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Determination of the precision of the kit for detecting SARS-CoV-2 virus RNA by real-time RT-PCR

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Abstract

This article presents an assessment of the precision of the set "Intifica SARS-CoV-2" produced by the group of companies "Alkor Bio". The kit is designed for qualitative detection of SARS-CoV-2 coronavirus RNA by reverse transcription and polymerase chain reaction (RT-PCR) with real-time hybridization-fluorescence detection in nucleic acid (NC) preparations obtained from clinical sample smears of the nasopharynx and/or oropharynx, bronchial lavage waters obtained by fibrobronchoscopy (bronchoalveolar lavage). The set of reagents "Intifica SARS-CoV-2" can be used in clinical laboratory diagnostics to detect the SARS-CoV-2 coronavirus-the causative agent of the new COVID-19 coronavirus infection, potentially causing acute respiratory syndrome.

To assess the precision of the set, tests were carried out using a single set series, with several operators participating in the experiment, several polymerase chain reaction formulations were carried out, and various concentrations of SARS-CoV-2 virus RNA were studied. The set is multiplex, the analysis involves three genetic targets of the coronavirus and one target for human DNA – it is an internal control of the system. For points with a low concentration of RNA, the results are not reproducible for different operators and experiments on different days. This is due to the features of multiplex amplification, in which there may be competition between specific targets: a target with a large number of matrix takes on more reaction components, thereby reducing the amplification of a target with a smaller number of matrix in a test tube. The accuracy indicators of the PCR kit "Intifica SARS-CoV-2" meet the acceptance criteria and technical requirements for the kit. The

coefficient of variation for high matrix concentrations was less than 2%, and for low matrix concentrations – less than 3%.

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