



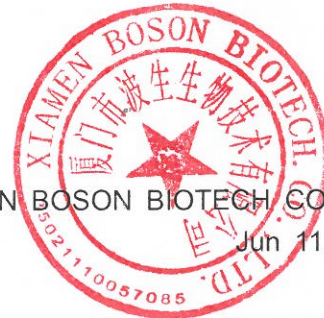
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Statement

To whom it may concern:

We Xiamen Boson Biotech Co., Ltd., a manufacturer of various types of Diagnostic Kits, having factories at 90-94 Tianfeng Road, Jimei North Industrial Park, Xiamen, P.R.C. do hereby confirm that the CE certificate of Boson Rapid SARS-CoV-2 Antigen Test Card (for Self-testing) has a validity date of May 26, 2024. But On 25 April 2024, European Commission published news with the headline Commission welcomes adoption by European Parliament of measures to improve the availability of in vitro diagnostics and approved Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical devices issued on 23 January 2024. According to Proposal Article 2: amendments to the IVDR, our company has signed an IVDR contract with the TÜV SÜD Product Service GmbH and meets the relevant conditions, so the validity date of CE certificate for Boson Rapid SARS-CoV-2 Antigen Test Card (for Self-testing) can be extended to December 31, 2027.



XIAMEN BOSON BIOTECH CO., LTD

Jun 11, 2024

Statement

To whom it may concern:

We Xiamen Boson Biotech Co., Ltd., a manufacturer of various types of Diagnostic Kits, having factories at 90-94 Tianfeng Road, Jimei North Industrial Park, Xiamen, P.R.C. do hereby confirm that the Boson Rapid SARS-CoV-2 Antigen Test Card detects the N protein of the SARS-CoV-2 virus.

Omicron evolved from the previous BA.1 variant into different subvariants of BA.2, BA.3, BA.4 and BA.5 et al. The biggest difference between the different Omicron subvariants occurs on the S protein, with very little difference on the N protein, as shown in the table below:



Variant	BA.1	BA.2	BA.2.3.20	BA.2.10	BA.2.12.1	BA.2.75 (Centaurus)	BA.2.75.2	BA.3
N protein mutation sites	P13L del31/33 R203K G204R	P13L del31/33 R203K G204R S413R	P13L del31/33 R203K G204R S413R	P13L del31/33 R203K G204R S413R	P13L del31/33 R203K G204R S413R	P13L del31/33 R203K G204R S413R	P13L del31/33 R203K G204R S413R	P13L del31/33 R203K G204R S413R
Variant	BA.4/BA.4.6	BA.5	BE.3	XE	BQ.1/BQ.1.1	BF.7	XBB/XBB.1.5	BJ.1
N protein mutation sites	P13L del31/33 P151S R203K G204R S413R	P13L del31/33 R203K G204R S413R	P13L del31/33 E136D P151S R203K G204R S413R	P13L del31/33 R203K G204R S413R	P13L del31/33 E136D R203K G204R S413R	P13L del30/31/33 R32del S33F R203K G204R S413R	P13L del31/33 R203K G204R S413R	P13L del31/33 R203K G204R T282I S413R

Boson internally evaluated the detection of BA.1, and external research included the detection of BA.1 and BA.2 (Denmark Statens Serum Institut) and BA.4 and BA.5 (Denmark Statens Serum Institut), the results were all detectable. The results of Omicron BA.1 and BA.2 can be found at <https://en.ssi.dk/-/media/arkiv/subsites/covid19/diagnostik/afprvning-af-sars-cov-2-antigentests-for-pvisning-af-varianter.pdf?la=en>. The results of Omicron BA.4 and BA.5 can be found at <https://en.ssi.dk/-/media/arkiv/subsites/covid19/diagnostik/afprvning-af-sarscov2-antigen-tests-for-pvisning-af-nye-varianter-i-dk-omikron-ba4-og-ba5.pdf?la=en>.

As shown in the table above, the N protein variation sites of BA.2, BA.2.3.20, BA.2.10, BA.2.12.1, BA.2.75, BA.2.75.2, BA.3, BA.5, XE and XBB/XBB.1.5 are completely identical, so Boson reagent can also detect BA.2.3.20, BA.2.10, BA.2.12.1, BA.2.75, BA.2.75.2, BA.3 and XE. BE.3 and BA.4/BA.4.6 are different except for the 136th amino acid, and other N protein variation sites are completely identical. Due to the amino acid mutation at position 136 of BE.3 lie without the epitope region for Boson Rapid SARS-CoV-2 Antigen Test Card, So Boson reagent can also detect BE.3. BQ.1/BQ.1.1 and BA.5 are different except for the 136th amino acid, and other N protein variation sites are completely identical. Due to the amino acid mutation at position 136 of BQ.1/BQ.1.1 lie without the epitope region for Boson Rapid SARS-CoV-2 Antigen Test Card, So Boson reagent can also detect BQ.1/BQ.1.1. BF.7 and BA.5 are different except for the 30th, 32nd and 33rd amino acid, and other N protein variation sites are completely identical. Due to the amino acid mutation at position 30-33 of BF.7 lie without the epitope region for Boson Rapid SARS-CoV-2 Antigen Test Card, So Boson reagent can also detect BF.7. BJ.1 and BA.2 are different except for the 282nd amino acid, and other N protein variation sites are completely identical. Due to the amino acid mutation at position 282 of BJ.1 lie without the epitope region for Boson Rapid SARS-CoV-2 Antigen Test Card, So Boson reagent can also detect BJ.1.

In summary, Boson Rapid SARS-CoV-2 Antigen Test Card can detect BA.1, BA.2, BA.2.3.20, BA.2.10, BA.2.12.1, BA.2.75, BA.2.75.2, BA.3, BA.4, BA.4.6, BA.5, BE.3, XE, BQ.1, BQ.1.1, BF.7, XBB, XBB.1.5 and BJ.1.

XIAMEN BOSON BIOTECH CO., LTD
Jan. 06, 2023

