

## Declaration

Date: November 29<sup>th</sup>, 2021

To whom it may concern,

In response to the recent emergence of multiple variants of the novel coronavirus, we, Wuhan Easy Diagnosis Biomedicine Co., Ltd., as the manufacturer of COVID-19 Antigen Rapid Test Kit (Saliva/Swabs) (CE) and COVID-19 (SARS-CoV-2) Antigen Test Kit (CE for professional use and self-test), has studied on the influence of the variants of the novel coronavirus on the above-mentioned products, in means of bioinformatics analysis, simulated samples and real samples validation. We confirm the above-mentioned products remain effective for the detection of the Variants of Concern and Variants of Interest designated by WHO.

In addition, basing on the current data published by GISAID (<https://www.gisaid.org/>) for the Omicron GR/484A (B.1.1.529) variant, no mutations were found in the nucleocapsid protein targeted by our COVID-19 Antigen Rapid Test Kit (Saliva/Swabs) and COVID-19 (SARS-CoV-2) Antigen Test Kit. Based on the bioinformatic analysis, the COVID-19 Antigen Rapid Test Kit (Saliva/Swabs) and COVID-19 (SARS-CoV-2) Antigen Test Kit can detect the Omicron GR/484A (B.1.1.529) variant.

Variants of Concern announced by WHO:

| 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<br>+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<br>+S:484K                       | India, Oct-2020              | VOI: 4-Apr-2021<br>VOC: 11-May-2021  |
| Omicron*  | B.1.1.529      | GR/484A      | 21K              | -  | Multiple countries, Nov-2021 | VUM: 24-Nov-2021<br>VOC: 26-Nov-2021 |

Variants of Interest announced by WHO:

| 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         |

Thank you for choosing EasyDiagnosis products, we will continue to provide you with high quality products and services.

Wuhan EasyDiagnosis Biomedicine Co., Ltd.

