PRODUCT PERFORMANCE NOTIFICATION

Dear Valued Customer,

This letter serves as formal notification that, the performance of BGI's Real time fluorescent RT- PCR kit for detecting SARS-CoV-2 is not influenced by the testing mutations identified in published SARS-CoV-2 genome.

The testing results showed that 51 of 51 testing target mutations did not compromise LOD of BGI's Real time fluorescent RT-PCR kit for detecting SARS-CoV-2, indicating that performance of the kit is not influenced by the testing mutations identified in published SARS-CoV-2 genome.

In terms of B.1.1.7 lineage strains reported by UK, the key mutations reported are in S-gene of SARS-CoV-2 while the target gene of BGI's kit for detecting SARS-CoV-2 is in orf1ab (3000bp-3500bp), indicating that the reported mutations in S-gene do not influence the performance of BGI's kit. Although 4 mutations are also reported in orf1ab in B.1.1.7 lineage (https://virological.org/t/preliminary-genomic-characterisation-of-an-emergent-sars-cov-2-lineage-in-the-uk-defined-by-a-novel-set-of-spike-mutations/563), only 1 mutation (C3267) is in the target region of BGI's kit, which corresponds to the mutation (15:G>A, NPC1-YR21). The wet laboratory testing has validated that the mutation does not compromise the performance of BGI's kit in detecting SARS-CoV-2.

In terms of B.1.351 lineage strains reported by South Africa, 190 strains were analyzed. Only 1 mutation at the 2nd nucleobase in forward primer (NPC1-YF22, 2:A>G) of BGI's RT-PCR kit is identified in 1 strain (EPI_ISL_700422), which does not influence the performance of BGI's kit in detecting SARS-CoV-2.

As for mutant strains reported in Brazil, reported mutations are located in orf1a. Although C3828T and C2749T are close to the target gene of our kit, neither is in the target region and will not influence the performance of BGI's kit in detecting SARS-CoV-2.

To ensure quality products supplied by BGI in the market, as manufacturer, we will closely monitor prevalence of the reported mutation with potential influence on BGI's RT-PCR kit for SARS-CoV-2 in published genomes and evaluate the potential influence on detection performance in term of prevalence, geological distribution, impact profile, etc. In addition, we will continue to analyze the newly published sequences regularly, identify any new mutations and evaluate their potential influence on the performance of BGI's RT-PCR kit in detecting SARS-CoV-2.

BGI

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