

Date: Sep 23, 2022

DN: PR21009

Declaration Letter

To whom it may concern,

On 26th of November, the World Health Organization (WHO) announced the classification of Omicron (B.1.1.529), a SARS-CoV-2 variant of Concern ^[1].

The B.1.1.529 variant was first reported to WHO from South Africa on 24 November 2021. This variant has more than 30 changes in the spike protein, the protein SARS-CoV-2 uses to recognize host cells and is the main target of the body's immune responses.

Omicron includes Pango lineage B.1.1.529 and descendent Pango lineages BA.1, BA.1.1, BA.2 and BA.3. As of 24.01.2022, the BA.2 descendent lineage, which differs from BA.1 in some of the mutations, including in the spike protein, is increasing in many countries. Investigations into the characteristics of BA.2, including immune escape properties and virulence, should be prioritized independently (and comparatively) to BA.1^[1]. New subvariants of omicron named BA.4 and BA.5 are sublineages of earlier omicron variants. These new strains are estimated to have emerged in mid-December 2021 and have reached 50 percent of sequences in South Africa as of the first week of April. Cases are rising rapidly again in South Africa. Omicron XE is a subvariant that is a combination of two previous variants: BA.1 and BA.2. This variant was first detected in the U.K. on Jan. 19, 2022.

The Omicron variant BA.2.75 is spreading at a very high rate, it was first emerged in India in May 2, 2022 and spreads to more regions of the globe. For BA.2.75 variant, additional mutation outside the spike protein: ORF1a: S1221L, ORF1a: P1640S, ORF1a: N4060S; ORF1b: G662S; E: T11A ^[2]. So there is no additional mutations in the nucleocapsid protein for BA.2.75 and it does not effect the performance of our SARS-CoV-2 Ag Tests.

Upon the announcement from WHO, VivaChek has completed initial bioinformatics analysis and concluded that all our SARS-CoV-2 Ag Tests (SARS-CoV-2 Ag Rapid Test, VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test, VivaDiag™ SARS-CoV-2 Ag Saliva Rapid Test, Verino® Pro SARS-CoV-2 Ag Rapid Test, VivaDiag™ SARS-CoV-2 Ag FIA Test and Rapid Gold Pro SARS-CoV-2 AG Test) can effectively detect the Omicron Variant. Further clinical validations have been arranged in several countries. Since the beginning of COVID-19 pandemic, bioinformatics and clinical validation studies have provided scientific insights and real-world data indicating our Tests detect popular variants including Delta, Omicron, with no sacrifice on specificity and sensitivity.

Currently designated Variants of Concern (VOCs)+:

WHO label	Pango lineage	GISAID clade	Nextstrain clade	Additional amino acid changes monitored	Earliest documented samples	Date of designation
Delta	B.1.617.2	G/478K.V1	21A, 21I, 21J	+S:417N +S:484K	India, Oct-2020	VOI: 4-Apr-2021 VOC: 11-May-2021
Omicron*	B.1.1.529	GR/484A	21K, 21L, 21M	+S: R346K +S:L452R/Q +S:F486V	Multiple countries, Nov-2021	VUM: 24-Nov-2021 VOC: 26-Nov-2021

*Includes BA.1, BA.2, BA.3, BA.4, BA.5 and descendent lineages. It also includes BA.1/BA.2 circulating recombinant forms such as XE.

Previously circulating VOCs:

WHO label	Pango lineage	GISAID clade	Nextstrain clade	Additional amino acid changes monitored	Earliest documented samples	Date of designation
Alpha	B.1.1.7	GRY	20I (V1)	+S:484K +S:452R	United Kingdom, Sep-2020	VOC: 18-Dec-2020 Previous VOC: 09-Mar-2022
Beta	B.1.351	GH/501Y.V2	20H (V2)	+S: L18F	South Africa, May-2020	VOC: 18-Dec-2020 Previous VOC: 09-Mar-2022
Gamma	P.1	GR/501Y.V3	20J (V3)	+S:681H	Brazil, Nov-2020	VOC: 11-Jan-2021 Previous VOC: 09-Mar-2022

Previously circulating VOIs:

WHO label	Pango lineage	GISAID clade	Nextstrain clade	Earliest documented samples	Date of designation
Epsilon	B.1.429/ B.1.427	GH/452R.V1	21C	United States of America, Mar-2020	VOI: 5-Mar-2021 Previous VOI: 6-Jul-2021
Zeta	P.2	GR/484K.V2	20B/S.484K	Brazil, Apr-2020	VOI: 17-Mar-2021 Previous VOI: 6-Jul-2021
Eta	B.1.525	G/484K.V3	21D	Multiple countries, Dec-2020	VOI: 17-Mar-2021 Previous VOI: 20-Sep-2021
Theta	P.3	GR/1092K.V1	21E	Philippines, Jan-2021	VOI: 24-Mar-2021 Previous VOI: 6-Jul-2021
Iota	B.1.526	GH/253G.V1	21F	United States of America, Nov-2020	VOI: 24-Mar-2021 Previous VOI: 20-Sep-2021

Kappa	B.1.617.1	G/452R.V3	21B	India, Oct-2020	VOI: 4-April-2021 Previous VOI: 20-Sep-2021
Lambda	C.37	GR/452Q.V1	21G	Peru, Dec-2020	VOI: 14-Jun-2021 Previous VOI: 9-Mar-2022
Mu	B.1.621	GH	21H	Colombia, Jan-2021	VOI: Aug-2021 Previous VOI: 9-Mar-2022

VivaChek commits to the development and supplying of IVD and POCT products with internationally recognized standards. We, as one of the leading Chinese IVD developers, invest significantly in the technology and ensure the quality of our product to fight the global pandemic. Any further information on this issue shall be shared to our valued partners and distributors.

Reference

- [1] "Classification of Omicron (B.1.1.529): SARS-CoV-2 Variant of Concern." [https://www.who.int/news/item/26-11-2021-classification-of-omicron-\(b.1.1.529\)-sars-cov-2-variant-of-concern](https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern) (accessed Feb 16, 2022).
- [2] "Omicron subvariants under monitoring" <https://www.who.int/activities/tracking-SARS-CoV-2-variants> (accessed Jul 13, 2022).