaneous detection in the same sample the coronavirus SARS-CoV-2 RNA (R6G detection channel) together with two more control reactions that exclude false negative results of the analysis:

- a reaction to evaluate the efficiency of nucleic acid extraction - IPS-Extr-RNA (FAM detection channel);

- a reaction that allows to evaluate the degree of inhibition of the reverse transcription and amplification reaction - IPS RT-PCR-Rt (Cy5 detection channel).

2. The ready-to-use reaction mixture, PC-nCoV, has been pipetted in 0.2 ml stripped PCR tubes and lyophilized. This format allows you to transport this kit at room temperature and store them at temperatures from plus 2 ° C to plus 8 ° C.

3. Detection of nucleic acid fragments of the coronavirus SARS-CoV-2 RNA is performing by the reverse transcription method combined with real-time polymerase chain reaction (RT-PCR-Rt) in one microtube, which allows to reduce the number of manipulations with the reaction mixture and thereby minimize the number of errors and the possibility of contamination during the proceeding of RT-PCR-Rt.

Analytical characteristics of OM-Screen-2019-nCoV-Rt

Sensitivity

1.0x10³ copies of coronavirus SARS-CoV RNA per milliliter of sample (copies · ml⁻¹). To achieve this level of sensitivity, it is recommended to use reagent kits for the extraction of RNA, allowing the selection of aliquots of the source material (samples) with a volume of at least 100 µl.

Specificity

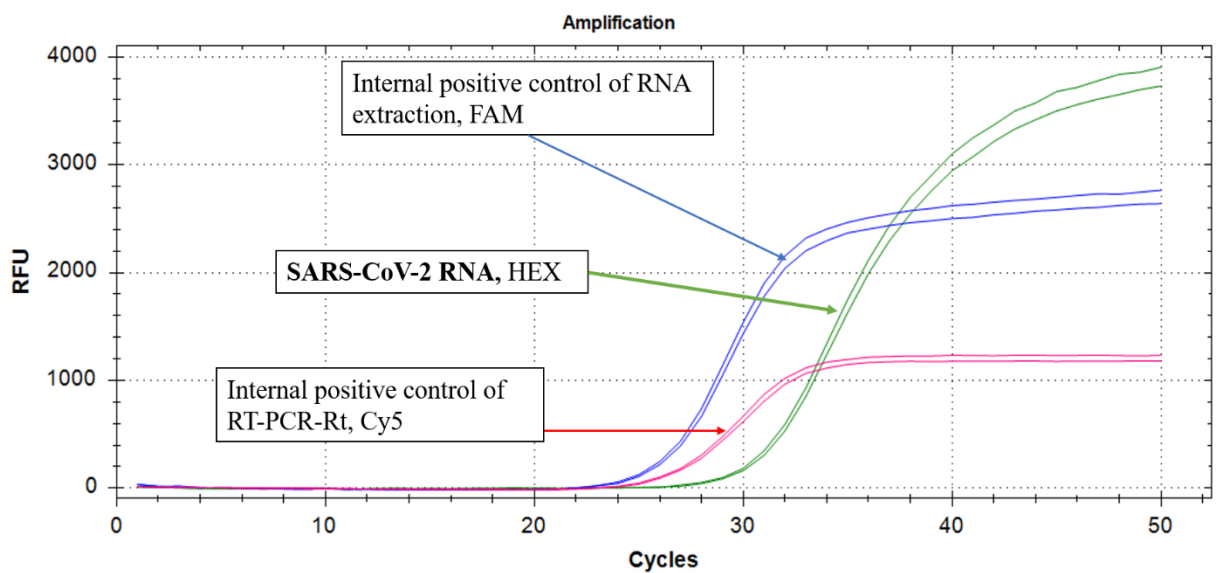
False positive and false negative results in the analysis of NA samples of respiratory infections: severe acute respiratory syndrome (SARS-CoV), Middle East respiratory syndrome (MERS-Cov), type A influenza H1N1, H5N1 and B, respiratory syncytial virus (RSV), adenoviruses, adenoviruses burnetii, Streptococcus pneumoniae, Haemophilus influenzae type B, Legionella pneumophila, Metapneumovirus, Human respirovirus 1, Rhinovirus (14 obviously negative samples) were absent.

During the studies, 100% intramuscular, interstitial, and interserial reproducibility was observed for all positive samples.

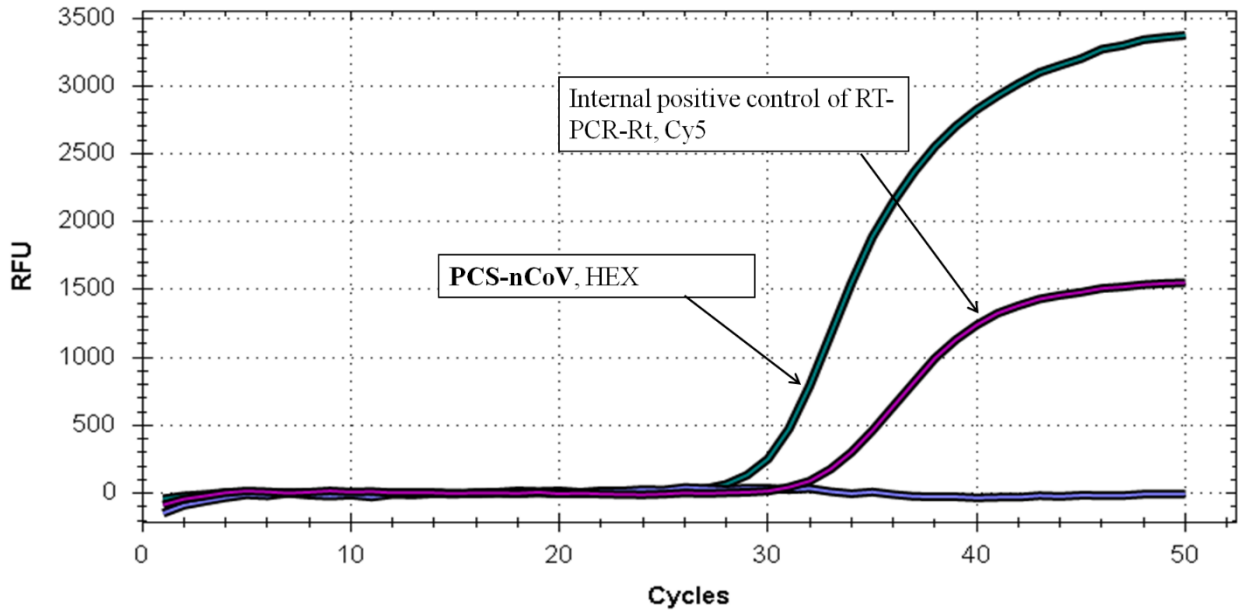
Currently, clinical trials of this kit based on the State Research Center "WB Vector" of Rospotrebnadzor have been successfully completed. Diagnostic indicators are specified.

RT-PCR-Rt is set up on real-time PCR instruments with FAM, R6G (HEX, JOE), Cy5 detection channels, for example, ANK-32, ANK-M, DTprime / DTlite, " CFX96 ", " Rotor-Gene Q / 6000" and others, equivalent in characteristics.

Interpretation of the analysis results for the detection of coronavirus SARS-CoV-2 RNA using the OM-Screen-2019-nCoV-RT kit on a CFX96 instrument (Bio-Rad, USA)

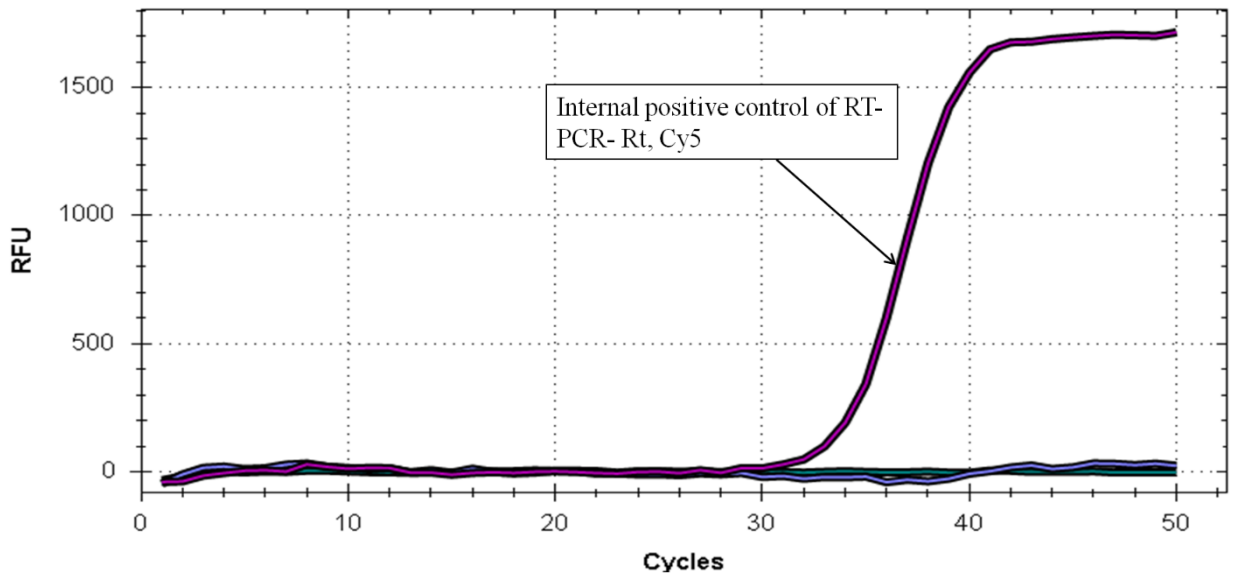


Amplification



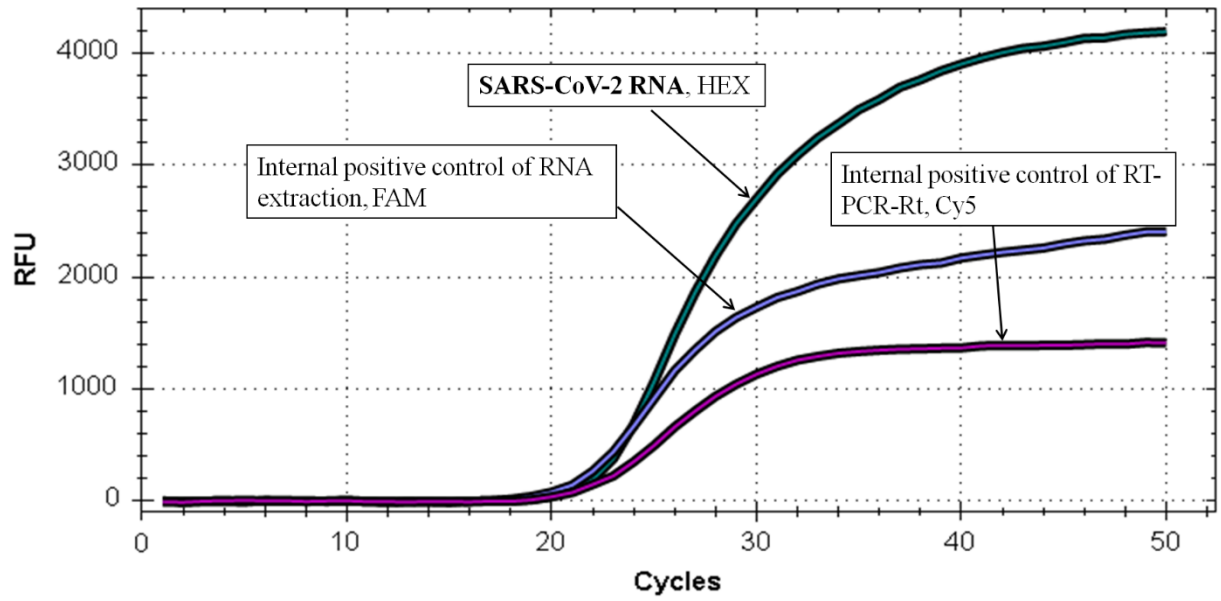
Positive control sample, PCS

Amplification



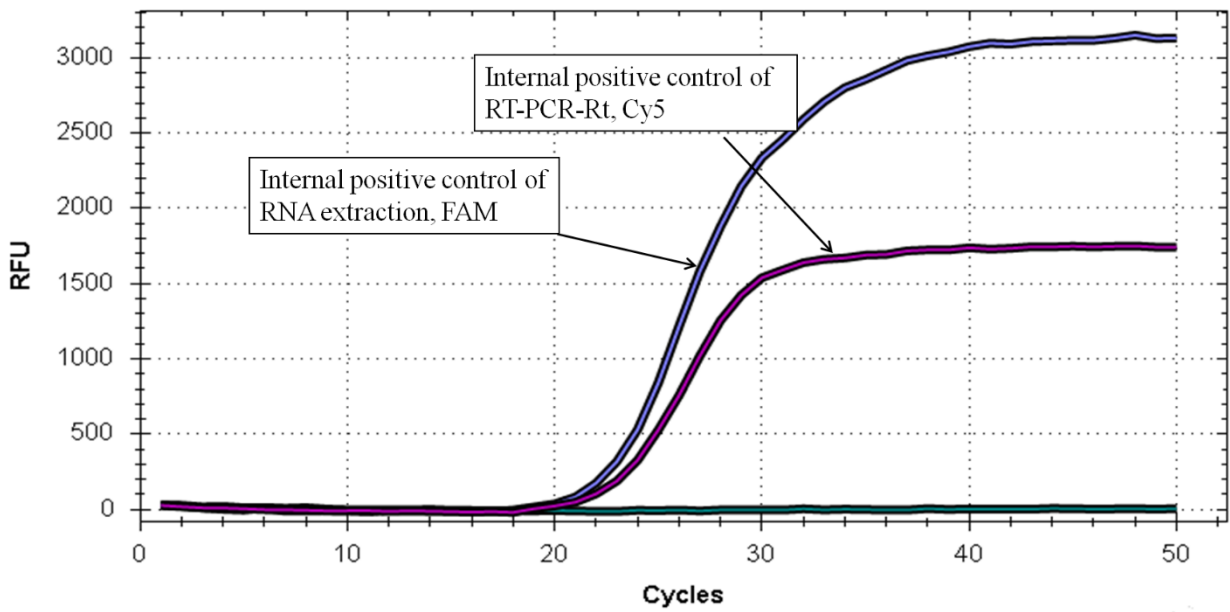
Negative control sample, NCS

Amplification



Coronavirus SARS-CoV RNA positive test sample

Amplification



Coronavirus SARS-CoV RNA negative test sample