Technical Bulletin

SARS-CoV-2 Virus Inactivation with the Sofia SARS Antigen FIA

The Sofia SARS Antigen FIA test procedure utilizes a patient nasal or nasopharyngeal swab specimen placed inside a reagent tube containing extraction reagent. The patient swab is incubated for a period of 1 minute where the extraction reagent disrupts the viral membrane to expose and release viral nucleoprotein (NP) into the solution.

A study was performed to investigate the effect of this extraction process on the infectivity of the sample since the extraction reagent acts by disrupting the viral membrane and exposing NP molecules.

The objectives of the study were to quantify the extent of viral inactivation during the extraction process (1 minute) under different viral challenges, and to investigate the effect of additional extraction time on the infectivity of the SARS-CoV-2 virus.

The effect of incubation with the extraction reagent was investigated in two ways: first, with a fixed high titer challenge of 4.57×10^5 $TCID_{50}$/mL, and second, with various titers spanning between 4.57×10^5 to 4.57×10 $TCID_{50}$/mL.

After a 1-minute incubation, a significant reduction of the viral infectivity is observed (>95% or 1.7 – 1.9 log_{10}), which is consistent regardless of the initial titer challenge. This reduction of infectivity was shown to increase with time at a rate of approximately 0.5 – 0.8 log for every minute of incubation at room temperature.

After an incubation period of 6 minutes, the initial nominal viral titer of 5.7 log was reduced to below the limit-of-detection (LOD) of the assay. The LOD of the assay can be estimated to be between 1 – 1.5 log.

Given the kinetics observed and assuming a similar rate of reduction of 0.5 – 0.8 log per minute, it is expected that the viral infectivity will become close to zero before 10 minutes of incubation. As the Sofia SARS Antigen FIA run time is 15 minutes, the material in contact with the extraction reagent is expected to become non-infectious by the time of completion of the assay.

The titers tested in this study can be correlated to more than 80% of the samples found to test positive "in the field" through the Virena® reporting system in the U.S. The results of this study are therefore highly relevant to the range of infectious titers observed in clinical settings and can be used as a guide for implementation decisions of testing with Sofia and Sofia 2.

In conclusion, it was determined that SARS-CoV-2 virus infectivity reduced by greater than 90% at the completion of the 1-minute extraction process and the SARS-CoV-2 virus is greater than 99% inactive at the completion of the test.

If you have any questions regarding the use of this product, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or technicalsupport@quidel.com. If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference **quidel.com** to see more options for Support.

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