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Statement Letter

Subject

: Confirmation on the detection ability for SARS-CoV-2 variants of Asan Easy Test COVID-19 Ag

We, Asan Pharmaceutical Co., Ltd., are a manufacturer for the rapid diagnosis test kits for the products related to COVID-19 virus and would like to confirm the detection ability to SARS-CoV-2 mutation variants with Asan East Test COVID-19 Ag kit in this letter.

It was confirmed that there is no problem on detecting various variants of major mutant from UK (B.1.1.7, Alpha variant), South Africa variant(B.1.357, Beta variant), as well as India(B.1.617.2, Delta variant) with Asan Easy Test COVID-19 Ag.

In the process of continuous variation of the novel corona viruses, the majority of the mutations occur at the S protein (spike protein) but in some cases the N protein (nucleocapsid protein) might be mutated. The several site mutations have occurred on the N-terminal side of the nucleocapsid protein at positions of 3, 63, 203, 204, 205, 234, 235, 377 and there were no mutations on the C-terminal side.

Recently, according to the novel corona virus sequences uploaded to the GISAID database, the mutation sites and corresponding proportions of N protein were analyzed.

Since the antigen detection kit mainly uses nucleocapsid protein as the detection target protein, some mutations of N protein may have an impact on the existing antigen detection reagents.

Based on the above information, we performed the confirmation tests on the detection potential of the recently found variants using inactivated viral culture and recombinant nucleocapsid protein, and there is no problem to detect above mutation virus.

We will continue to update if there are new data on the products related to COVID-19 virus, and try to provide stably good, satisfied products with a high quality control system

Sincerely,

Yeom, Jeong Gyu

President

Asan Pharmaceutical Co., Ltd.