



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). Epitope of capture antibody and detection antibody was not in the mutation area. Thus, all mentioned spike protein mutation SARS-CoV-2 and other protein mutation SARS-CoV-2 can be detected, such as [Alpha | B.1.1.7(U.K.)]; [Beta | B.2.351 (South Africa)]; [Gamma | P.1 (Brazil)]; [Delta | B.1.617.2(India)]; [Lambda|C.37 (Peru)]; [Zeta|P.2 (Brazil)]; [Kappa|B.1.617.1(India)]; [Eta|B.1.525 (Nigeria)]; [Lota|B.1.526 (U.S.A)]; [Epsilon | B.1.427/B.1.429 (U.S.A)], and [Omicron|B.1.1.529(South Africa)].

Singclean COVID-19 Test Kit (Colloidal Gold Method) can detect the above-mentioned COVID-19 Variants.

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