



Letter of Declaration

To whom it may concern,

We, HANGZHOU ALLTEST BIOTECH CO., LTD., located at #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

Declare that:

Alltest SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test is designated to detect the nucleocapsid protein (NP) of SARS-CoV-2 virus. Epitope of capture antibody and detection antibody used in Alltest SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test is not in the mutation area. Thus, abovementioned SARS - CoV - 2 variants with spike protein mutation and nucleocapsid protein mutation of Alpha(B.1.1.7), Beta(B.1.351), Gamma(P.1), Delta(B.1.617.2), Lambda(C.37), Zeta(P.2), Kappa(B.1.617.1), Eta(B.1.525), Iota(B.1.526), Epsilon(B.1.427), Theta(P.3), Omicron(B.1.1.529) , Omicron(BA.1), Omicron(BA.2),Omicron(BA.3), Omicron XE, Omicron BA.4, Omicron BA.5, Omicron BA.2.12.1 BA.2.75, BF.7, BJ.1, BA.2.75.2, BQ.1.1, XBB, BQ.1, XBB.1.5, BA.5.2, BN.1.2, BN.1.3, XBB.1.16, XBB.1.9.1, EU.1.1, EG.5.1, EG.5 and BA.2.86 do not affect the detection performance of Alltest SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test.

Signature:

R&D Manager: Kael Chen

Date: Aug. 25th, 2023

Hangzhou Alltest Biotech CO., Ltd



Add: #550 Yinhai Street, Hangzhou Economic and Technologic Development Area
310018, P.R China



WHO label	Pango lineage	GISAID clade/lineage	Neststrain clade	Spike protein mutations	Nucleocapsid protein mutations
Alpha	B.1.1.7	GRY, GR/501Y.V1	20I/501Y.V1, 20B/501Y.V1	del69/70, del144/144, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H	D3L, R203K, G204R, S235F
Beta	B.1.351	GH/501Y.V2	20H/501Y.V2	D80A, D215G, K417N, E484K, N501Y, D614G, A701V	T205I
Delta	B.1.617.2	G/452R.V3	21A/S:478K	T19R, G142D, E156G, del157/158, L452R, T478K, D614G, P681R, D950N	D63G, R203M, D377Y
Epsilon	B.1.427 & B.1.429	GH/452R.V1	20C/S.452R	S13I, W152C, L452R, D614G	T205I
Eta	B.1.525	G/484K.V3	20A/S484K	Q52R, A67V, del69/70, del144/144, E484K, D614G, Q677H, F888L	S2Y, del3/3, A12G, T205I
Gamma	P.1	GR/501Y.V3	20J/501Y.V3	L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, D614G, H655Y, T1027I, V1176F	P80R, R203K, G204R
Kappa	B.1.617.1	G/452R.V3	21A/S:154K	L452R, E484Q, D614G, P681R, Q1071H	R203M, D377Y



Lambda	C.37	GR/452Q.V1	20D	G75V, T76I, R246N, del247/253, L452Q, F490S, D614G, T859N	P13L, R203K, G204R, G214C
Lota	B.1.526	GH	20C/S:484K	L5F, T95I, D253G, D614G	/
Omicron	B.1.1.529	GR/484A	21K	A67V, del69/70, T95I, G142D, del143/145, N211I, del212/212, G339D, S371L, S373P, K417N, N440K, G446S, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, N856K, Q954H, N969K, L981F	P13L, del31/33, R203K, G204R
Theta	P.3	GR	20B/S:265C	E484K, N501Y, D614G, P681H, E1092K, H1101Y, V1176F	R203K, G204R
Zeta	P.2	GR	20B/S.484K	E484K, D614G, V1176F	A119S, R203K, G204R, M234I
Omicron	BA.1	n/a	n/a	A67V, del69/70, T95I, G142D, del143/145, N211I, del212/212, G339D, S371L, S373P, S375F, K477N, T478K, E484A, Q493R,	P13L, del31/33, R203K, G204R



				Q496S, Q498R, N510Y, Y505H, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, N856K, Q954H, N969K, L981F	
Omicron	BA.2	n/a	n/a	T95I, L24S, del25/27, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, S477N, T478K, E484A, Q493R, Q498R, N510Y, Y505H, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K,	P13L, del31/33, R203K, G204R, S413R
Omicron	BA.3	n/a	n/a	A67V, del69/70, T95I, G142D, del143/145, N211I, del212/212, T478K, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	P13L, del31/33, R203K, G204R, S413R
Omicron	XE	n/a	n/a	T19I,L24del,P25del,P26del,A27S,G142D,V2 13G,G339D,S371F,S373P,S375F,T376A,D40 5N,R408S,K417N,N440K,S477N,T478K,E484	P13L,E31del,R32del,S33del,R203K ,G204R,S413R



				A,Q493R,Q498R,N501Y,Y505H,D614G,H655 Y,N679K,P681H,N764K,D796Y,Q954H,N969 K	
Omicron	BA.4	n/a	n/a	T95I, L24S, del25/27, del69/70, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N510Y, Y505H, D614G, H655Y, N679K, P681H, D796Y, Q954H, N969K	P13L, del31/33, P151S, R203K, G204R, S413R
Omicron	BA.5	n/a	n/a	T95I, L24S, del25/27, del69/70, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N510Y, Y505H, D614G, H655Y, N679K, N764K, P681H, D796Y, Q954H, N969K	P13L, del31/33, R203K, G204R, S413R



Omicron	BA.2.75	n/a	n/a	T19I,L24del,P25del,P26del,A27S,G142D,K147E,W152R,F157L,I210V,V213G,G257S,G339H,S371F,S373P,S375F,T376A,D405N,R408S,K417N,N440K,G446S,N460K,S477N,T478K,E484A,Q498R,N501Y,Y505H,D614G,H655Y,N679K,P681H,N764K,D796Y,Q954H,N969K	P13L,E31del,R32del,S33del,R203K,G204R,S413R
Omicron	BF.7	n/a	n/a	T19I,L24del,P25del,P26del,A27S,H69del,V70del,G142D,V213G,G339D,R346T,S371F,S373P,S375F,T376A,D405N,R408S,K417N,D614G,H655Y,N679K,P681H,N764K,D796Y,Q954H,N969K	P13L,G30del,E31del,R32del,S33F,R203K,G204R,S413R
Omicron	BJ.1	n/a	n/a	T19I,L24del,P25del,P26del,A27S,V83A,G142D,Y144del,H146Q,Q183E,V213E,G339H,R346T,L368I,S371F,S373P,S375F,T376A,D405N,R408S,K417N,N440K,V445P,G446S,S477N,T478K,V483A,E484A,F490V,Q493R,Q498R,N	P13L,E31del,R32del,S33del,R203K,G204R,T282I,S413R



				501Y,Y505H,D614G,H655Y,N679K,P681H,N764K,D796Y,G798D,Q954H,N969K,S1003I	
Omicron	BA.2.75.2	n/a	n/a	T19I,L24del,P25del,P26del,A27S,G142D,K147E,W152R,F157L,I210V,V213G,G257S,G339H,R346T,S371F,S373P,S375F,T376A,D405N,R408S,K417N,N440K,G446S,N460K,S477N,T478K,E484A,F486S,Q498R,N501Y,Y505H,D614G,H655Y,N679K,P681H,N764K,D796Y,Q954H,N969K,D1199N	P13L,E31del,R32del,S33del,R203K,G204R,S413R
Omicron	BQ.1.1	n/a	n/a	T19I,L24del,P25del,P26del,A27S,H69del,V70del,G142D,V213G,G339D,S371F,S373P,S375F,T376A,D405N,R408S,K417N,N440K,L452R,S477N,T478K,E484A,F486V,Q498R,N501Y,Y505H,D614G,H655Y,N679K,P681H,N764K,D796Y,Q954H,N969K	P13L,E31del,R32del,S33del,E136D,R203K,G204R,S413R



Omicron	XBB	n/a	n/a	T19I,L24del,P25del,P26del,A27S,V83A,G142D,H146Q,Q183E,V213E,G339H,R346T,L368I,S371F,S373P,S375F,T376A,D405N,R408S,K417N,N440K,V445P,G446S,N460K,S477N,T478K,E484A,F486S,F490S,Q498R,N501Y,Y505H,D614G,H655Y,N679K,P681H,N764K,D796Y,Q954H,N969K	P13L,E31del,R32del,S33del,R203K,G204R,S413R
Omicron	BQ.1	n/a	n/a	T19I,L24del,P25del,P26del,A27S,G142D,V213G,G339D,S371F,S373P,S375F,T376A,D405N,R408S,K417N,N440K,K444T,L452R,N460K,S477N,T478K,E484A,F486V,Q498R,N501Y,Y505H,D614G,H655Y,N679K,P681H,N764K,D796Y,Q954H,N969K	P13L,E31del,R32del,S33del,E136D,R203K,G204R,S413R
Omicron	XBB.1.5	n/a	n/a	T19I,L24del,P25del,P26del,A27S,V83A,G142D,Y144del,H146Q,Q183E,V213E,G252V,G339H,R346T,L368I,S371F,S373P,S375F,T376A,	P13L,E31del,R32del,S33del,R203K,G204R,S413R



				D405N,R408S,K417N,N440K,V445P,G446S, N460K,S477N,T478K,E484A,F486P,F490S,Q 498R,N501Y,Y505H,D614G,H655Y,N679K,P 681H,N764K,D796Y,Q954H,N969K	
Omicron	BA.5.2	n/a	n/a	T19I,L24del,P25del,P26del,A27S,H69del,V7 0del,G142D,V213G,G339D,S371F,S373P,S3 75F,T376A,D405N,R408S,K417N,N440K,L45 2R,S477N,T478K,E484A,F486V,Q498R,N501 Y,Y505H,D614G,H655Y,N679K,P681H,N764 K,D796Y,Q954H,N969K	P13L,E31del,R32del,S33del,R203K ,G204R,S413R
Omicron	BN.1.2	n/a	n/a	T19I,L24del,P25del,P26del,A27S,G142D,K14 7E,W152R,F157L,I210V,V213G,G257S,G339 H,R346T,K356T,S371F,S373P,S375F,T376A, D405N,R408S,K417N,N440K,G446S,N460K, S477N,T478K,E484A,F490S,Q498R,N501Y,Y 505H,D614G,H655Y,N679K,P681H,N764K,D	P13L,E31del,R32del,S33del,R203K ,G204R,S413R



				796Y,Q954H,N969K	
Omicron	BN.1.3	n/a	n/a	T19I,L24del,P25del,P26del,A27S,G142D,K147E,W152R,F157L,I210V,V213G,G257S,G339H,R346T,K356T,S371F,S373P,S375F,T376A,D405N,R408S,K417N,N440K,G446S,N460K,S477N,T478K,E484A,F490S,Q498R,N501Y,Y505H,D614G,H655Y,N679K,P681H,N764K,D796Y,Q954H,N969K	P13L,E31del,R32del,S33del,R203K,G204R,S413R
Omicron	XBB.1.16	n/a	n/a	T19I,L24del,P25del,P26del,A27S,V83A,G142D,H146Q,E180V,Q183E,V213E,G339H,R346T,L368I,S371F,S373P,S375F,T376A,D405N,R408S,K417N,N440K,V445P,G446S,N460K,S477N,T478R,E484A,F486P,F490S,Q498R,N501Y,Y505H,D614G,H655Y,N679K,P681H,N764K,D796Y,Q954H,N969K	P13L,E31del,R32del,S33del,R203K,G204R,S413R
Omicron	XBB.1.9.1	n/a	n/a	T19I,L24del,P25del,P26del,A27S,V83A,G142	P13L,E31del,R32del,S33del,R203K



				D,H146Q,Q183E,V213E,G339H,R346T,L368I ,S371F,S373P,S375F,T376A,D405N,R408S,K 417N,N440K,V445P,G446S,N460K,S477N,T4 78K,E484A,F486P,F490S,Q498R,N501Y,Y50 5H,D614G,H655Y,N679K,P681H,N764K,D79 6Y,Q954H,N969K	,G204R,S413R
Omicron	EU.1.1	n/a	n/a	T19I,L24del,P25del,P26del,A27S,V83A,G142 D,Y144del,H146Q,Q183E,V213E,G252V,G33 9H,R346T,L368I,S371F,S373P,S375F,T376A, D405N,R408S,I410V,K417N,N440K,V445P,G 446S,N460K,S477N,T478K,E484A,F486P,F49 0S,Q498R,N501Y,Y505H,P521S,D614G,H65 5Y,N679K,P681H,N764K,D796Y,Q954H,N96 9K	P13L,E31del,R32del,S33del,R203K ,G204R,S413R
Omicron	EG.5.1	n/a	n/a	T19I,L24del,P25del,P26del,A27S,Q52H,V83 A,G142D,Y144del,H146Q,Q183E,V213E,G25	P13L,E31del,R32del,S33del,R203K ,G204R,S413R



				2V,G339H,R346T,L368I,S371F,S373P,S375F, T376A,D405N,R408S,K417N,N440K,V445P, G446S,F456L,N460K,S477N,T478K,E484A,F 486P,F490S,Q498R,N501Y,Y505H,D614G,H 655Y,N679K,P681H,N764K,D796Y,Q954H,N 969K	
Omicron	EG.5	n/a	n/a	T19I,L24del,P25del,P26del,A27S,V83A,G142 D,Y144del,H146Q,Q183E,V213E,G252V,G33 9H,R346T,L368I,S371F,S373P,S375F,T376A, D405N,R408S,K417N,N440K,V445P,G446S,F 456L,N460K,S477N,T478K,E484A,F486P,F49 0S,Q498R,N501Y,Y505H,D614G,H655Y,N67 9K,P681H,N764K,D796Y,Q954H,N969K	P13L,E31del,R32del,S33del,L161F, R203K,G204R,S413R
Omicron	BA.2.86	n/a	n/a	A27S,S50L,H69del,V70del,V127F,G142D,Y1 44del,F157S,R158G,N211del,L212I,V213G,L 216F,H245N,A264D,I332V,G339H,K356T,S3	P13L,E31del,R32del,S33del,R203K ,G204R,Q229K,S413R



				71F,S373P,S375F,T376A,R403K,D405N,R408S,K417N,N440K,V445H,G446S,N450D,L452W,N460K,S477N,T478K,N481K,E484K,F486P,Q498R,N501Y,Y505H,E554K,A570V,D614G,P621S,H655Y,N679K,P681R,N764K,D796Y,S939F,Q954H,N969K,P1143L	
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