

Date: Jan 13, 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. Based on current knowledge, WHO's Technical Advisory Group on Virus Evolution concluded that it is no yet clear whether Omicron is more transmissible and infection with Omicron causes severe disease compared to infections with other variants [2].

Upon the announcement from WHO, VivaChek has completed initial bioinformatics analysis and concluded that all our SARS-CoV-2 Ag Tests (VivaDiag™ 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, Wellion SARS-CoV-2 PLUS Rapid Antigen 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, 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
Alpha	B.1.1.7	GRY	20I (V1)	+S:484K +S:452R	United Kingdom, Sep-2020	18-Dec-2020
Beta	B.1.351	GH/501Y.V2	20H (V2)	+S: L18F	South Africa, May-2020	18-Dec-2020
Gamma	P.1	GR/501Y.V3	20J (V3)	+S:681H	Brazil, Nov-2020	11-Jan-2021
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	GRA	21K, 21L, 21M	+S: R346K	Multiple countries, Nov-2021	VUM: 24-Nov-2021 VOC: 26-Nov-2021

VUM: Variants Under Monitoring

Currently designated Variants of Interest (VOIs):

WHO label	Pango lineage	GISAID clade	Nextstrain clade	Earliest documented samples	Date of designation
Lambda	C.37	GR/452Q.V1	21G	Peru, Dec-2020	14-Jun-2021
Mu	B.1.621	GH	21H	Colombia, Jan-2021	30-Aug-2021
Epsilon [§]	B.1.429/ B.1.427	GH/452R.V1	21C	United States of America, Mar-2020	VOI: 5-Mar-2021 VUM: 6-Jul-2021 Reclassified: 9-Nov-2021

§ Former VOI

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 Nov. 30, 2021).
- [2] “Update on Omicron.” <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/> (accessed Jan 13, 2022).

