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Declaration on detection of SARS-CoV-2 variant

Subject : Performance of COVID-19 Antigen Rapid Test (Colloidal Gold)(FGCOVG100/FGCOVG300) are theoretically not be impacted by recently discovered variants including United Kingdom variant etc.

Dear Valued customers:

Joinstar Biomedical Technology Co.,Ltd , would like to confirm that our COVID-19 Antigen Rapid Test (Colloidal Gold) remains suitable for the detection of SARS-CoV-2 antigen even in the outbreak of newly discovered variants including United Kingdom variant etc.

Based on open information, several epitope mutations have occurred on spike protein at epitope of, including but not limited to N501Y, E484K, K417N for SA mutant strain 501Y.V2 , and N501Y, P681H, 69-70 for UK mutant strain b.1.1.7. The recognition binding epitope of the raw materials used in our antigen test are from the nucleocapsid protein(N protein) and are therefore different from the reported mutation epitope. In summary as all the Novel Coronavirus mutant strains are based on S-protein mutation, they will have no impact on the performance of our COVID-19 Antigen Rapid Test (Colloidal Gold).

We will continue to monitor the changing situation and will continue with our efforts to comply with high quality management standards to ensure we deliver consistently a high quality product which meets our customer expectations and the market needs. If you have any questions, please contact our sales representative.

Joinstar Biomedical Technology Co.,Ltd
2020-01-20

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Declaration on detection of SARS-CoV-2 variant

Subject： Performance of COVID-19 Antigen Rapid Test (Latex) (FLCOVA100/ FLCOVA200) are not impacted by recently discovered variants including United Kingdom variant etc.

Dear Valued customers：

Joinstar Biomedical Technology Co.,Ltd , would like to confirm that our COVID-19 Antigen Rapid Test (Latex) remains suitable for the detection of SARS-CoV-2 antigen even in the outbreak of newly discovered variants including United Kingdom variant etc.

Based on the assay design, in theory, the COVID-19 Antigen Rapid Test (Latex) can detect any mutations of the novel coronavirus. As has been reported in the literature the SARS-Cov-2 infects human cells, due to the specific high affinity of the virus S1 protein to the ACE2 receptor on the human cell membrane (see Figure 1). In our test, the recombinant human ACE2 receptor protein labeled color latex is used to capture SARS-Cov-2 particles in the sample, so in theory, it is not affected by virus mutation, unless the mutated virus does not act by binding to the ACE2 receptor .

In addition, our assay consists of two anti-novel coronavirus S1 monoclonal antibodies with different epitopes, one relatively conservative epitope in the RBD region but not in the ACE2 receptor binding region; the other, in the non-RBD region, is also a relatively conservative epitope. Therefore, it can also respond to various mutations of novel coronavirus with no impact to the assay specificity.

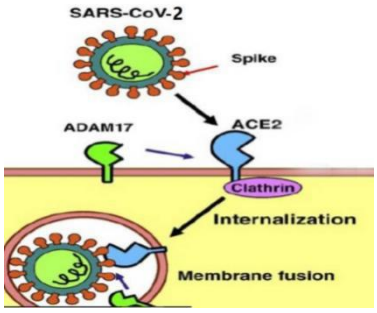

Fig.1 The role of ACE2 in SARS-CoV-2 infection

Studies has also been conducted which show that the COVID-19 Antigen Rapid Test (Latex) is also highly sensitive to the mutation detection of many novel coronavirus (see the experimental report for details).

In summary we are confident that our COVID-19 Antigen Rapid Test (Latex) can meet the market needs for the detection of the SARS-CoV-2 S protein and any variants thereof. Based on open information, several epitope mutations have occurred on spike protein at epitope of, including but not limited to N501Y, E484K, K417N for SA mutant strain 501Y.V2 , and N501Y, P681H, 69-70 for UK mutant strain b.1.1.7.

If you have any questions, please contact our sales representative.

Joinstar Biomedical Technology Co.,Ltd
2020-01-20