

MANUFACTURER DECLARATION: SARS-CoV-2 VARIANTS OF CONCERN INCLUDINGOMICRON

Manufacturer: **Artron Laboratories Inc., 3938 North Fraser Way, Burnaby, B.C,**

hereby declares that the SARS-CoV-2 virus detection with the use of the following COVID-19 Antigen tests as the in-vitro diagnostic medical device listed below:

COVID-19 Antigen Test (for nasopharyngeal / nasal swab specimens, professional and POCT use)

COVID-19 Antigen Home Test

COVID-19 Antigen Self-Test

is not affected by any of the mutations in N gene encoding the Nucleocapsid protein of the SARS-CoV-2 virus, including mutations in the Omicron variant (B.1.1.529).

Through internal studies carried out at Artron Laboratories Inc., it was verified that the above listed Artron COVID-19 Antigen Tests can be used to detect the following variants of the SARS-COV-2: "UK mutant (Alpha) B.1.1.7", "South Africa mutant (Beta) B.1.351" "Brazil mutant (Gamma) P.1", Delta (B.1.617.2), and Omicron (B.1.1.529).

Below is the summary of the study:

Recombinant wild type Nucleocapsid protein (N protein) and recombinant mutant Nucleocapsid proteins N protein-B.1.1.7, N protein-B.1.351, N protein-P.1, and N protein-B.1.1.529 of mutant strains- "UK mutant B.1.1.7", "South Africa mutant B.1.351", "Brazil mutant P.1" and Omicron (B.1.1.529) respectively, were expressed and purified by the R&D team at Artron laboratories. The above mentioned five recombinant N proteins were diluted to 1mg/mL, and then gradually 10-fold serially diluted from 1mg/mL to 100pg/mL with negative healthy swab matrix. Each diluted sample was tested with Artron COVID-19 Antigen Test cassettes in triplicates. It was demonstrated that Artron COVID-19 Antigen Test could identify original wild type recombinant SARS-CoV-2 nucleocapsid protein and the four recombinant



mutant nucleocapsid proteins from mutants- "UK mutant B.1.1.7", "South Africa mutant B.1.351", "Brazil mutant P.1" and Omicron (B.1.1.529). The results showed that Artron COVID-19 Antigen Test had similar detection sensitivity against these four recombinant mutant N proteins with respect to the sensitivity against original wild type N protein when testing at a concentration of 100pg/mL.

We will continue to adhere to high-quality management standards to ensure customer satisfaction and product safety.

Thank you

Jun Zhang 

R&D Manager

Artron Laboratories Inc.