



杭州协合医疗用品有限公司
Hangzhou Singclean Medical Products Co., Ltd

质量第一，管理优先
建和谐企业，创协合品牌
Quality First, Management Priority,
Building Harmonious Enterprise, Creating Singclean Brand

Statement

To Whom It May Concern:

We, Hangzhou Singclean Medical Products Co., Ltd., the manufacturer of Singclean COVID-19 Test Kit (Colloidal Gold Method), hereby state as follows:

Singclean COVID-19 Test Kit (Colloidal Gold Method) is a solid phase immunochromatographic assay for the rapid, qualitative detection of antigen from COVID-19 (SARS-CoV-2) in human nasal cavity.

Declare that:

Singclean COVID-19 Test Kit (Colloidal Gold Method) is designated to detect SARS-CoV-2 Nucleocapsid Protein(NP). The mutated sites of the virus strains that have been found so far are not on the detection sites of our products, and all our products can be accurately detected. The S protein is more likely to mutate due to its special gene sequence. So far, the COVID-19 mutant strains are basically mutated in the S protein gene. [Omicron]BA.2.75.2], [Omicron]XBB], [Omicron]BQ.1.1] and [Omicron]XBC] are mutated in the S protein gene, so our products can detect the above-mentioned COVID-19 Variants.

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