



Statement on the validity of SARS-CoV-2 Antigen Rapid Test Kit and 2019-nCoV antigen, Influenza A virus antigen, Influenza B virus antigen detection kit

We, Beijing Lepu Medical Technology Co.,Ltd, would like to inform you that our SARS-CoV-2 Antigen Rapid Test Kit and 2019-nCoV antigen, Influenza A virus antigen, Influenza B virus antigen detection kit remain suitable for the detection of SARS-CoV-2 antigen even in the emergence of newly discovered variants including the Omicron (XBB.1,BF.7, BA.2.75.2, BQ.1.1).

According to our investigation, several site mutations have occurred of the nucleocapsid protein at positions of E31-, R32-, S33-, R203K, G204R, S413R for Omicron (XBB.1) and of P13L, G30-,E31-, R32-, S33-, R203K, G204R, S413R for Omicron (BF.7)and of E31del, G204R, P13L, R32del, R203K, S33del, S413R for Omicron (BA.2.75.2) and of E136D, G204R, P13L, R203K, S413R for Omicron (BQ.1.1) . None of the mutations were included in the recognition sites of the raw materials used in our antigenic tests. Therefore, our product is theoretically capable of detecting variants including Omicron(XBB.1,BF.7). We also verified the recombinant N protein of XBB.1 and BF.7, and the results showed that there was indeed no effect, and the kit could detect variant XBB.1,BF.7 , BA.2.75.2 and BQ.1.1 normally.

Meanwhile, we will promptly communicate any updates regarding SARS-CoV-2 Antigen Rapid Test Kit and 2019-nCoV antigen, Influenza A virus antigen, Influenza B virus antigen detection kit. In addition, we will continue our efforts to comply with high quality management standards and to maintains a consistent high quality management system to ensure customer's satisfaction and product safety. If you have any questions, please contact our sales representative.

北京乐普诊断科技股份有限公司

Beijing Lepu Medical Technology Co., Ltd.

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