

Statement

To Whom It May Concern

We, Wuhan Uni-science Biotechnology Co., Ltd, hereby, declare below information.

Our SARS-CoV-2 Antigen Rapid Test Kit is designated to detect nucleocapsid protein (NP) of SARS-CoV-2 virus. Most SARS-CoV-2 variants mainly have mutation in spike gene, some of the variants are listed below:

(1) B.1.1.7 (Alpha)

Location: United Kingdom

Spike Protein Substitutions: Deletion 69-70, Deletion 144, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H

(2) B.1.351 (Beta)

Location: S. Africa

Spike Protein Substitutions: D80A, D215G, K417N, E484K, N501Y, L18F, D80A, D215G, L242-244del, R246I, D614G, A701V

(3) P.1 (Gamma)

Location: Brazil

Spike Protein Substitutions: E484K, K417T, and N501Y

(4) B.1.525 (Eta)

Location: United Kingdom/Nigeria

Spike Protein Substitutions: A67V, 69del, 70del, 144del, E484K, D614G, Q677H, F888L

(5) B.1.526 (Iota)

Location: United States

Spike Protein Substitutions: L5F, T95I, (Y144-*), (F157S*), D253G, (L452R*), (S477N*), E484K, D614G, A701V, (T859N*), (D950H*), (Q957R*)

(6) B.1.429 (Epsilon)

Location: United States

Spike Protein Substitutions: S13I, W152C, L452R, D614G

(7) B.1.427 (Epsilon)

Location: United States

Spike Protein Substitutions: L452R, D614G

(8) B.1.167.2 and AY lineages (Delta)

Location: India

Spike Protein Substitutions: T19R, (V70F*), T95I, G142D, E156-, F157-, R158G, (A222V*), (W258L*), (K417N*), L452R, T478K, D614G, P681R, D950N

(9) C.1.2

Location: S. Africa

Spike Protein Substitutions: R190S, D215G, N484K, N501Y, H655Y, T859N, Y144del, L242-A243del

(10) C.37 (Lambda)

Location: Peru

Spike Protein Substitutions: Δ247-253, G75V, T76I, L452Q, F490S, T859N.

(11) B.1.621 (Mu)

Location: Colombia

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Spike Protein Substitutions: T95I, Y144S, Y145N, R346K, E484K, N501Y, D614G, P681H, D950N.

(12) P.3 (Theta):

Location: Philippines

Spike Protein Substitutions: L141del, G142del, V143del, A243del, L244del, E484K, N501Y, D614G, P681H, E1092K, H1101Y, V1176F

(13) P.2 (Zeta)

Location: Brazil

Spike Protein Substitutions: E484K, D614G, V1176F.

(14) B.1.1.529 (Omicron)

Location: S. Africa

Spike Protein Substitutions: P681H, N679K, H655Y, L981F, N969K, Q954H, N856K, D796Y, N764K, H655Y, D614G, T547K, G446S, N440K, K417N, S373P, S371L, G339D, DEL212/212, N211I, DEL143/145, G142D, T95I, DEL69/70, A67V.

(15) B.1.640.2 (IHU)

Location: France

Spike Protein Substitutions: P9L, E96Q, R190S, D215H, R346S, N394S, Y449N, E484K, F490S, N501Y, D614G, P681H, T859N, D1139H, C136-, N137-, D138-, P139-, F140-, L141-, G142-, V143-, Y144-.

(16) BA.2 (Lineages of Omicron)

Location: United Kingdom

Spike Protein Substitutions: T19I, L24S, Δ25-27, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K.

(17) BA.5 (Lineages of Omicron)

Location: South Africa

Spike Protein Substitutions: T19I, L24S, Δ25-27, DEL69-70, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452N, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K.

Thus, the abovementioned spike protein mutation SARS-CoV-2 variants found in the U.K., S. Africa, Brazil, Peru, Philippines, America, Nigeria, France, Colombia and India are not affecting the detection performance of CP04009 (SARS-CoV-2 Antigen Rapid Test Kit).

Wuhan Uni-science Biotechnology Co. Ltd.

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